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Virtual Reality in Clinical Nursing Practice Over the Past 10 Years: Umbrella Review of Meta-Analyses

Yanjie Hu[1,*], MM; Xingzhu Yuan[1,*], BSCM; Peiling Ye[1], BSCM; Chengting Chang[1], BSCM; Yue Han Hu[1], BSc; Weihua Zhang[2], PhD; Ka Li[1], MBA

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*these authors contributed equally

Corresponding Author:
Ka Li, MBA

Abstract

Background: Virtual reality (VR) has shown promising levels of effectiveness in nursing education, pain management, and rehabilitation. However, meta-analyses have discussed the effects of VR usage in nursing unilaterally and inconsistently, and the evidence base is diffuse and varied.

Objective: We aimed to synthesize the combined evidence from meta-analyses that assessed the effects of nurses using VR technology on nursing education or patient health outcomes.

Methods: We conducted an umbrella review by searching for meta-analyses about VR intervention in clinical nursing practice on Web of Science, Embase, Cochrane, and PubMed, and in reference lists. Eligible studies were published in English between December 1, 2012, and September 20, 2023. Meta-analyses of ≤2 intervention studies and meta-analyses without 95% CI or heterogeneity data were excluded. Characteristic indicators, population information, VR intervention information, and 95% CIs were extracted. A descriptive analysis of research results was conducted to discern relationships between VR interventions and outcomes. I^2 and *P* values were used to evaluate publication bias. AMSTAR (A Measurement Tool to Assess Systematic Reviews) 2 and the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) checklist were used to appraise literature quality.

Results: In total, 768 records were identified; 74 meta-analyses were included for review. The most reported VR study conditions were neuronursing (25/74, 34%), pediatric nursing (13/74, 18%), surgical and wound care (11/74, 15%), oncological nursing (11/74, 15%), and older adult nursing (10/74, 14%). Further, 30% (22/74) of meta-analyses reported publication bias, and 15% (11/74) and 8% (6/74) were rated as "high" based on AMSTAR 2 and the GRADE checklist, respectively. The main outcome indicators among all included meta-analyses were pain (37/214, 17.3%), anxiety (36/214, 16.8%), cognitive function (17/214, 7.9%), balance (16/214, 7.5%), depression (16/214, 7.5%), motor function (12/214, 5.6%), and participation in life (12/214, 5.6%). VR treatment for cognition, pain, anxiety, and depression was effective (all *P* values were <.05), while the utility of VR for improving motor function, balance, memory, and attention was controversial. Adverse effects included nausea, vomiting, and dizziness (incidence: range 4.76%-50%). The most common VR platforms were Pico VR glasses, head-mounted displays, the Nintendo Wii, and the Xbox Kinect. VR intervention duration ranged from 2 weeks to 12 months (typically ≥4 wk). VR session length and frequency ranged from 5 to 100 minutes and from 1 to 10 times per week, respectively.

Conclusions: VR in nursing has positive effects—relieving patients' pain, anxiety, and depression and improving cognitive function—despite the included studies' limited quality. However, applying VR in nursing to improve patients' motor function, balance, memory, and attention remains controversial. Nursing researchers need to further explore the effects and standard operation protocols of VR in clinical practice, and more high-quality research on VR in nursing is needed.

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KEYWORDS

virtual reality; clinical nursing; artificial intelligence; AI-assisted medical rehabilitation; health promotion; umbrella review

Introduction

Virtual reality (VR) refers to an immersive digital technology that was first conceptualized in the 20th century [1,2] and involves using computer devices and hardware to interact with a specific artificial sensory environment. VR technology can create a standardized, safe, flexible, and virtual environment and provide real-time, strategic, and goal-directed feedback [3]. Because of these advantages, VR technology entered the medical field in 1993 [4]. More and more countries have introduced policies to promote the application of VR technology in the field of health care [5]. Evidence suggests that VR could be beneficial in enhancing the surgical abilities of physicians and minimizing errors during surgical procedures [6]. Additionally, some research indicates that VR may elicit neurophysiological changes, beyond basic distraction, that contribute to its efficacy for pain management [7,8]. The potential of VR indicates that there will be few areas of medicine that do not take advantage of this improved computer interface.

As popular equipment for health care assistance, VR technology plays an important role in the field of clinical nursing, and VR environments are ideally suited to the measurement of many variables of interest in clinical nursing practice. VR was first used by nurses in the field of clinical rehabilitation nursing and gradually became extensively used in the fields of neurological disease, cancer, and wound care [9-11]. Several studies indicate that VR rehabilitation training is more effective among patients with Parkinson disease, especially in improving gait and balance ability [12,13]. VR can also be used as a distraction from pain and anxiety among pediatric patients and patients with cancer. Mohammad and Ahmad [14] found that immersive VR is an effective distraction intervention for managing pain and anxiety among patients with breast cancer. It is also reported that using immersive VR as an auxiliary intervention is more effective than using morphine alone in relieving pain and anxiety [15]. Moreover, the use of VR technology may be an effective, auxiliary, nondrug method for managing kinesiophobia [16].

Although it has been shown in various publications that VR has the potential to help in clinical nursing practice, there remain controversies on the functions, effects, and intervention protocols of VR application in clinical nursing. In addition, the results of multiple meta-analyses that discussed VR intervention effects in different patients are inconsistent [17-19]. Further, the methodological limitations of current evidence impede definitive conclusions regarding the superiority of VR interventions over conventional approaches. A meta-analysis that examined the effect of VR training on patients' participation noted uncertainty regarding evident publication bias [2], indicating that conclusions regarding the superiority of VR should be made cautiously. Researchers believe that further rigorous research is required to engender robust evidence substantiating the prospective benefits of VR technology [20].

Umbrella reviews can evaluate the strength of the evidence from existing meta-analyses. An umbrella review integrates data and evaluates information on all clinical outcomes, and it can be used to provide a thorough, high-level summary of the evidence landscape for VR application in clinical nursing practice [21].

Given the background presented herein, we performed an umbrella review in which we synthesized and appraised evidence from selected meta-analyses to generate robust conclusions regarding the state of the literature.

Methods

Study Design

An umbrella review of meta-analyses was carried out according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guidelines, as described in Checklists 1 and 2. The research questions used to guide this umbrella review were as follows:

1. What is the current scope and extent of VR technology integration in clinical nursing practice?
2. For which clinical nursing issues has VR been principally used as an intervention, and what evidence exists regarding the efficacy and safety of VR in these contexts?
3. What are the primary barriers impeding the broader adoption of VR in clinical nursing settings, and what are the future research directions that may facilitate expanded VR application in nursing practice?

Inclusion and Exclusion Criteria

The eligibility criteria were as follows: studies that used a meta-analytic method, meta-analyses about VR intervention in clinical nursing practice, and meta-analyses published in English. The exclusion criteria were as follows: meta-analyses that collected ≤2 intervention studies and meta-analyses that had no 95% CI and heterogeneity data.

Search Strategy

We conducted the umbrella review by searching Web of Science, Embase (Ovid), Cochrane Library, PubMed, and relevant reference lists. Eligible studies were published between December 1, 2012, and September 1, 2023. The searches were rerun on September 20, 2023, to identify any recent publications. We reran the searches before the submission of this paper, and no extra literature was found. We searched for publications that included the following terms (including variations of these terms) in the title, abstract, and keywords list: *virtual reality*, *VR*, *virtual environment*, *immersive*, *nursing*, *care*, *meta-analysis*, and *review*. We also searched the reference lists of the most recent systematic reviews and meta-analyses. The literature retrieval strategy is shown in Multimedia Appendix 1.

Data Extraction and Collection

One researcher conducted the electronic database searches, eliminated duplicates and titles that were clearly outside the scope of the umbrella review, and then uploaded the remaining citations to NoteExpress version 3.7.09258 (Aegean Software Corp). Two reviewers independently examined the remaining full-text articles to identify those that met the inclusion and exclusion criteria. If there were multiple meta-analyses with the same research objectives and outcome indicators, the one with the highest quality score was selected. Any disagreements were resolved through discussion with a third reviewer.

Data were extracted and managed independently by 2 reviewers using a predefined extraction form. Any concerns were discussed with a third reviewer.

The following data were extracted: (1) characteristic indicators of meta-analyses (first author, year of publication, study design, study period, and number of component primary studies); (2) characteristics of primary studies (trial design, number of participants, and sectionalization); (3) population information (diagnosis and sample size); (4) VR intervention information (VR platform, population, and intervention course); and (5) statistical summaries (outcomes and effect measures with 95% CIs and heterogeneity).

Data Analysis

We did not reanalyze the other data or primary studies included in the meta-analyses because of the clinical and statistical heterogeneity between the study objectives and outcome indicators of the meta-analyses, and many of the articles did not provide the original data of the original clinical studies. As a result, a descriptive analysis was conducted to encapsulate the impact of VR on clinical nursing practice over the past decade. The process of executing this descriptive analysis involved presenting research results, such as participant details, outcomes, sample sizes, and study designs. These data were meticulously extracted into a predefined Excel (Microsoft Corp) form by YH and XY. Following this, the two authors conducted a thorough review and verification of the collected data to ensure their accuracy and reliability. In instances of disagreement, a consensus was achieved through discussion. In particular, the theme—discerning the relationships between VR interventions and patient outcomes—was summarized.

Quality Evaluation of Included Literature

AMSTAR (A Measurement Tool to Assess Systematic Reviews) 2 [22] and the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) checklist [23] were used to independently evaluate the methodological quality of the selected meta-analyses. Two researchers separately evaluated the evidence strength of meta-analyses. If there was disagreement, another researcher was asked to make a judgment.

We reviewed the full texts and supplementary materials of included meta-analyses. Two researchers extracted the estimated pooled effect and heterogeneity of each outcome reported in the meta-analyses. The estimated pooled effect, along with its 95% CI, for each included meta-analysis was extracted. We used the I^2 metric to assess heterogeneity (<25%: might show no heterogeneity; 25%-50%: might show moderate heterogeneity; 50%-75%: might show substantial heterogeneity; 75%-100%: considerable heterogeneity), and heterogeneity and *P* values (significant at $P<.05$) were used to assess publication bias.

Ethical Considerations

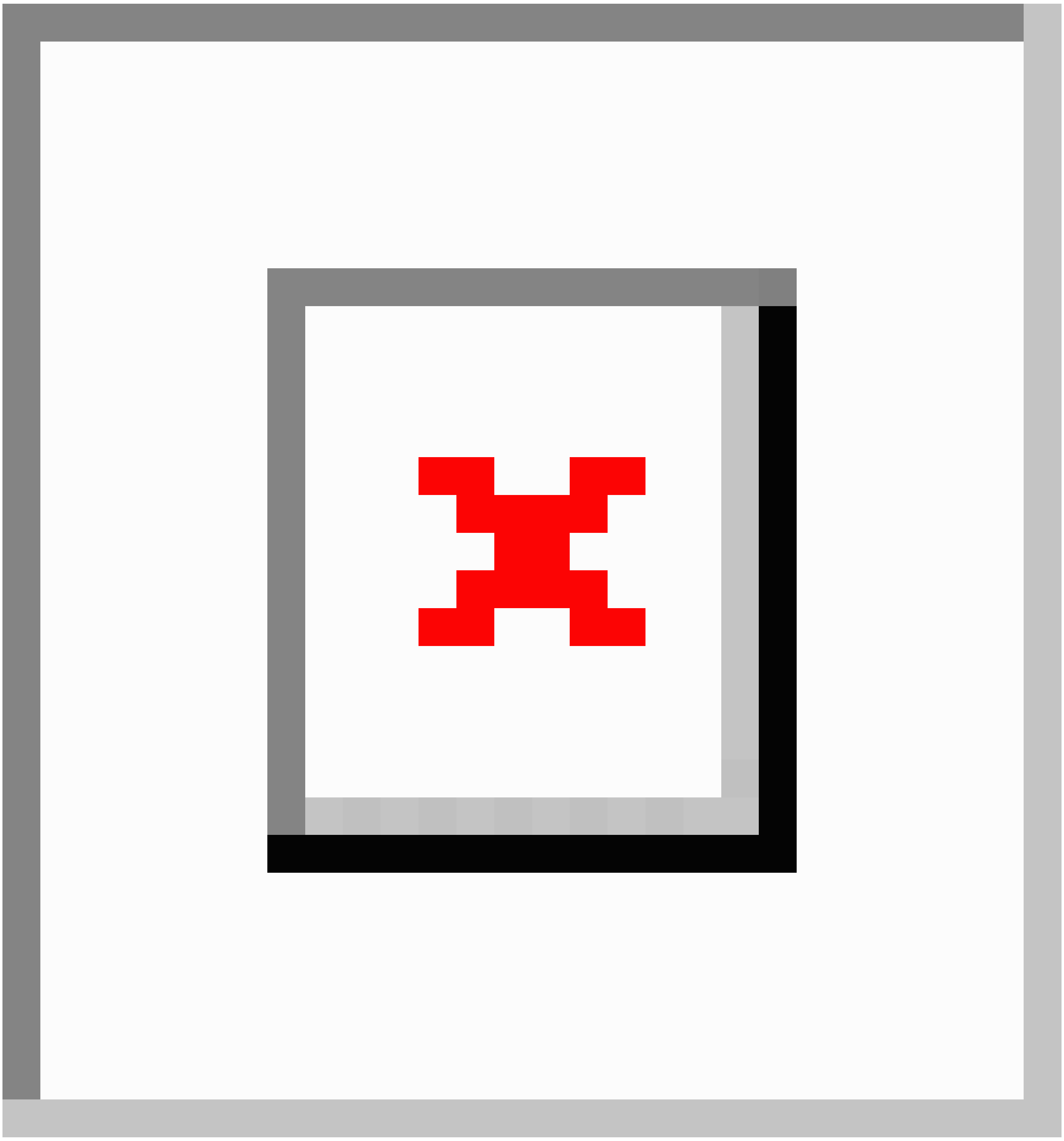
The protocol for this umbrella review was originally registered with PROSPERO in December 2022 (registration number: CRD42022381382). No ethical approval was needed, as we used data from published studies.

Results

Study Selection

The electronic literature search identified 768 records from 4 databases and the reference lists of included reviews. We screened the titles and abstracts of 634 records after removing 134 duplicate records. A total of 260 reviews remained after the titles and abstracts were screened for inclusion against predefined criteria. After reading the full texts, 74 articles were finally selected. Further details can be found in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for the search and selection of the eligible studies included in the umbrella review. Studies were identified via databases and registers. VR: virtual reality.



Basic Features of Included Studies

The included meta-analyses were meta-analyses of randomized controlled trials (RCTs), cross-over studies, pre-post studies, interrupted time series studies, quasi-controlled trials, case reports, controlled trials, or controlled clinical trials, and details of all included meta-analyses are listed in Tables 1 and 2.

Table . Characteristics of all included meta-analyses.

Study (author, year)	Period	Study design analyzed	Population analyzed	Sample size, n (VR[a] group and control group)
Chen et al [24], 2014	1993-2013	RCT[b]/CR[c]	Neurology	128 (100 and 28)
Välimäki et al [25], 2014	1994-2012	RCT	Pediatrics	156 (80 and 76)
Cheok et al [26], 2015	2010-2014	RCT	Neurology	166 (84 and 84)
Chen et al [27], 2015	2008-2015	RCT	Neurology	76 (38 and 38)
Christensen et al [28], 2016	1997-2013	RCT	Older adults	343 (183 and 160)
Howes et al [29], 2017	2003-2015	RCT	Older adults	719 (364 and 355)
Bukola and Paula [30], 2017	2002-2013	RCT	Cancer	144 (71 and 73)
Laver et al [31], 2017	2004-2017	RCT	Neurology	2470 (N/A[d])
Scheffler et al [32], 2018	1981-2013	RCT	Sugery/wound	178 (135 and 43)
Wang et al [33], 2019	2003-2018	RCT	Osteoarthritis	126 (63 and 63)
Eijlers et al [18], 2019	1999-2018	RCT/ITSS[e]	Pediatrics	N/A
Lei et al [13], 2019	2011-2018	RCT	Neurology	555 (N/A)
Kim et al [34], 2019	2003-2017	RCT/CT[f]	Neurology	271 (150 and 121)
Perrochon et al [35], 2019	2013-2017	RCT	Neurology	613 (306 and 305)
Zeng et al [36], 2019	2013-2018	RCT/CCT[g]/PPS[h]	Cancer	225 (137 and 136)
Corregidor-Sanchez et al [37], 2020	2011-2019	RCT	Older adults	491 (336 and 155)
Custodio et al [38], 2020	2012-2018	RCT	Pediatrics	N/A
De Miguel-Rubio et al [19], 2020	2010-2018	RCT/COS[i]/CR	Pediatrics	188 (131 and 57)
De Miguel-Rubio et al [39], 2020	2012-2018	RCT	Pediatrics	150 (81 and 69)
De Miguel-Rubio et al [40], 2020	2011-2018	CT	Pediatrics	103 (57 and 46)
Ding et al [41], 2020	2013-2019	RCT	Surgery/wound	723 (363 and 360)
Dominguez-Tellez et al [42], 2020	2007-2018	RCT	Neurology	874 (440 and 434)
Georgescu et al [43], 2020	2000-2018	RCT	Surgery/wound	1452 (659 and 793)
Lauwens et al [44], 2020	2000-2019	RCT/CR	Surgery/wound	142 (N/A)
Lopez-Valverde et al [45], 2020	2001-2009	RCT	Pediatrics	891 (485 and 406)
Low et al [46], 2021	2004-2019	RCT	Pediatrics	297 (154 and 143)
Czech et al [47], 2021	2002-2018	RCT	Pediatrics	617 (394 and 223)
Fandim et al [48], 2021	2003-2019	RCT	Neurology	1233 (629 and 604)
Chen et al [49], 2021	2007-2020	RCT	Neurology	1428 (656 and 772)
Jung et al [50], 2021	2010-2021	RCT	Neurology	41 (21 and 21)
Li et al [51], 2021	2012-2020	RCT	Neurology	836 (426 and 410)
Sajeev et al [52], 2021	2005-2020	RCT	Pediatrics	1085 (537 and 548)
Yen and Chiu [53], 2021	2012-2020	RCT	Older adults	1022 (503 and 519)
Zhang et al [54], 2021	2011-2019	RCT	Neurology	3540 (1783 and 1757)
Zhang et al [55], 2021	2011-2020	RCT	Neurology	894 (414 and 480)
Zhong et al [56], 2021	2014-2021	RCT	Neurology	744 (374 and 370)

Study (author, year)	Period	Study design analyzed	Population analyzed	Sample size, n (VR[a] group and control group)
Blasco-Peris et al [57], 2022	2006-2021	RCT	Older adults	152 (81 and 71)
Bu et al [58], 2022	2013-2021	RCT/QCT[j]/PPS	Cancer	478 (330 and 148)
Chan et al [59], 2022	2012-2021	RCT	Neurology	48 (16 and 32)
Chen et al [60], 2022	2007-2021	RCT	Neurology	789 (380 and 409)
Chen et al [61], 2022	2016-2021	RCT	Neurology	1149 (571 and 578)
Chen et al [62], 2023	2017-2019	RCT	Surgery/wound	529 (263 and 266)
Czech et al [2], 2022	2005-2021	RCT/COS	Surgery/wound	587 (481 and 106)
Huber et al [63], 2022	2008-2020	RCT	Neurology	214 (108 and 106)
Kim et al [64], 2022	2012-2021	RCT	Neurology	793 (357 and 436)
Mo et al [65], 2022	2012-2021	RCT/PPS	Cancer	N/A
Obrero-Gaitán et al [66], 2022	2015-2022	RCT/PPS	Cancer	1547 (783 and 764)
Saliba et al [67], 2022	2006-2020	RCT	Pediatrics	930 (468 and 462)
Simonetti et al [68], 2022	2017-2019	RCT	Surgery/wound	602 (297 and 305)
Suleiman-Martos et al [69], 2022	2012-2021	RCT	Surgery/wound	603 (300 and 303)
Tas et al [20], 2022	1999-2020	RCT/ITSS	Pediatrics	1695 (N/A)
Thi et al [70], 2022	1998-2017	RCT	Cancer	201 (92 and 109)
Wang et al [16], 2023	2015-2021	RCT	Kinesiophobia	488 (208 and 280)
Wang et al [71], 2022	2019-2021	RCT	Surgery/wound	1146 (571 and 575)
He et al [72], 2022	2007-2021	RCT	Surgery/wound	1258 (588 and 670)
Zhang et al [73], 2022	2016-2020	RCT/QCT	Cancer	443 (236 and 207)
Zhang et al [74], 2022	2016-2019	RCT	Neurology	609 (303 and 306)
Wong et al [75], 2023	2002-2022	RCT	Anxiety	720 (N/A)
Liu et al [76], 2023	2017-2019	RCT	Neurology	752 (N/A)
Hao et al [77], 2023	2017-2022	RCT/CCT	Cancer	799 (N/A)
Kodvavi et al [78], 2023	2018-2022	RCT	Surgery/wound	375 (188 and 187)
Parra et al [79], 2023	2011-2022	RCT	Neurology	898 (N/A)
Chen et al [80], 2023	2008-2022	RCT	Older adults	482 (N/A)
Kavradim et al [81], 2023	2013-2022	RCT	Older adults	739 (369 and 370)
Shen et al [82], 2023	2012-2021	RCT	Neurology	423 (N/A)
Bok et al [83], 2023	2009-2017	RCT	Neurology	761 (383 and 378)
Tian et al [84], 2023	2004-2021	RCT/QCT	Cancer	797 (N/A)
Yan et al [85], 2023	2012-2022	RCT	Pediatrics	818 (404 and 414)
Gao et al [86], 2023	2017-2022	RCT	Surgery/wound	892 (N/A)
Wu et al [87], 2023	2018-2022	RCT	Cancer	425 (202 and 223)
Ren et al [88], 2023	2011-2021	RCT	Older adults	2404 (1181 and 1223)
Lee et al [89], 2023	Not reported	RCT	Older adults	1095 (N/A)
Burrai et al [90], 2023	2003-2022	RCT/COS	Cancer	459 (222 and 237)

Study (author, year)	Period	Study design analyzed	Population analyzed	Sample size, n (VR[a] group and control group)
Percy et al [91], 2023	2015-2021	RCT	Older adults	265 (162 and 103)

[a]VR: virtual reality.

[b]RCT: randomized controlled trial.

[c]CR: case report.

[d]N/A: not applicable.

[e]ITSS: interrupted time series study.

[f]CT: controlled trial.

[g]CCT: controlled clinical trial.

[h]PPS: pre-post study.

[i]COS: cross-over study.

[j]QCT: quasi-controlled trial.

Table . Outcomes of included meta-analyses.

Studies (author, year) and outcomes		Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
Chen et al [24], 2014				
	Motion	1.00 (0.45 to 1.56)	56	N/A[a]
Välimäki et al [25], 2014				
	Cognition	4.67 (–1.76 to 11.1)	8	N/A
	Satisfaction	5.1 (1.03 to 9.17)	0	N/A
Cheok et al [26], 2015				
	Balance	0.39 (–0.25 to 1.04)	85	.02
Chen et al [27], 2015				
	BI[b]	−0.5 (−2.4 to 0.13)	27	N/A
	Balance	−0.5 (−0.7 to 0.37)	0	N/A
Christensen et al [28], 2016				
	HbA_{1c}[c]	–0.10 (–0.33 to 0.14)	0	.71
Howes et al [29], 2017				
	Balance	0.56 (0.25 to 0.87)[d]	66	.10
	Mobility	–0.12 (–0.48 to 0.03)	6	.54
	Cognition	–0.65 (–1.03 to –0.28)	58	.07
	Fear	0.28 (–0.50 to 1.05)	0	.55
Bukola and Paula [30], 2017				
	Pain	–0.64 (–1.10 to –0.17)[d]	61.3	N/A
Laver et al [31], 2017				
	Gait	0.09 (–0.04 to 0.22)[d]	10	N/A
	Balance	0.39 (–0.09 to 0.86)[d]	10	N/A
	Mobility	–4.76 (–8.91 to –0.61)[d]	50	N/A
	Motion	0.01 (–0.60 to 0.61)[d]	0	N/A
Scheffler et al [32], 2018				
	Pain	0.69 (0.40 to 0.98)[d]	72	No
	Anxiety	0.36 (0.20 to 0.52)[d]	0	No
Wang et al [33], 2019				
	Pain	–0.25 (–0.48 to –0.02)[d]	32	N/A
	Balance	29.36 (–6.99 to 65.71)[d]	88	N/A
Eijlers et al [18], 2019				
	Pain	1.30 (0.68 to 1.91)	93	No
	Anxiety	1.32 (0.21 to 2.44)	96	No
Lei et al [13], 2019				
	Gait	0.15 (–0.50 to 0.19)	32	High
	Balance	0.22 (0.01 to 0.42)[d]	0	High
	Mobility	–1.95 (–2.81 to –1.06)[d]	60	High
Kim et al [34], 2019				
	Cognition	0.42 (0.24 to 0.60)	5	.001

Studies (author, year) and outcomes		Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
	Physical fitness	0.41 (0.16 to 0.65)	0	<.001
	Emotion	0.14 (0.07 to 0.36)	36	.20
	Execution	0.07 (0.34 to 0.49)	66	.34
	Feasibility	0.12 (0.10 to 0.34)	54	.30
Perrochon et al [35], 2019				
	Motion	0.53 (–0.35 to 1.42)	0	.58
	Satisfaction	0.08 (0.03 to 0.13)	0	.001
	Safety	0.17 (–0.02 to 0.36)	1	.15
Zeng et al [36], 2019				
	Anxiety	–3.03 (–6.20 to 0.15)	95	.001
	Depression	–1.11 (–3.17 to 0.96)	0	.51
	Fatigue	–2.50 (–4.28 to –0.73)[d]	16	.27
	Pain	–1.63 (–4.15 to 0.89)	94	.001
	Cognition	0.40 (4.64 to 5.44)	36	N/A
Corregidor-Sanchez et al [37], 2020				
	Motion	–0.56 (–0.90 to –0.21)	55	High
Custodio et al [38], 2020				
	Pain	–0.46 (–0.91 to –0.01)[d]	82	No
	Anxiety	–3.37 (–4.57 to –2.81)[d]	71	No
De Miguel-Rubio et al [19], 2020				
	Balance	3.42 (2.54 to 4.29)[d]	70	N/A
De Miguel-Rubio et al [39], 2020				
	BI	–0.37 (–1.38 to 0.64)	68	N/A
De Miguel-Rubio et al [40], 2020				
	ROM[e]	–0.93 (–1.95 to 0.09)	0	N/A
	Balance	–0.27 (–0.82 to 0.27)	56	N/A
Ding et al [41], 2020				
	Pain	–0.64 (–1.05 to –0.22)	69	N/A
Dominguez-Tellez et al [42] , 2020				
	Motion	1.53 (0.51 to 2.54)[d]	92	No
	QOL[f]	2.37 (–0.25 to 4.98)	0	No
	MBI[g]	0.77 (0.05 to 1.49)[d]	95	No
Georgescu et al [43], 2020				
	Pain	0.95 (0.32 to 1.57)[d]	86	No
	Cognition	0.94 (0.33 to 1.56)[d]	51	No
Lauwens et al [44], 2020				
	Pain	0.94 (0.92 to 1.27)	52	N/A
Lopez-Valverde et al [45], 2020				
	Pain	–0.67 (–1.58 to 0.24)	0	.18
	Anxiety	0.20 (–0.48 to 0.87)	0	.54
Low et al [46], 2021				

Studies (author, year) and outcomes		Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
	Satisfaction	0.45 (–0.07 to 0.97)	70	N/A
	Dissatisfaction	0.72 (0.25 to 1.20)	44	N/A
Czech et al [47], 2021				
	Pain	−2.85 (−3.57 to −2.14)[d]	0	N/A
	Fear	−0.19 (−0.58 to 0.202)	94	N/A
	Anxiety	N/A	93	N/A
	Satisfaction	N/A	83	N/A
Fandim et al [48], 2021				
	Motion	–0.08 (–0.45 to 0.29)	6	No
	Balance	1.43 (0.61 to 2.24)[d]	53	No
Chen et al [49], 2021				
	BI	0.23 (0.13 to 0.34)[d]	0	.28
Jung et al [50], 2021				
	Cognition	0.45 (0.20 to 0.71)	42	.58
Li et al [51], 2021				
	Balance	0.66 (N/A)	64	.23
	QOL	–0.28 (N/A)	0	<.001
	MBI	0.62 (N/A)	0	<.001
	Depression	–0.75 (N/A)	80	.75
Sajeev et al [52], 2021				
	Pain	–0.43 (–0.67 to –0.20)[d]	81	N/A
	Anxiety	–0.61 (–0.88 to –0.34)[d]	89	N/A
Yen and Chiu [53], 2021				
	Cognition	0.53 (0.32 to 0.73)[d]	2	.57
	Memory	0.51 (0.06 to 0.96)[d]	58	.50
	Attention	0.49 (–0.10 to 1.08)	88	.44
	Execution	0.05 (–0.37 to 0.46)	81	.79
	Depression	–1.00 (–1.51 to –0.45)	55	.90
Zhang et al [54], 2021				
	Motion	3.01 (1.91 to 4.11)	70	N/A
	Balance and gait	3.51 (2.10 to 4.92)	80	N/A
	Cognition	0.81 (−0.41 to 2.03)	66	N/A
	MBI	7.02 (4.96 to 9.08)	18	N/A
Zhang et al [55], 2021				
	Cognition	0.32 (–0.43 to 1.06)	89	.29
	Attention	0.78 (0.23 to 1.33)[d]	6	.04
	Depression	0.20 (–0.25 to 0.64)	16	.55
	QOL	3.01 (1.51 to 4.31)	12	.17
Zhong et al [56], 2021				
	Cognition	0.42 (0.04 to 0.79)	3	No
	Attention	0.09 (−0.26 to 0.44)	0	No

Studies (author, year) and outcomes		Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
Blasco-Peris et al [57], 2022				
	QOL	0.22 (−0.37 to 0.81)	3	N/A
	Depression	0.17 (−0.36 to 0.70)	0	N/A
Bu et al [58], 2022				
	Anxiety	–6.47 (–7.21 to –5.73)[d]	83	No
	Depression	–4.27 (–4.64 to –3.91)[d]	0	No
	Pain	–1.32 (–2.56 to –0.09)[d]	87	No
	Fatigue	8.80 (8.24 to 9.36)[d]	0	No
Chan et al [59], 2022				
	Balance	0.12 (–0.66 to 0.89)[d]	0	N/A
	Motion	0.13 (–0.65 to 0.91)[d]	0	N/A
Chen et al [60], 2022				
	Anxiety	–0.35 (–0.70 to 0.01)	0	N/A
	Depression	–0.48 (–0.84 to –0.12)[d]	0	N/A
Chen et al [61], 2022				
	Cognition	3.00 (2.28 to 3.71)	7	No
	BI	6.14 (4.56 to 7.72)	0	No
	MBI	6.06 (1.27 to 10.85)	86	No
Chen et al [62], 2023				
	Anxiety	−0.91 (−1.43 to −0.39)[d]	86	Low
Czech et al [2], 2022				
	Pain	–0.47 (–0.78 to –0.15)[d]	41	N/A
	ROM	0.44 (−0.23 to 1.11)	50	N/A
Huber et al [63], 2022				
	Cognition	0.43 (0.22 to 0.64)[d]	24	N/A
Kim et al [64], 2022				
	Depression	−0.54 (−0.79 to –0.29)	73	No
Mo et al [65], 2022				
	Pain	–0.59 (–1.15 to –0.04)	78	No
	Fatigue	–0.53 (–0.88 to –0.18)	15	No
	Depression	–0.60 (–1.04 to –0.15)	29	No
	Satisfaction	–0.68 (–1.25 to –0.11)	55	No
Obrero-Gaitán et al [66], 2022				
	Pain	–1.03 (–1.52 to –0.54)[d]	7	.09
	Anxiety	–1.79 (–2.7 to –0.91)[d]	32	.55
	Depression	–2.7 (–4.39 to –0.99)[d]	46	.92
	QOL	0.76 (0.42 to 1.11)[d]	0	.90
Saliba et al [67], 2022				
	Pain	2.54 (0.14 to 4.93)[d]	99	N/A
	Anxiety	0.89 (0.16 to 1.63)[d]	95	N/A

Studies (author, year) and outcomes		Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
Simonetti et al [68], 2022				
	Anxiety	–0.34 (–0.62 to –0.11)[d]	39	No
Suleiman-Martos et al [69], 2022				
	Anxiety	–10.62 (–13.85 to –7.39)[d]	84	No
Tas et al [20], 2022				
	Pain	–0.67 (–0.89 to 0.45)[d]	68	.30
	Anxiety	–0.74 (–1.00 to 0.48)[d]	59	.56
Thi et al [70], 2022				
	Pain	–0.93 (–2.63 to 0.76)	86	N/A
Wang et al [16], 2023				
	Fear	−0.53 (−0.90 to −0.17)[d]	64	N/A
Wang et al [71], 2022				
	Fear	−1.52 (−2.18 to –0.86)	51	N/A
	Anxiety	−2.79 (−4.07 to –1.54)	0	N/A
	Pain	−2.17 (−3.37 to –0.97)	92	N/A
He et al [72], 2022				
	Pain	–1.13 (–2.01 to –0.26)[d]	97	No
Zhang et al [73], 2022				
	Anxiety	–2.07 (–3.81 to –0.34)	95	N/A
	Fatigue	–0.92 (–4.47 to 2.62)	99	N/A
Zhang et al [74], 2022				
	BI	0.31 (0.10 to 0.51)	31	No
	Grip	0.40 (0.08 to 0.71)	0	No
	Motion	0.71 (0.43 to 0.99)	0	No
Wong et al [75], 2023				
	Anxiety	–1.17 (–2.06 to –0.28)[d]	42	N/A
Liu et al [76], 2023				
	Depression	–0.75 (–1.35 to –0.15)	92.2	N/A
Hao et al [77], 2023				
	Pain	–1.53 (–2.55 to –0.50)	34	N/A
	Fatigue	0.86 (0.44 to 1.28)	97	N/A
	Anxiety	–3.02 (–5.27 to –0.77)	34	N/A
	Motion	–0.66 (–1.02 to –0.31)	47	N/A
	QOL	0.53 (0.14 to 0.93)	34	N/A
Kodvavi et al [78], 2023				
	Anxiety	–0.73 (–1.08 to –0.39)[d]	22	Low
	Pain	–0.25 (–0.44 to –0.05)[d]	67	Low
Parra et al [79], 2023				
	Loss	0.13 (0.02 to 0.24)	N/A	Low
Chen et al [80], 2023				
	Balance	0.62 (0.29 to 0.95)	68	Low

Studies (author, year) and outcomes		Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
	Cognition	0.90 (0.61 to 1.19)	16	Low
Kavradim et al [81], 2023				
	Anxiety	–0.85 (–1.55 to –0.14)	91.92	High
	Motion	0.54 (0.01 to 1.08)[d]	1.702	High
	Stress	–0.36 (–0.60 to –0.11)	0	High
	Depression	–0.39 (–0.68 to –0.11)	73.979	High
Shen et al [82], 2023				
	Balance	1.35 (0.58 to 1.86)	44	N/A
	MBI	5.26 (1.70 to 8.82)	72	N/A
Bok et al [83], 2023				
	Balance	–0.113 (–0.547 to 0.32)	73.3	N/A
Tian et al [84], 2023				
	Anxiety	–4.93 (–8.00 to –1.87)	NA	High
	Depression	–2.89 (–5.46 to –0.32)	7.05	High
	Pain	–1.2 (–2.05 to –0.50)	66	High
	Cognition	2.69 (1.95 to 3.44)	10	High
	Motion	–0.79 (–5.00 to 3.42)	25	High
	Grip	0.38 (–0.19 to 0.96)	9	High
Yan et al [85], 2023				
	Anxiety	–1.74 (–2.46 to –1.02)	95	.75
	Pain	–1.5 (–2.22 to –0.91)	91	.81
	Heart rate	–10.54 (–20.26 to –0.81)	99	.60
Gao et al [86], 2023				
	Anxiety	–0.77 (–1.24 to –0.31)	85	N/A
Wu et al [87], 2023				
	Anxiety	–0.83 (–1.25 to –0.42)	82	N/A
	Pain	–0.86 (–1.36 to –0.35)	85	N/A
	Depression	–0.46 (–0.74 to –0.18)	76	N/A
	Fear	–0.82 (–1.60 to –0.03)	69	N/A
	Distress	–1.16 (–1.96 to –0.37)	72	N/A
	QOL	1.01 (–0.67 to 2.70)	94	N/A
Ren et al [88], 2023				
	Motion	1.30 (0.08 to 2.51)	88	.19
Lee et al [89], 2023				
	Balance	0.62 (0.14 to 1.10)	80.92	High
Burrai et al [90], 2023				
	Anxiety	–6.57 (–11.59 to –1.54)	92	N/A
	Fatigue	–0.18 (–0.46 to 0.09)	0	N/A
	Pain	–1.95 (–6.96 to 3.06)	99	N/A
Percy et al [91], 2023				
	Motion	−0.91 (−1.38 to −0.44)	95	N/A

Studies (author, year) and outcomes	Estimated effect (95% CI)	Heterogeneity (I^2), %	Publication bias, *P* value
Balance	−0.54 (−1.80 to 0.71)	74	N/A

[a]N/A: not applicable.

[b]BI: Barthel Index.

[c]HbA_{1c}: hemoglobin A_{1c}.

[d]Significant at the *P*<.05 level.

[e]ROM: range of motion.

[f]QOL: quality of life.

[g]MBI: modified Barthel Index.

Among all included meta-analyses, the most common participant groups investigated were neuronursing (25/74, 34%), pediatric nursing (13/74, 18%), surgical and wound care (11/74, 15%), oncological nursing (11/74, 15%), and older adult nursing (10/74, 14%) populations. The number of participants in each meta-analysis ranged from 103 to 3540, and 214 outcome indicators were found. The main outcome indicators in all included meta-analyses were pain (37/214, 17.3%), anxiety (36/214, 16.8%), cognitive function (17/214, 7.9%), balance (16/214, 7.5%), depression (16/214, 7.5%), motor function (12/214, 5.6%), and participation in life (12/214, 5.6%), among others. The distribution of populations and outcome indicators of VR application in nursing is shown in Multimedia Appendix 2.

Quality of Included Reviews

Publication Bias

With regard to publication bias, 30% (22/74) of meta-analyses reported publication bias, 23% (17/74) had no publication bias, and 47% (35/74) did not have such data available. Specific data are shown in Tables 1 and 2.

GRADE Classification and AMSTAR 2 Score

The meta-analyses were classified into 4 levels, with approximately 15% (11/74) rated as "high," approximately 28% (21/74) rated as "moderate," approximately 39% (29/74) rated as "low," and approximately 18% (13/74) rated as "very low" via AMSTAR 2. The main reasons for lower ratings were that many meta-analyses neither evaluated publication bias nor drafted research protocols in advance, and only a few meta-analyses reported the sources of funding for the studies included in the analysis. Approximately 49% (36/74) of meta-analyses were rated as "very low," approximately 34% (25/74) were rated as "low," approximately 9% (7/74) were rated as "moderate," and approximately 8% (6/74) were rated as "high" via the GRADE system. The detailed results of the AMSTAR 2 and GRADE evaluations are presented in Multimedia Appendices 3 and 4.

VR Application in Clinical Nursing Practice

VR in Neuronursing

A total of 25 articles focused on the effectiveness of VR in neurological nursing. These studies mainly concentrated on motor function, cognition, depression, participation in life, and quality of life. Of these studies, 18 included RCTs. The results showed that VR intervention for cognitive function [61] and depression [51] was effective (*P*<.05). However, its efficacy for motor function, participation in life, and quality of life was controversial. Chan et al [59] reported that VR training was more effective than traditional rehabilitation training in improving balance function (standardized mean difference [SMD] 0.22, 95% CI 0.01-0.42; *P*=.04) and mobility (mean difference −1.95, 95% CI −2.81 to –1.08; *P*<.01), while a study by Parra et al [79] showed that no statistical differences were found in balance and gait between patients with Parkinson disease in the VR group and those in the control group (odds ratio 0.83, 95% CI 0.62-1.12). The differences between meta-analyses were probably the result of the different heterogeneous populations or the interventions being used at different points in the disease course. Heterogeneity was low for depression and cognitive function (range 0.01-0.24).

VR in Pediatric Nursing

A total of 13 meta-analyses focused on children and were mainly about nursing for pain, anxiety, and fear. The results of these meta-analysis studies showed that VR technology intervention by nurses to reduce pain and anxiety was effective for most patients. For example, VR was effective in reducing dental anxiety (SMD −1.74, 95% CI −2.46 to −1.02; *P*<.001; I^2=95%) and pain (SMD −1.57, 95% CI −2.22 to –0.91; *P*<.001; I^2=91%) among pediatric patients in a study by Yan et al [85]. Further, Eijlers et al [18] stated that when VR was applied as a distraction during venous access or during dental, burn, or oncological care in pediatric nursing, pain (SMD 1.30, 95% CI 0.68-1.91) and anxiety (SMD 1.32, 95% CI 0.21-2.44) were reduced. However, the effect of VR on fear was controversial [25,39]. In a meta-analysis by Saliba et al [67], VR seemed to be useful in reducing the fear of 648 children with burns (SMD 0.89, 95% CI 0.16-1.63; *P*=.02), but they found that there was significant heterogeneity among included studies. Czech et al [47] considered fear scores, and their study revealed no significant differences between the VR and no VR conditions. Heterogeneity was moderate or substantial in many studies (range 0.56-0.99), which may be the result of the different assessment scales used in each included study.

VR in Surgical and Wound Care

A total of 11 meta-analyses focused on surgical and wound care. The results of these meta-analysis studies showed that VR technology intervention for pain [43] (SMD 0.95, 95% CI 0.32-1.57) and anxiety [32] (SMD 0.36, 95% CI 0.20-0.52) was effective. Heterogeneity was low for anxiety (range 0.00-0.23) [2] but substantial for pain (range 0.44-0.80) [72]. Georgescu et al [43] summarized RCTs and found that the cognition of

1452 patients who underwent surgery or wound care statistically improved (SMD 0.94, 95% CI 0.33-1.56; I^2=51%), while the range of motion of patients with burns did not show better progress [2].

VR in Oncological Nursing

A total of 11 meta-analyses focused on cancer nursing, including symptom management and rehabilitation nursing, especially for breast cancer. The results of these meta-analysis studies showed that VR technology intervention was effective for pain (mean difference −1.27, 95% CI −2.05 to –0.50; *P*=.001), depression (SMD −2.89, 95% CI −5.46 to –0.32; *P*=.03), and anxiety (SMD −4.93, 95% CI −8.00 to –1.87; *P*=.002) among most patients with breast cancer [66]. However, when combined with its effects for other types of cancer, the effect of VR on pain, anxiety, and depression became controversial. Heterogeneity was substantial for anxiety and pain [73] but low for depression.

VR in Gerontological Nursing

A total of 10 meta-analyses focused on gerontological nursing. The results of these meta-analysis studies showed that VR technology intervention by nurses to improve balance (SMD 0.56, 95% CI 0.25-0.87; *P*<.001) was effective [29], while its effectiveness for motion capacity was controversial. Studies showed that virtual motor training had no significant positive effects [37,80]. Heterogeneity was moderate or substantial for exercise capacity, cognitive function, and balance [29,37,80].

Safety Concerns Regarding VR-Related Adverse Effects

Only a few papers reported adverse effects caused by using VR. The prevalence of adverse effects in these studies ranged from 4.76% to 50%, and these adverse effects included nausea, vomiting, sickness, dizziness, fatigue, pain, and the risk of losing balance.

VR Platforms and Intervention Times Among Different Populations

There were various platforms used for VR. We summarize the typical VR technology platforms used for different populations and outcome indicators in Table 3. The most commonly used VR platforms were Pico VR glasses, head-mounted displays, the Nintendo Wii, and the Xbox Kinect. The duration of VR intervention ranged from 2 weeks to 12 months (the most commonly reported durations were ≥4 weeks), and the length and frequency of VR sessions ranged from 5 to 100 minutes and from 1 to 10 times per week, respectively.

Table . Typical virtual reality (VR) platforms and intervention times among different patients.

Populations and outcome indicators		Platforms	Intervention duration	Session length and frequency
Neurology				
	Depression	Nintendo Wii, Xbox Kinect, and HMD[a]	6-12 wk	30-60 min, 2-5 times/wk
	Cognition	Pico UI 4.0, Nintendo Wii, Xbox 360 Kinect, BioMaster 2012, Lokomat, and Oculus	2-12 wk	20-100 min, 2-10 times/wk
	Daily living	Pico UI 4.0, Nintendo Wii, Xbox 360 Kinect, Armeo Spring, RehabMaster, BioMaster 2012, and Toyra VR	2-12 wk	12-60 min, 2-5 times/wk
	QOL[b]	Nintendo Wii, Xbox 360 Kinect, and Armeo Spring	3-8 wk	30-60 min, 2-5 times/wk
	Motion	Pico UI 4.0, Xbox 360 Kinect, Nintendo Wii, HMD, BioFlex, BioMaster, BioRescue, and ReJoyce	2-12 wk	20-90 min, 2-10 times/wk
Pediatrics				
	Motion	Pico UI 4.0, Nintendo Wii, and Xbox 360 Kinect	3-12 wk	30-100 min, 2-7 times/wk
	Distraction	Xbox 360 Kinect, HMD, ReJoyce, and Oculus	N/A[c]	5-35 min
Surgical and wound care				
	Distraction	Pico UI 4.0 and HMD	4 wk	30 min, 5 times/wk
Cancer				
	Anxiety, depression, and pain	Pico UI 4.0 and HMD	N/A	15-20 min
	Motion	HMD, Xbox 360 Kinect, and Nintendo Wii	4-8 wk	20-50 min, 2-5 times/wk
Older adults				
	Exercise capacity	HMD, Nintendo Wii, and Xbox 360 Kinect	2 wk to 12 mo	18-45 min, 1-5 times/wk
	Cognition	Xbox 360 Kinect, Nintendo Wii, and BioRescue	8-13 wk	18-30 min, 2-3 times/wk

[a]HMD: head-mounted display.

[b]QOL: quality of life.

[c]N/A: not applicable.

Discussion

Principal Findings

Clinical applications of VR in nursing practice predominately concentrate on neurology, pediatrics, oncology, surgical and wound care, and gerontology. Extant evidence indicates that VR interventions confer benefits for alleviating patient anxiety, pain, and depression, especially in pediatrics, among patients with breast cancer, and in wound care processes. VR is also a promising intervention for enhancing cognitive function in neurology patients. However, research on the utility of VR for improving motor function, balance, memory, and attention remains equivocal.

Many meta-analyses suggested that VR in nursing is useful for relieving anxiety and pain in patients, especially in pediatrics, among patients with breast cancer, and in wound care processes. Chen et al [62] found that a VR operation before surgery helped people familiarize themselves with the environment and understand the preoperative preparation procedures, thereby effectively reducing anxiety and improving compliance. Additionally, VR is a promising intervention for procedural pain [18,30], as reported in a study by Addab et al [92]. As a nondrug distraction intervention in nursing, VR can reduce the side effects of pain, depression, and anxiety drugs. However, heterogeneity was substantial in oncology studies and surgical and wound care studies. More high-quality studies are needed to help define the effectiveness of VR in these fields [93].

Further, VR can potentially be used to interfere with cognitive function, as it has been shown to affect cognitive plasticity and neuroplasticity. One study demonstrated plasticity in patients diagnosed with mild cognitive impairment and confirmed that repeated VR situational interactive training improved the excitability of the remaining nerve cells, promoted the functional reorganization of the damaged brain area, and resulted in the formation of new neural circuits, thereby improving the patients' cognition [94]. In a systematic review and meta-analysis that included 21 original studies (1149 participants), Chen et al [61] suggested that compared with a controlled group, VR training increased cognition because VR training increased the 1-naphthylacetic acid to creatine ratio in the hippocampus, which indicated that VR could improve the levels of hippocampal metabolites in patients with poststroke cognitive impairment, thereby promoting neuronal repair and improving cognitive function. However, several studies indicated that the effects of VR in nursing on cognition need to be clarified in more well-designed RCTs with large sample sizes because of small effect sizes, insufficient outcome indicators, and the low quality of current evidence [34,50,56].

The meta-analysis results showed that VR in nursing probably increased the exercise capacity of individuals undergoing neurologic rehabilitation when compared with usual nursing [60]. In contrast, many meta-analyses showed that there was little confidence that VR in nursing improves physical outcomes in older adults when compared with usual nursing [29,57]. The lack of allocation concealment and the absence of assessor blinding were the main causes of bias. As such, the final grade of the evidence was low, and the conclusions were hard to accept [37]. Some researchers thought that the results of VR therapy showed a trend of gait and upper limb function improvement in individuals [95,96], but Laver et al [31] believed that VR video gaming was not more beneficial than conventional nursing approaches in improving upper limb function, as did Voinescu et al [5]. Further, heterogeneity in protocols, VR task performance, and the different characteristics of the participants could have influenced the results [39]. Zhang et al [54] and Lei et al [13] pointed out that VR training helped to improve balance when compared with usual care. Similarly, Gates et al [97] and Saragih et al [98] concluded that VR training helped to improve balance when compared with usual nursing. All of these included studies did not analyze which subtypes of patients can benefit more from VR training in terms of improved balance, did not assess the long-term effects of VR on balance and mobility, and often included a relatively small number of patients and inadequate control groups [99]. The results need to be interpreted with caution due to the high heterogeneity, small sample sizes, and different outcome measures. In terms of improving memory, even after excluding studies with high heterogeneity, several meta-analyses still concluded that the effects of VR nursing measures on patients' instantaneous memory, long-term memory, and attention were not statistically significant [31,54,56]. The possible reasons for this are that VR training duration was too short to result in significant improvements [56] and only 6 studies (within the meta-analyses included in this umbrella review) with small samples were used to evaluate the effects of VR on attention.

It is also important to classify and summarize the VR platforms and frequencies of VR use that are commonly used in different nursing scenarios because of their influence on nursing outcomes. Meta-regression analyses showed that the number of VR sessions and the frequency of VR training had statistically significant impacts on balance scores [51]. There are few studies that explain why VR devices and scenes are chosen in a particular context, and there is no comparative analysis of the effects of using different VR devices and scenes in the same session. With regard to these biases, the included studies claimed that heterogeneity was due to the use of VR hardware with multiple types of VR software and variation in the duration of VR therapy sessions [93], which resulted in patients experiencing different levels of immersion, presence, and interactivity. Future research on VR in nursing should focus on providing a detailed report on VR device and platform instructions, the length and frequency of VR sessions, and the duration of VR intervention.

Comparison to Prior Work

Previous reviews on VR in nursing mostly discussed the impact of VR on nursing education and training at different levels [100,101]. However, the role of VR in clinical nursing practice is also very important. Therefore, we conducted this umbrella review, which aimed to effectively synthesize the combined evidence from meta-analyses that assessed the effects of nurses using VR technology on patients' health outcomes.

Strengths

This review followed the PRISMA reporting guidelines; thus, it can be viewed as a transparent and reproducible review. The findings in our review are more likely to be comprehensive and provide evidence for further VR application in clinical nursing practice. This study has a low risk of publication bias because we searched all relevant databases by using a reliable search strategy to identify as many eligible studies as possible. Moreover, we controlled the risk of selection bias by having 2 independent authors perform the research process, including the study selection, data extraction, and quality assessment processes.

Limitations

First, the quality of many included meta-analyses was not high. Therefore, the conclusions should be considered with care. Second, our study only reports on meta-analyses published in English, which may have resulted in language bias. Third, a quantitative data synthesis was not conducted in this review, given the significant clinical heterogeneity of the included studies in terms of study designs, intervention and population characteristics, and outcome measurements. This was one of the main reasons for the inconclusive research evidence found in this review. Follow-up studies can search for more literature, without strict language restrictions, and try to conduct high-quality quantitative syntheses to establish more reliable conclusions.

Future Directions

VR games have distinct clinical advantages, as they offer challenging and interesting environments [54]. Authoritative conclusions on the applications of VR in nursing might promote the application of VR games. It is suggested that nursing researchers should improve the quality of research; carry out large-scale, multicenter randomized controlled studies; and make authoritative conclusions on VR in nursing. In addition, the research outcomes of VR application in nursing are mostly subjective indicators, such as anxiety, depression, and satisfaction, and more objective outcome indicators, such as serological indicators, should be mentioned in the future. In the existing research, VR platforms, the duration of VR intervention, and the length and frequency of VR sessions are different. We hope that further research considers establishing standard operation protocols for VR intervention in specific populations.

Conclusions

Our study comprehensively summarized and indicated the potentially beneficial role of VR intervention in enhancing the management of pain, depression, anxiety, and cognition in neurology, pediatrics, oncology, surgical and wound care, and gerontology; the effects of VR intervention on improving motor function, balance, memory, and attention remain equivocal. However, these findings should be interpreted with caution due to the unsatisfactory quality of the included studies. It is recommended that more research of rigorous methodological quality is necessary to further determine the role of VR in promoting health care outcomes.

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Data Availability

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

YH, XY, and KL conceptualized this study. XY, YH, and PY were responsible for the methodology. YH, YHH, PY, CC, WZ, and XY were responsible for the software used. YH, PY, KL, CC, and XY were responsible for validation. YH, KL, and XY performed the formal analysis. YH, KL, WZ, and XY were responsible for the resources used. YH, PY, CC, WZ, and KL curated the data. YH, YHH, PY, CC, and XY wrote and prepared the original draft. YH, KL, and XY reviewed and edited this paper. KL supervised this study. YH and KL were responsible for project administration. YH and KL were responsible for funding acquisition. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Checklist 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File, 28 KB - games_v11i1e52022_app1.docx]

Checklist 2
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) abstract checklist.
[DOCX File, 22 KB - games_v11i1e52022_app2.docx]

Multimedia Appendix 1
Literature retrieval strategy.
[DOCX File, 15 KB - games_v11i1e52022_app3.docx]

Multimedia Appendix 2
Distribution of populations and outcome indicators of virtual reality application.
[DOCX File, 14 KB - games_v11i1e52022_app4.docx]

Multimedia Appendix 3
Detailed results of the AMSTAR (A Measurement Tool to Assess Systematic Reviews) 2 evaluation.
[XLSX File, 21 KB - games_v11i1e52022_app5.xlsx]

Multimedia Appendix 4
Detailed results of the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) evaluation.
[XLSX File, 16 KB - games_v11i1e52022_app6.xlsx]

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Abbreviations

AMSTAR: A Measurement Tool to Assess Systematic Reviews
GRADE: Grading of Recommendations Assessment, Development, and Evaluation
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
SMD: standardized mean difference

VR: virtual reality

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Original Paper

A Safe Place to Learn: Peer Research Qualitative Investigation of gameChange Virtual Reality Therapy

Jessica Bond[1], MSc; Alexandra Kenny[1], BA; Vanessa Pinfold[1], PhD; Lisa Couperthwaite[1], BA; The gameChange Lived Experience Advisory Panel[1]; Thomas Kabir[1], PhD; Michael Larkin[2], PhD; Ariane Beckley[3,4], MA, MSc; Laina Rosebrock[3,4,5], PhD; Sinéad Lambe[3,4,5], DClinPsy; Daniel Freeman[3,4,5], DClinPsy, PhD; Felicity Waite[3,4,5], DClinPsy; Dan Robotham[1], PhD

[1]McPin Foundation, London, United Kingdom
[2]School of Psychology, Aston University, Birmingham, United Kingdom
[3]Department of Psychiatry, University of Oxford, Oxford, United Kingdom
[4]Oxford Health National Health Service Foundation Trust, Oxford, United Kingdom
[5]National Institute for Health and Care Research Oxford Health Biomedical Research Centre, Oxford, United Kingdom

Corresponding Author:
Jessica Bond, MSc
McPin Foundation
7-14 Great Dover Street
London, SE1 4YR
United Kingdom
Phone: 44 207 922 7877
Email: contact@mcpin.org

Abstract

Background: Automated virtual reality (VR) therapy has the potential to substantially increase access to evidence-based psychological treatments. The results of a multicenter randomized controlled trial showed that gameChange VR cognitive therapy reduces the agoraphobic avoidance of people diagnosed with psychosis, especially for those with severe avoidance.

Objective: We set out to use a peer research approach to explore participants' experiences with gameChange VR therapy. This in-depth experiential exploration of user experience may inform the implementation in clinical services and future VR therapy development.

Methods: Peer-led semistructured remote interviews were conducted with 20 people with a diagnosis of psychosis who had received gameChange as part of the clinical trial (ISRCTN17308399). Data were analyzed using interpretative phenomenological analysis and template analyses. A multiperspectival approach was taken to explore subgroups. Credibility checks were conducted with the study Lived Experience Advisory Panel.

Results: Participants reported the substantial impact of anxious avoidance on their lives before the VR intervention, leaving some of them housebound and isolated. Those who were struggling the most with agoraphobic avoidance expressed the most appreciation for, and gains from, the gameChange therapy. The VR scenarios provided "a place to practise." Immersion within the VR scenarios triggered anxiety, yet participants were able to observe this and respond in different ways than usual. The "security of knowing the VR scenarios are not real" created a safe place to learn about fears. The "balance of safety and anxiety" could be calibrated to the individual. The new learning made in VR was "taken into the real world" through practice and distilling key messages with support from the delivery staff member.

Conclusions: Automated VR can provide a therapeutic simulation that allows people diagnosed with psychosis to learn and embed new ways of responding to the situations that challenge them. An important process in anxiety reduction is enabling the presentation of stimuli that induce the original anxious fears yet allow for learning of safety. In gameChange, the interaction of anxiety and safety could be calibrated to provide a safe place to learn about fears and build confidence. This navigation of therapeutic learning can be successfully managed by patients themselves in an automated therapy, with staff support, that provides users with personalized control. The clinical improvements for people with severe anxious avoidance, the positive experience of VR, and the maintenance of a sense of control are likely to facilitate implementation.

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KEYWORDS

peer research; lived experience; qualitative methods; interpretative phenomenological analysis; IPA; anxiety; psychosis; virtual reality; VR; cognitive therapy; automated; implementation

Introduction

Background

gameChange is an automated virtual reality (VR) cognitive therapy designed to reduce agoraphobic avoidance and distress in everyday situations. In a multicenter randomized controlled trial with 346 people with psychosis, we found that gameChange led to significant reductions in avoidance and distress [1]. Overall, there were small effect size improvements in agoraphobic avoidance, agoraphobic distress, and perceptions of recovery. However, patients with the most severe agoraphobia, for example, those struggling to leave the home, had large effect size improvements in agoraphobic distress and avoidance as well as significant improvements in persecutory ideation, quality of life, and perceived recovery, which were maintained at 6 months.

Agoraphobic avoidance is understood from a cognitive perspective in gameChange. The avoidance is a defense (or safety-seeking) behavior in response to fearful thoughts [2,3]. Fearful thoughts often develop because of past unpleasant or threatening experiences. However, the fears are maintained as the absence of harm in the present moment is attributed to the use of defenses rather than there being no current threat. Even when in the anxiety-provoking situations, the use of more subtle defenses (eg, rushing or avoiding eye contact) plays the same maintaining role for catastrophic cognitions [4]. In treatment, defenses must be dropped so that the threat beliefs can be evaluated fully. This is not to overlook the fact that many patients with psychosis have had difficult experiences and may currently be living in adverse circumstances and potentially facing ongoing threats. Although there may not be current overt actions against the person, there can be more implicit and subtle forms of threat, particularly linked to stigma. Therefore, clinicians working with patients should always be aware of the potential for actual threat and assess appropriately.

On the basis of cognitive psychology principles, gameChange VR therapy was developed through a user-centered design process involving >500 hours of input from people with lived experience [5,6]. In 6 sessions, people enter interactive computer-generated simulations of everyday scenarios such as a café, a bus, or a physician's waiting room. Guided by a virtual coach, patients are encouraged to experiment with dropping defense behaviors and to evaluate their fears. A member of the staff is present to assist with the equipment and help plan homework tasks to consolidate the learning from VR. Consistent with the cognitive model, we found in the trial that improvements in agoraphobic anxiety and avoidance were mediated by reductions in both a wide range of threat cognitions and the use of within-situation defense behaviors [1].

Objectives

In this study, we used a peer research approach to try to understand the participant experience of gameChange VR therapy in depth. Peer research is steered and conducted by people with relevant lived experiences. Peer methods have the potential to facilitate greater depth and more nuanced data collection and analysis by enhancing rapport [7] and leveling power [8]. Working collaboratively with researchers from different backgrounds, including lived experience, can enhance the validity and trustworthiness of qualitative analysis [9,10]. Interpretative phenomenological analysis (IPA) is a qualitative approach that focuses on participants' lived experiences and how they make sense of them [11,12]. IPA was chosen as it explicitly acknowledges the role of the researcher in the interpretation, which complements the peer research approach of valuing the insights that lived experience can bring [11]. Template analysis can be used to extend and develop IPAs for larger samples [13]. We conducted a peer-methods qualitative study incorporating IPA and template analysis to explore participants' experiences with gameChange.

Methods

Overview

This was a qualitative peer-methods study investigating the experiences with gameChange VR therapy for agoraphobic avoidance. A multiperspectival design was used [14], and a peer research approach was taken, including collaboration with the gameChange Lived Experience Advisory Panel (LEAP). The LEAP was a panel of 12 people with lived experience of psychosis. Full details of the study methodology are provided in the published study protocol [15]. Criteria to ensure credibility in qualitative research [16,17] were used to inform the design and ensure rigor in the conduct of the study.

Ethics Approval

The study received Health Research Authority approval and Health and Care Research Wales approval (IRAS 256895), as well as ethics approval from the National Health Service (NHS) South Central - Oxford B Research Ethics Committee (19/SC/0075) as part of the gameChange trial.

Research Team

People with lived experience of psychosis and anxious social avoidance were involved in all stages of the study. The research team included peer researchers who had had similar experiences to those being explored, a qualitative researcher with lived experience of mental health issues that did not directly overlap with those of the participants, clinical psychologists who designed and used VR therapy, and a qualitative researcher who pioneered the IPA approach. The LEAP, facilitated by the McPin Foundation, a charity that promotes the use of lived experience in research, contributed to the design, conduct, and analysis of the study. We aimed to use the peer knowledge within the study at all stages, including the design, data collection, analysis, and presentation of the findings.

Participants

We recruited participants who had received gameChange VR therapy as part of the trial (ISRCTN17308399). The participants were people accessing NHS mental health services with a diagnosis of psychosis and self-reported difficulties going into everyday social situations because of anxiety. The inclusion and exclusion criteria for the trial are listed in the trial protocol [18]. The additional inclusion criteria for this qualitative study were willingness and ability to provide informed consent to participate in the interview and willingness to have the interview audio recorded.

Sampling and Recruitment

Consistent with IPA principles, the recruitment procedure sought homogeneity—the locus of homogeneity in this study was receipt of gameChange therapy. The primary sampling method was to invite a consecutive cohort of people in the final phase of the trial between April 2021 and September 2021. To explore different experiences of treatment using a multiperspectival design, we sought a larger sample size (N=20), including participants with low, medium, and high uptake of therapy. When possible, this was supplemented with purposive sampling to ensure variation across demographic characteristics (including age, gender, and ethnicity) and trial centers. The recruitment strategy was revised because of the high uptake of therapy in the trial (just under 90% of participants received a dose of therapy, which was defined as a minimum of 3 sessions). Therefore, the subgroups for the multiperspectival design were derived retrospectively from the data and are presented in the *Results* section.

A total of 27 people were invited to participate, of whom 7 (26%) declined and 20 (74%) consented. Participants were from each of the 5 trial centers that recruited participants from NHS mental health trusts across England: Avon and Wiltshire Mental Health Partnership NHS Trust; Greater Manchester Mental Health NHS Foundation Trust; Cumbria, Northumberland, Tyne, and Wear NHS Foundation Trust; Nottinghamshire Healthcare NHS Foundation Trust; and Oxford Health NHS Foundation Trust. Recruitment was facilitated by the local trial coordinator. Written or audio informed consent, including consent to the use of pseudonymized quotes, was obtained from all participants.

Procedure

The semistructured interview guide (Multimedia Appendix 1) was developed in collaboration with the LEAP, with reference to existing literature, and in line with the principles of IPA [19-21]. The guide was refined following pilot interviews with members of the LEAP. The guide was used flexibly, with a focus on eliciting the participants' own account. This involved using open-ended descriptive and narrative questions to explore the context, followed by individually tailored prompts to elicit further information or clarification and using the participants' own language whenever possible. The focus of the interview guide was on participants' experience with the gameChange therapy. It included questions such as *What is your experience of going out of the house or going into social situations?What was it like to be in everyday situations in virtual reality?* and *Compared to what you told us about your life before gameChange, is life different in any way now? How so?*

Interviews were conducted between April 2021 and September 2021. The first 40% (8/20) of interviews were conducted jointly by JB and AK, a further 55% (11/20) were facilitated by AK alone, and 5% (1/20) were facilitated by JB alone. Interviews were conducted remotely, either by phone (14/20, 70%) or web-based video call (6/20, 30%). The mean duration was 80 (SD 22; range 40-105) minutes, with most (13/20, 65%) completed over 2 sessions. The peer researcher chose when, how, and what to disclose about their related mental health experiences, and this differed between interviews. Both interviewers kept field notes, including on the use and impact of sharing the peer identity. Interviews were audio recorded, transcribed verbatim, and deidentified.

Analysis

A total of 25% (5/20) of the transcripts were coded using IPA [11,20]. IPA focuses on participants' lived experiences and how they make sense of them [11]. The remaining transcripts were analyzed using the initial IPA themes as a preliminary *template*. This work was conducted using template analysis [22], which can be used with IPA to analyze larger samples [13].

The multiperspectival design provides a structure for exploring both the individual account and related groups [14]. In our study, the subsamples were identified via preliminary analysis rather than via sampling strategies. Four subsamples related to overall experience and the impact of therapy were identified: (1) *Big changes* (4/20, 20%), (2) *Better ways to cope* (9/20, 45%), (3) *Hard to say or hard to hang on to* (5/20, 25%), and (4) *Struggling on* (2/20, 10%).

The 25% (5/20) of transcripts included in the IPA analysis were selected based on the richness of the data and to ensure a range of trial sites and ages and a balance of gender. To maintain the homogeneity of the sample, a requirement of IPA, the 5 transcripts expressed a similar perspective on gameChange. The analytical procedure for IPA followed the approach outlined by Smith et al [11,20]. This included line-by-line annotation of each transcript, mapping what mattered to each participant ("objects of concern") with the meaning assigned to the experience ("experiential statements"). Meanings were clustered and interpreted for each case. Across cases, themes were identified that encompassed the phenomenological experiences and understanding of the 25% (5/20) of participants, forming superordinate and subordinate themes. IPA provided the foundation for the subsequent template analysis.

A provisional *template* was developed from the IPA themes and used to initiate the template analysis of the remaining data. The template analysis followed the steps outlined by King et al [22]. In line with the multiperspectival design [14], the transcripts were introduced in subgroups, focusing on each in turn. Analyzing the data in these batches made comparisons between perspectives starker. New codes were assigned and the template was updated at least once after each group was added. Once all data had been analyzed, the template was reviewed against all transcripts. Two analysis sessions were held with the LEAP to develop the template. LEAP members were given an overview of the themes and shown a selection of quotes. The focus was on identifying patterns within the data, resolving ambiguity in the accounts, and considering how the participants' experiences resonated with their own.

The IPA analysis was conducted by JB, AK, and LC. DR and VP contributed to the template analysis. Supervisory support was provided at each stage of the analysis by ML and FW.

Reflexivity and Credibility

All members of the research team reflected on the different perspectives that they brought to the study design, setup, data collection, and analysis. For example, in the analysis, the peer researchers drew on their lived experience to support their interpretation of meaning in the data; this was particularly relevant when exploring meanings related to participants' experiences of anxious avoidance and psychosis.

Credibility checks were conducted with members of the gameChange LEAP. Their input was used to corroborate and deepen the interpretation of the themes. The reflexive logs, transcripts, interview schedule development, and minutes of supervisory research team meetings provided an audit trail for analysis. Illustrative quotes, description of the study context, and participant characteristics allowed for an assessment of the transferability of the findings to other settings and contexts.

Results

Contextualizing the Data

A total of 20 people participated: 11 (55%) women and 9 (45%) men. The average age of the participants was 37 (SD 12.9) years. In total, 85% (17/20) of the participants identified as White British individuals, 10% (2/20) identified as British Asian individuals, and 5% (1/20) identified as Polish. As can be seen in Table 1, most (15/20, 75%) participants were unemployed. A total of 20% (4/20) of the participants said that they spent a lot of time playing computer games and described themselves as "gamers." In total, 60% (12/20) of the participants attended 6 sessions of therapy, and 40% (8/20) attended 7 sessions. For 55% (11/20) of the participants, these VR sessions were facilitated by a clinical psychologist; for 30% (6/20) of the participants, it was an assistant psychologist; and 15% (3/20) of the participants worked with peer support workers. The participant characteristics in this qualitative study were consistent with those in the main trial (see the trial outcome report [1]).

Table 1. Participant characteristics (N=20).

Demographic and clinical characteristics	Participants, n (%)
Marital status	
Single	15 (75)
Married	3 (15)
Divorced	1 (5)
Cohabiting	1 (5)
Employment	
Unemployed	15 (75)
Retired	2 (10)
Carer	1 (5)
Employed (full-time)	1 (5)
Student (part-time)	1 (5)
Living situation	
Living with parents or another relative	8 (40)
Living alone	7 (35)
Living with others	4 (20)
Living with a spouse or partner	1 (5)
Mental health service context at the time of interview	
CMHT[a]	15 (75)
EIP[b] team	5 (25)

[a]CMHT: community mental health team.

[b]EIP: early intervention in psychosis.

Overview of Findings

An overview of the key findings is presented. This is followed by a description of the subgroups identified for the multiperspectival design. The cross-case analysis of participants' experiences with the intervention is then presented. Illustrative quotes, with details omitted to protect anonymity, are presented in the text and in Multimedia Appendix 2.

Summary of Key Findings

There were 5 superordinate themes (Textbox 1). First, anxious avoidance carries a cost. Participants described living restricted lives in which fears made it hard to do everyday activities. Second, participants shared their curiosity and motivation to try VR therapy. Third, VR therapy provided a place to learn about anxiety and practice different or new responses. Fourth, the VR simulations triggered an anxiety response, yet participants simultaneously recognized that the environments were largely safe. This interaction of anxiety and safety could be calibrated by the individual to provide a safe place to learn about fears and build confidence. Finally, VR was a training ground to do things differently. Through practice and conversations with the member of the staff who was present, participants took the key learning from VR into the real-world situations that mattered to them.

Textbox 1. Overview of superordinate and subordinate themes.

- Experience and cost of anxious avoidance
- Reasons to try: curiosity and motivation
- A place to practice
  - An immersive experience
  - A chance to observe anxiety
  - New ways of responding
- The security of knowing it is not real
  - The sweet spot of safety and anxiety
  - Calibrating for a personalized approach
- Taking it into the real world
  - From training wheels to real-world practice
  - One thing to hold onto

The 4 Perspectives

Overview of the 4 Perspectives

We identified 4 subgroups of participants based on the descriptions of their experience and impact of the gameChange therapy. The descriptions varied from life-changing to experiencing little change, although all described gameChange as a valuable experience. Illustrative quotes for each subgroup are presented in Table 2.

Table 2. Illustrative quotes from the participant subgroups (N=20).

Subgroup	Participants, n (%)	Illustrative quotes
Big changes	4 (20)	• "It's very different now, I can open my curtains and look out my window, I can go out to local shops and places, I can meet up with friends and family, I can do such a lot more." [Participant 27] • "Before I would never do that, ever. But I did that and I was talking to new people and I was having a great time. It's just being in social situations instead of hiding from them, I'm just trying to embrace them." [Participant 8]
Better ways to cope	9 (45)	• "It definitely helped with anxiety. I still suffer from some of the things I did, well, all of the things I did before, but it's definitely, definitely helped it in some way." [Participant 3] • "Before I'm just looking at the floor wherever I'm going but now I'm looking at everyone, like, in their eyes and stuff. Even though I'm still too scared to go to the supermarket on my own, I have been able to walk past it on my own, like walk up there and past it, whereas before I wouldn't have been able to do that. I've been in small shops on my own and the bus, I can do that on my own now without worrying." [Participant 25]
Hard to say or hard to hang onto	5 (25)	• "Now because my mood is quite good, I'm thinking, 'Yeah, actually. I did take away stuff.' But when I'm really anxious, like I have been really anxious over the last couple of weeks...and then I'm like, I haven't learnt anything." [Participant 17] • "I mean I wasn't too bad with a lot of the situations anyway, so I don't know if I've taken a lot from it, but I'd like to think I have but I'm not entirely sure. I'm not entirely sure if it's had any massively notable impact on me." [Participant 13]
Struggling on	2 (10)	• "It has not really made a magical difference for me, unfortunately, but I can see how it can be very helpful. I think I'm just too entrenched in my avoidance little bubble, that it wasn't strong enough to pull me out of it. It's just the same." [Participant 19] • "Like, I say, still go to cafes, still get on the bus, go shopping. I didn't go food shopping yesterday. I was really, really anxious yesterday in town with the boys. I couldn't do my food shopping. My body wouldn't let me do it. My mind affects my body." [Participant 26]

Big Changes

A total of 20% (4/20) of the participants described gameChange as a transformative experience. Participants in this group marveled at how far they had come—they were able to do things they had not imagined at the start of therapy, when they were often housebound and experiencing very low mood. These accounts were characterized by excitement and enthusiasm.

Better Ways to Cope

A total of 45% (9/20) of the participants described experimenting with new ways to approach and cope with situations despite some ongoing anxiety. For these participants, social situations were less stressful but not yet comfortable.

Hard to Say or Hard to Hang Onto

A total of 25% (5/20) of the participants noted some small changes following therapy but found these hard to identify when asked directly or hard to maintain when anxiety increased or mood dipped. Participants valued aspects of the therapy but did not necessarily find that the VR scenarios triggered their anxiety. Participants in this group were often able to engage in some social situations before starting therapy.

Struggling On

In total, 10% (2/20) of the participants recognized the potential of the therapy but described little personal benefit as they struggled with psychotic experiences. They continued to feel anxious in the familiar and often essential (eg, shopping) situations they were able to engage in even before the start of therapy.

Main Themes

The Experience and Cost of Anxious Avoidance

All participants spoke about the cost of anxious avoidance. Some participants described themselves as almost housebound, others avoided specific situations, and a few could perform essential tasks in an area where they felt safe. However, all felt the burden and restriction of anxious avoidance:

> *It affects my life big time because I can't do half the things that I want to do or what a normal everyday person would do. I want to do something but sometimes it can hold me back and it can really affect the way you think, the way you act and the person that you are.* [Participant 27, Big changes subgroup]

As in the previous extract, participants shared the reasons for withdrawal: many felt threatened by others, at risk of physical or social harm, or that others were observing or talking about them. Some were anxious about showing symptoms in public as they feared that this would draw attention and invite judgment. Participants described the tactics that they had developed to try to reduce these risks, but some strategies had life-limiting effects. Some described their situation as intolerable, affecting self-esteem and quality of life, disrupting careers, impeding friendships, and making them feel "almost not like a human being." Although all participants described life being "limited" by anxious avoidance, not all were distressed by inhabiting a small world.

Reasons to Try: Curiosity and Motivation

As VR therapy was new to the participants, most had no preconceived notions of what gameChange would be like or how it would help. Many said that they were “open-minded” to try gameChange. However, the reasons to engage differed:

> *I went in with an open mind. I was willing to give anything a go because I just didn’t want to be in the same state I was in after episode one.* [Participant 3, Better ways to cope subgroup]

> *I’m interested in technology, new technology. It’s quite exciting. So, that really encouraged me to get involved as well.* [Participant 1, Big changes subgroup]

As mentioned previously, for some, the opportunity appeared when they were ready to receive and engage with it. Others noted that experiencing a difficult time before gameChange fueled their desire for change. This was often accompanied by a sense of personal responsibility for the intervention’s success. Some were open to gameChange as they had been unwell for a long time and were keen to try anything that could alleviate their symptoms. Others simply saw it as an opportunity to do something in an otherwise restricted life: “I don’t really have anything to do so I was like: ‘Go on then, I might as well do it’” (participant 7, *Hard to say* subgroup).

The use of VR in gameChange was appealing to more than half (11/20, 55%) of the participants. Those who had heard of VR were attracted by its novelty, they were “interested” or “intrigued” to see what it would be like. They understood its therapeutic use as “a modern new way to treat social anxiety”:

> *I was, like, curious, I suppose, yeah. Its cutting-edge technology, isn’t it?* [Participant 26, Struggling on subgroup]

Of the 4 participants who identified as gamers, 3 (75%) were primarily attracted to the intervention as it was a chance to use VR.

A Place to Practice

> *I really enjoyed it. Well, I say enjoyed it, it was actually quite hard work. I found it very realistic when I went in, more than I expected, I think. And it was a lot harder than I thought it was going to be.* [Participant 1, Big changes subgroup]

Most (14/20, 70%) participants, including one of the 4 gamer participants, were surprised by how realistic it was. Participants seemed to be struck by its immersive quality:

> *Going into VR was like going into another world, kind of thing. It was really like everything was not realistic, you could tell it was all fake, but at the same time you felt like you were actually in there.* [Participant 25, Better ways to cope subgroup]

> *It was like being in a film, it was. You put the helmet [VR headset] on and you’re taken to another world.* [Participant 26, Struggling on subgroup]

Immersion was created by the graphics, background noise, and interactive details:

> *You can open the door. You can lift a can of beans up and put your bank card on the meter to pay for it. I thought it was amazing.* [Participant 21, Better ways to cope subgroup]

This immersion and perceived realism meant that many participants saw the VR scenarios as a meaningful environment to practice in. Participants who identified as gamers tended to be less impressed with the VR world.

Participants described developing new insights into their experience of anxiety, as described in the following extract:

> *I didn’t realise things like I was looking for an escape route and going to it. And now, I’m aware of that, I cannot do it so much. You know, it’s just sort of being aware.* [Participant 1, Big changes subgroup]

Being in the VR simulations could trigger anxiety. Participants spoke of sweaty palms and racing hearts and of realizing that they were unconsciously trying to use coping mechanisms such as looking for an escape route or exit, avoiding eye contact, or diminishing their physical presence. For some, this was a hard and shocking realization:

> *...that was really an eye-opener, and I was quite shocked at how it has affected my life for so long.* [Participant 27, Big changes subgroup]

VR provided an opportunity to observe anxiety and automatic responses with some emotional distance. It was “a buffer” or a chance “to step back and think about how they are reacting,” as members of the LEAP described it. Responses that were overwhelming and panicked in real life could be slowed, picked apart, and rerun. A LEAP member commented that VR was like a magnifying glass, clarifying the details and nuances of the situation. This led to participants developing greater understanding of what happens in moments of anxiety. This could be empowering and raised the potential to change these automatic responses.

Participants described VR as a place to practice new ways of responding in situations:

> *Make eye contact. I smile a bit more at people. Little things you don’t realise you haven’t been doing till you go and do the headset. It made me realise a lot, that I had just focused my life around the voices and not taken any notice of the outside world. That’s why I’ve been taking more notice of things when I’m out now.* [Participant 23, Better ways to cope subgroup]

The automated virtual coach and staff member made suggestions to drop defenses and try new strategies to build confidence. Despite the anxiety, it was safe to try new approaches as participants knew that the VR was not real.

“The Security of Knowing It Is Not Real”

The nature of VR means that, despite knowing that it is a simulation, reactions are typically real—as evidenced in the anxiety responses that the participants experienced:

> *Even though you’d tell yourself that you’re in a safe environment and the people weren’t going to necessarily react as you would expect a real-life person to react, your brain is still telling you that you’re in danger and you’re at risk here so yes, it did*

> *make you feel quite anxious.* [Participant 2, Big changes subgroup]

However, knowing that the VR simulations were not real allowed participants to feel a sense of safety:

> *It makes you face your fears but in a less extreme way because these people, you know aren't real, but you still have the feeling of it being people.* [Participant 16, Better ways to cope subgroup]

Participants described an active interaction between safety and anxiety. For example, a sense of safety was required for participants to "slowly push themselves out of their comfort zone" (participant 8, *Big changes* subgroup), try the new ways of responding that the automated virtual coach and staff member suggested, and learn to tolerate discomfort. This was a delicate balance. If anxiety was "dialled" too low, VR was perceived as boring and ineffective. If safety was "dialled" too low (or anxiety too high), VR was intense and draining:

> *It's a fine line: you want it to be realistic enough, so it's a good practice, but it's also quite helpful if it's not totally realistic because then you get that security of knowing that it's not real.* [Participant 1, Big changes subgroup]

As mentioned previously, participants understood the importance of locating this "sweet spot," noting that it was sometimes helpful that the VR was not photorealistic or that they knew they were in no danger despite feeling bodily symptoms of anxiety. Finding the right balance could be difficult. For some participants, aspects of the VR scenarios matched real-world triggers, leading to fears or memories of past difficulties and resulting in spikes in anxiety. At these moments, it was sometimes hard to feel safe enough to create new learning in VR.

Levels of anxiety and safety could be calibrated by and to the individual through choice of the levels within the program or by the actions of the staff member:

> *The deliverer knew if I was putting defences up and she would tell me different ways to cope. There was one scenario where I was in the street and people walked past and I put my defences up because I kept looking at them walking past and my therapist said to relax and look at the cars and describe what's in the cars and stuff.* [Participant 11, Hard to say or hard to hang onto subgroup]

The features of the software that often increased anxiety were "realness" and immersion in the scenarios, background noise, the scenarios becoming more crowded, and specific tasks such as waiting in a queue. Features that increased the sense of safety were that the characters and scenarios did not look as real as the real-world situations, the gradual increase in intensity of the levels, and having the option of removing the headset.

There were layers of support from the virtual coach, Nic, and the staff member. Those with higher baseline levels of anxiety described the coach as comforting, and participants appreciated her guidance and encouragement:

> *When I did a level, she would be like, "Well done, you did great." She was good in that sense. It was someone familiar that I would see every time I went in.* [Participant 25, Better ways to cope subgroup]

Those who were more confident in VR described the coach as "repetitive," "slow," and at times "irritating."

The staff member was able to build on the generic support that was programmed in the software through the virtual coach, increasing the participants' sense of safety to facilitate more exploration and experimentation in VR. The staff member was attuned to the participants' responses, suggesting pauses, encouraging repetition of scenarios or levels that they found challenging, or helping identify and drop specific defenses:

> *I think the deliverer was quite helpful in saying: "In that one you appeared more anxious, do you want to do that one again? You spoke a bit quietly in that one, did you want to do it again, you didn't seem that confident doing that one, would you like to try it again?"* [Participant 15, Better ways to cope subgroup]

> *I would use coping strategies. I didn't realise until the deliverer would tell me what I did—I didn't recognise it myself—so, the deliverer would tell me certain things that would give me more confidence for the VR, but also, when leaving the session as well.* [Participant 3, Better ways to cope subgroup]

In this way, the sweet spot of anxiety and safety could usually be found for each person, creating the conditions for them to try new ways of responding in the VR scenario.

Taking It Into the Real World

> *The fear was there but what I was fearing didn't actually happen which was good. That, for me, was part of the therapy in the sense that it made you realise that what you fear is going to happen isn't necessarily what will happen. It made you re-evaluate if you like your way of thinking.* [Participant 2, Big changes subgroup]

Participants understood that VR was a safe place to do things that scared them—"training wheels" where they could take "baby steps"—before translating them to the real world:

> *The everyday situations that I found difficult, the more I practised them in the VR, the more I could get confident and be more confident in day-to-day life. I think because I was learning about it in the VR and practising and practising and practising, I could then take that and build up more confidence and do it in the everyday real world.* [Participant 27, Big changes subgroup]

> *I guess it's like the training wheels, isn't it? You get used to a situation simulating it and then go and try it in the real world.* [Participant 5, Hard to say or hard to hang onto subgroup]

Many participants recognized the need to practice between VR sessions and appreciated being given "homework." Some acknowledged that this structure helped them push themselves.

Others found additional ways to reinforce learning, such as writing notes and asking questions, periods of active reflection, and debriefing with the deliverer and other people. Some used sessions with their care teams to implement homework tasks. These participants were not deterred by circumstances such as COVID-19 restrictions hindering what they could do in the real world, and they were able to adjust the tasks around them. These participants tended to describe gaining the most benefit from the therapy and were in the *Big changes* and *Better ways to cope* subgroups.

Participants needed motivation to face anxiety-provoking situations—the potential rewards needed to be high enough for the effortful process of overcoming anxiety. This was observed in the descriptions of the 15% (3/20) of participants who already felt safe in their local environment and were unsure about the value of going further afield. These participants were in the *Struggling on* and *Hard to say* subgroups. For some, the relationship with the staff member was an important motivator to put into practice the learning from VR.

Through practicing in VR, participants described creating new learning and finding new explanations and understandings about themselves, other people, and the world. A common realization was that reality was not as bad as participants feared. The seed for these new beliefs was often found in VR—opportunities to make this discovery were embedded in the VR scenarios, for example, when characters smiled during interactions or simply did not respond as feared (eg, laughing or criticizing the participant). This new learning was tailored and reinforced by the staff member, ensuring that the key messages were personalized, succinct, and easy to recall. This learning often became most powerful when participants grew confident enough to push themselves in real life, making eye contact or small talk with people. These layers of corroboration, including discovery in VR, discussion with the deliverer, and real-world practice, made for a powerful learning experience. As well as embedding new beliefs, participants held onto memories created during gameChange. Some spoke of recalling scenes in VR or of positive experiences they had had afterward in the real world. This had a calming effect when they found themselves in a challenging situation:

> *It's like [the staff member] says, "stand confident and people will see you as confident. No one is looking at you. People do look, it doesn't say they're going to hurt you." It really helped me, because when I went out I thought of the gameChange.* [Participant 21, Better ways to cope subgroup]

The result of this practice and learning was that some participants saw changes that were important to them. The world had opened up for people whose lives were most restricted by agoraphobic avoidance:

> *I've been out on a couple of nights out and yeah, I've loved it really. Instead of hiding from it, I'm actually embracing it, I'm enjoying spending time with my friends because like I said I didn't see them for a long time in the first lockdown because of my mental health and the state of mind I was in, it's great seeing them now.* [Participant 8, Big changes subgroup]

> *It's a case of not thinking twice about getting the bus and getting take away coffee now. I'm quite happy to do it which was a big change for me.* [Participant 2, Big changes subgroup]

Discussion

Principal Findings

Facilitated by peer methods, participants provided rich and informative accounts of the problem of agoraphobic anxiety and avoidance, the experience with automated VR therapy, and its impact on their lives. The restriction caused by severe agoraphobic avoidance has a substantial cost in people's lives. Variations in the benefits of VR therapy were observed across the participant groups. Participants who were close to housebound (4/20, 20%) tended to report "big changes" from the gameChange VR therapy, whereas individuals who were reasonably comfortable with the boundaries of the locations that they could visit (5/20, 25%) tended not to report so much impact from the VR sessions. This perspective from the qualitative interviews of variation in benefits of VR therapy was gained before the trial outcome results were known by those involved in the qualitative analysis but were entirely consistent with the main trial findings. The largest group identified (9/20, 45%) derived benefit from gameChange—they developed "better ways to cope"—but in a less transformational way than the group who saw "big changes." Their accounts suggest that, before the intervention, they were more able to perform everyday activities than the other group, but they were still distressed by their agoraphobia. These results support the conclusion that the implementation of gameChange is best focused first on people with the most severe agoraphobic difficulties.

There was further consistency with the quantitative findings. Participants reported a wide range of fears contributing to agoraphobic avoidance, as has been found using self-report assessments [4]. Furthermore, the participants viewed VR as a popular treatment option with limited mention of any side effects, which is consistent with our surveys across the whole group that received gameChange [23]. However, the interviews provided greater depth on several important issues. They provided an intriguing perspective on the therapeutic nature of immersive technology. Participants reported how VR—as they knew they were experiencing simulations—provided the chance to gain distance on anxious responses and try new alternative ways of thinking and behaving. Therapeutic gains arose out of a delicate balance of experiencing typical anxious responses but only to a degree in which safety could also be kept in mind. In this way, safety feelings could begin to feel like a realistic appraisal of the situations. This calibration was largely determined by the users, for example, selecting the scenario or level within the program, but there could also be invaluable support from the staff member who was present. A degree of guided support, even with automated therapies, is likely to be very important. It was also clear that participants considered that, to make change, it was important to apply the learning to real-world situations via the homework tasks. Conversations with the supporting staff member were valued. A common realization among those who gained benefits was that reality was not as bad as they feared. There are opportunities to further tailor the treatment to the individual by increasing the range of scenarios available and adapting the demographics of the virtual coach.

Conclusions

The interviews provided fascinating in-depth insights into the experience with automated VR therapy, which will inform the delivery of gameChange alongside other implementation and health economic studies [23-25]. This study has several limitations. The participants interviewed were not representative of all those who received VR therapy. For instance, we only succeeded in interviewing participants who completed therapy, which is largely a reflection of the high uptake of VR therapy in the trial. This means that we would have missed important specific challenges and barriers for individuals who did not complete VR therapy. The participant group was also not representative of the wider population of people attending mental health services. There was a lack of ethnic diversity in the participants interviewed. Understanding the potential barriers faced by underserved and underrepresented groups will be important for future implementation. We also note that the interviews and therapy were conducted during the COVID-19 pandemic. The context of restrictions, disruption, and anxiety may have affected the experience of agoraphobic avoidance and VR therapy. Finally, the lengthy interviews that covered multiple questions mean that it is likely that we may only have been able to capture a fraction of participants' experiences in this report.

Acknowledgments

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Authors' Contributions

All the authors contributed to the study design. TK facilitated the LEAP. Data were collected by JB and AK. JB, AK, and LC conducted the primary analysis with contributions from DR and VP. FW and ML provided supervision. JB, FW, DF, and DR wrote the first draft of the manuscript. All the authors approved the final version of the manuscript.

Conflicts of Interest

DF is a founder and nonexecutive board director of Oxford VR, a University of Oxford spin-out company, which programmed and commercializes the gameChange treatment. DF holds equity in Oxford VR and receives personal payments. DF holds a contract for his university team to advise Oxford VR on treatment development. The University of Oxford, Oxford Health National Health Service Foundation Trust, and the McPin Foundation received a share of the licensing fee from Oxford VR for the gameChange software. SL does some consultancy work for Oxford VR. The other authors have no conflicts to declare.

Multimedia Appendix 1
Interview schedule for the gameChange experience study.
[DOCX File , 35 KB - games_v11i1e38065_app1.docx]

Multimedia Appendix 2
Illustrative quotes by superordinate and subordinate theme.
[DOC File , 86 KB - games_v11i1e38065_app2.doc]

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Abbreviations

IPA: interpretative phenomenological analysis
LEAP: Lived Experience Advisory Panel
NHS: National Health Service
VR: virtual reality

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Original Paper

Engagement With Gamification Elements in a Smoking Cessation App and Short-term Smoking Abstinence: Quantitative Assessment

Nikita B Rajani[1,2], PhD; Luz Bustamante[3,4], MSci; Dominik Weth[2], MSc; Lucia Romo[3,5], PhD; Nikolaos Mastellos[1], PhD; Filippos T Filippidis[1], PhD

[1]Department of Primary Care and Public Health, Imperial College London, London, United Kingdom

[2]NextStage Consulting, Dubai, United Arab Emirates

[3]Laboratoire EA 4430-Clinique Psychanalyse Developpement, Department of Psychology, University of Paris Nanterre, Paris, France

[4]Research and Development Department, Kwit SAS, Strasbourg, France

[5]Inserm–Le Centre de Recherche en Epidémiologie et Santé des Populations 1018 UPS, Hôpital Raymond-Poincaré, Paris, France

Corresponding Author:
Nikita B Rajani, PhD
Department of Primary Care and Public Health
Imperial College London
St Dunstan's Road
London, W6 8RP
United Kingdom
Phone: 44 7427615928
Email: nikita.rajani14@imperial.ac.uk

Abstract

Background: Gamification in smoking cessation apps has been found to improve cognitive outcomes associated with higher odds of quitting. Although some research has shown that gamification can also positively impact behavioral outcomes such as smoking cessation, studies have largely focused on physical activity and mental health. Only a few studies have explored the effects of gamification on smoking cessation outcomes, of which the majority have adopted qualitative methodologies and/or assessed engagement with apps using self-report.

Objective: This study aimed to explore levels of user engagement with gamification features in a smoking cessation app via in-app metrics. Specifically, the objective of this paper was to investigate whether higher engagement with gamification features is associated with the likelihood of quitting in the short term.

Methods: Data from a larger online study that recruited smokers seeking to quit were analyzed to address the objectives presented in this paper. The study took place between June 2019 and July 2020, and participants were primarily recruited via social media posts. Participants who met the eligibility criteria used 1 of 2 mobile apps for smoking cessation. In-app metrics shared by the developer of one of the smoking cessation apps, called Kwit, were used to assess engagement with gamification features. Out of 58 participants who used the Kwit app, 14 were excluded due to missing data or low engagement with the app (ie, not opening the app once a week). For the remaining 44 participants, mean (SD) values were calculated for engagement with the app using in-app metrics. A logistic regression model was used to investigate the association between engagement with gamification and 7-day smoking abstinence.

Results: In total, data from 44 participants who used the Kwit app were analyzed. The majority of participants were male, married, and employed. Almost 30% (n=13) of participants self-reported successful 7-day abstinence at the end of the study. On average, the Kwit app was opened almost 31 (SD 39) times during the 4-week study period, with the diary feature used the most often (mean 22.8, SD 49.3). Moreover, it was found that each additional level unlocked was associated with approximately 22% higher odds of achieving 7-day abstinence after controlling for other factors such as age and gender (odds ratio 1.22, 95% CI 1.01-1.47).

Conclusions: This study highlights the likely positive effects of certain gamification elements such as levels and achievements on short-term smoking abstinence. Although more robust research with a larger sample size is needed, this research highlights the important role that gamification features integrated into mobile apps can play in facilitating and supporting health behavior change.

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KEYWORDS

gamification; smoking cessation; smoking abstinence; mHealth; mobile apps; mobile phone; smartphone; digital health; user engagement; cognitive outcome; self-support; in-app metrics

Introduction

Despite steps taken to tackle the global tobacco epidemic, smoking-related health disability and mortality remain concerning [1]. While the majority of smokers want to quit smoking, research shows that in many countries such as the United Kingdom, long-term abstinence rates remain low [2]. In addition to low smoking cessation rates, face-to-face access to cessation services has been falling in several countries [3]. Digital health solutions, such as mobile apps, have been found to be effective methods of reaching individuals unwilling or unable to access in-person services. However, low engagement and retention are common challenges for mobile apps. The integration of gamification, the use of game elements in a nongame context [4], has been found to be positively associated with higher app engagement [5,6]. Some examples of gamification elements, also known as on-screen features or tactics, include goal setting, levels and badges, progress tracking, and progress sharing. Since gamification shares key elements with behavior change theories, it is often applied to health behavior change interventions [6].

Prior research shows that engagement with gamification elements in smoking cessation apps can positively impact cognitive constructs vital for abstinence such as self-efficacy and motivation to quit [7]. Although research also shows the positive effects of gamification on behavioral outcomes, the majority of existing studies have focused on physical activity and mental health [8]. A few studies that explored the association between engagement with gamification and smoking cessation adopted qualitative methodologies and assessed engagement using self-reported data rather than objective app usage metrics [6,7]. We aimed to explore the level of user engagement with gamification elements in a smoking cessation app via the analysis of in-app metrics. We also aimed to investigate whether engagement with gamification elements is associated with the likelihood of achieving short-term smoking abstinence.

Methods

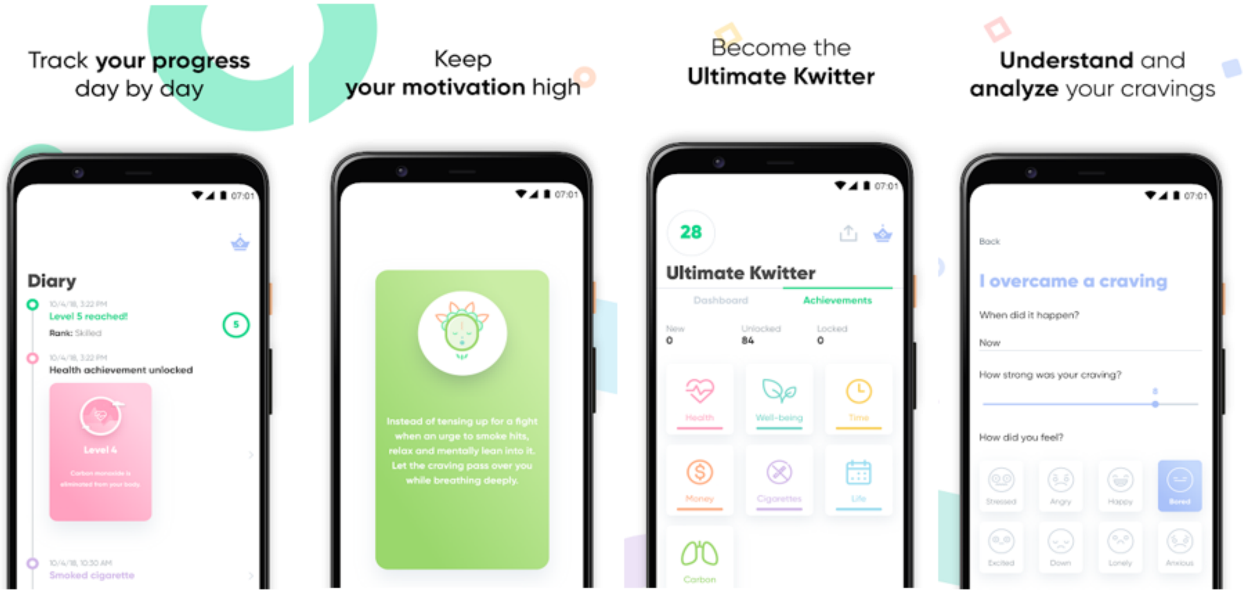
Study Overview

The data used for this paper's analyses were collected as part of a larger online study that took place from June 2019 to July 2020 and explored the effects of gamification on cognitive constructs vital for smoking cessation [7]. Participants were recruited via posters in public places in London, United Kingdom, and posts on various social media channels such as Facebook and Instagram. Interested participants were asked to fill out a screening questionnaire to assess eligibility. Eligible participants (Table S1, Multimedia Appendix 1) were assigned 1 of 2 smoking cessation apps; this paper focuses on users of Kwit, a gamified mobile app designed to help smokers quit smoking using cognitive behavior therapy [9]. Participants had to use the app at least once a week for 4 weeks and complete a questionnaire before (baseline), 2 weeks after (mid-study), and 4 weeks after app use (end of study). In-app metrics shared by the app developer were used to assess engagement with features. Out of the 70 participants who were assigned Kwit, 58 (83%) completed the study. A participant was considered to have completed the study if they self-reported to have engaged with the app at least once a week for the duration of the study and completed all questionnaires. Aside from free app access, participants had a chance to win a £50 (US $60) Amazon voucher.

The Kwit App

Kwit is a mobile app, developed by Kwit SAS, that aims to help smokers quit and successfully remain abstinent from smoking. It uses cognitive behavior therapy principles and gamification to assist individuals [9]. The app consists of features such as a smoking diary to log cravings and triggers, motivation cards, and a calculator/tracker to monitor self-progress in relation to key achievements. Figure 1 presents screenshots of the app, showing the smoking diary feature, an example of a motivation card, the achievements tracking page, and how users can track cravings. App versions 4.1 to 4.4 (June 2019 to July 2020) were used by participants.

Figure 1. Screenshots of the Kwit app.



Measures

Sociodemographic measures included age (18-29 years, 30-41 years, 42-53 years, and 54-65 years), gender (male or female), marital status (single, married, or civil partnered), and employment status (unemployed: individuals willing or able to work but not employed; employed; nonemployed: students, individuals unable to work, and homemakers). Similar to other studies, the Fagerström questionnaire was used to assess nicotine dependence with responses categorized as low (0-4 points), moderate (5-7 points), and high (8-10 points) [10,11]. Additionally, to measure abstinence, participants were asked at the end of the study, "Have you smoked at all in the past seven days?" to assess the 7-day point prevalence of smoking abstinence. Participants who responded "No, not even a puff" were considered short-term quitters. Participants who selected other responses ("Yes, just a few puffs"; "Yes, between 1 and 5 cigarettes"; and "Yes, more than 5 cigarettes") were categorized as smokers.

Aside from self-reported data, objective in-app metrics were also used in the analysis. Kwit SAS routinely collects and maintains a database of app usage statistics, including various user interactions with specific features and the app overall. Kwit SAS provided in-app metrics for the participant identification numbers shared with them. The metrics included the number of times the app was opened, levels completed, smoking diaries logged, achievements unlocked, and motivation cards viewed. Additional information on the in-app metrics is presented in Table S2 (Multimedia Appendix 1).

Statistical Analysis

The statistical software Stata 16 (StataCorp) was used for the analysis. Descriptive statistics were used to present general participant characteristics, nicotine dependence, and 7-day abstinence. Mean (SD) values were calculated for the in-app metrics. Unadjusted logistic regression models were run for each in-app metric to explore its association with 7-day abstinence. The specifications of the adjusted logistic regression model were based on an iterative process that considered collinearity. Significance was set at the 5% level (*P*<.05), and 95% CIs were presented.

Ethics Approval

The study was conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly Declaration of Helsinki 1964 and later versions.

Ethical approval was obtained from the Joint Research Imperial College London Research Ethics Committee prior to the beginning of the study (reference: 19IC5158).

Results

Among the 58 participants who completed the study (self-reported app usage once a week over the study duration and completion of all questionnaires), 14 participants were excluded from the analysis due to issues with the in-app metrics (eg, missing or inconsistent data; n=9) or due to inadequate engagement according to the in-app data (ie, the app was not used once a week; n=5). Table 1 shows that more than half of Kwit app users were 18 to 29 years of age (n=24, 55%). A majority were male (n=27, 61%), married (n=35, 80%), and employed (n=28, 64%). Moreover, the majority of participants had low to moderate dependence on nicotine (n=42, 95%). Almost a third (n=13, 30%) reported at the end of the study that they successfully abstained from smoking in the past 7 days.

As seen in Table 2, Kwit users opened the app almost 31 (SD 39) times on average over the 4-week study period. Among the metrics that were collected, the most frequently used features were logging of smoking diaries (mean 22.8, SD 49.3) and unlocking of achievements (mean 22.3, SD 16.5). Additionally, over the study period, motivation cards were opened on average 8.0 (SD 11.2) times and 7.7 (SD 4.9) levels were unlocked by Kwit users.

In the adjusted logistic regression model (Table 3), each additional level unlocked was associated with approximately 22% higher odds of achieving 7-day abstinence after controlling for other factors such as age and gender (odds ratio 1.22, 95% CI 1.01-1.47). The number of diaries logged and motivation cards opened were not significantly associated with 7-day abstinence in the adjusted model. The number of achievements was not included in the model since it was highly correlated with the number of levels. However, when the logistic regression model was rerun with the number of achievements instead of levels, the results suggested that each interaction with the achievements feature was associated with a 7% increased likelihood of reporting 7-day abstinence (95% CI 1.01-1.15).

Table 1. Characteristics of the study sample.

Characteristics	Participants (N=44), n (%)
Age	
18-29 years	24 (55)
30-41 years	13 (30)
42-53 years	4 (9)
54-65 years	3 (7)
Gender	
Male	27 (61)
Female	17 (39)
Marital status	
Single	9 (21)
Married or civil partnered	35 (80)
Employment status	
Employed	28 (64)
Nonemployed	13 (30)
Unemployed	2 (5)
Prefer not to answer	1 (2)
Nicotine dependence	
Low (0-4 points)	25 (57)
Moderate (5-7 points)	17 (39)
High (8-10 points)	2 (5)
7-day smoking abstinence	
Yes	13 (30)
No	31 (70)

Table 2. Summary of engagement with mobile app features after 4 weeks of app use.

In-app metric	Value, mean (SD)
Number of times the app was opened	30.8 (39)
Number of motivation cards opened	8 (11.2)
Number of achievements unlocked	22.3 (16.5)
Number of diaries logged	22.8 (49.3)
Number of levels completed	7.7 (4.9)

Table 3. Logistic regression investigating the association between gamification and 7-day smoking abstinence at the end of the study (N=44).

Variable	7-day smoking abstinence, OR[a,b] (95% CI)
Age	0.98 (0.91-1.05)
Gender	
Male	Ref[c]
Female	2.27 (0.45-11.52)
Number of diaries logged	0.97 (0.91-1.03)
Number of motivation cards opened	1.03 (0.97-1.11)
Number of levels unlocked	1.22 (1.01-1.47)

[a]OR: odds ratio.

[b]Adjusted for all the variables included in the table.

[c]Ref: referent.

Discussion

Principal Findings

We found that after 4 weeks of app use, almost 30% of smokers reported 7-day abstinence. This rate is generally within the range reported by other mobile app studies [12]. However, direct comparisons are difficult due to differences between interventions and varying methods of measuring cessation. Mobile app interventions such as Kwit can be associated with an increased likelihood of abstinence compared to no assistance or using willpower alone [13]. This study opens the possibility of using smoking cessation apps to aid individuals who are not accessing face-to-face services [14].

The analysis also found that engaging with levels was significantly associated with 7-day abstinence. According to Gnauk et al [15], levels are important as they can function as a goal-setting tool that marks progression and signals accomplishment. Similarly, the achievements or badges feature was also found to be associated with an increased likelihood of reporting abstinence. Achievements and levels are similar as they both provide regular feedback to users and remind them of their successes. This can lead to an increase in perceived competence, which facilitates health behavior change [16]. Generally, the positive effect of providing regular feedback in both remote and face-to-face interventions is well established [17]. Aside from the importance of features such as levels and achievements, it was also found that the likelihood of reporting abstinence was not statistically different with regards to age and gender after adjusting for engagement with app features. This could imply that any effects that Kwit may have on smokers might not vary by age or gender. However, it is important to note that the small sample size could impact the generalizability of the findings.

Limitations

The observational nature of the study does not allow for causal inference; future research could carry out a rigorously designed randomized controlled trial with apps that differ only with regards to the type and number of gamification features. Aside from the sample size, the attrition of participants from 70 to 44 participants could pose a threat to the internal validity of the study and limit the generalizability of the findings. Additionally, since research has shown that relapses in abstinence can occur over a longer period of time, the relationship between engagement with gamification features and long-term quitting cannot be determined; future research could consider having a longer follow-up period [18,19]. Furthermore, validating smoking abstinence using biochemical verification is the gold standard and would be recommended to increase the robustness of future research studies.

Although the use of in-app metrics in mobile app studies is sparse and provides an objective method of assessing engagement with app features, it may not have captured the full engagement experience of users. For example, we were able to assess the number of times users engaged with specific gamification elements but not the length of engagement. While this is an imperfect measure of engagement, it can be considered a more objective method (compared to self-report) that is not frequently adopted in mobile app studies.

Conclusions

The overall learnings from this research highlight that features such as levels and achievements can positively impact short-term smoking abstinence. While further investigation is warranted with a larger, diverse sample and a longer follow-up period, our findings have positive implications for the use of gamification in mobile apps to support behavioral outcomes such as smoking cessation.

Acknowledgments

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Authors' Contributions

NBR, NM, and FTF were involved in the study design. NBR collected the necessary data and drafted the manuscript. DW and LB contributed to the data analysis and manuscript write-up. All authors read and approved the final manuscript.

Conflicts of Interest

LB undertakes consultancy and research for the Kwit app (Kwit SAS) in a PhD contract involving the National Association of Research and Technology and the University of Paris Nanterre. The other authors have no conflicts to interest to declare.

Multimedia Appendix 1
Eligibility criteria and in-app metrics.
[DOCX File , 14 KB - games_v11i1e39975_app1.docx]

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Original Paper

A Serious Game About Hematology for Health Care Workers (SUPER HEMO): Development and Validation Study

Julien Perrin[1,2], PhD, PharmD; Amélie Meeus[1]; Julien Broseus[2,3], MD, PhD; Pierre-Jean Morieux; Valentine Di Ceglie; Julien Gravoulet[1], PharmD; Maud D'Aveni[2,3], MD, PhD

[1]Faculté de Pharmacie, Université de Lorraine, Nancy, France

[2]Centre Hospitalier Régional Universitaire, Nancy, France

[3]Faculté de Médecine, Maïeutique et Métiers de la Santé, Université de Lorraine, Vandoeuvre-Lès-Nancy, France

Corresponding Author:
Maud D'Aveni, MD, PhD
Faculté de Médecine, Maïeutique et Métiers de la Santé
Université de Lorraine
9 avenue de la Forêt de Haye
Vandoeuvre-Lès-Nancy, 54505
France
Phone: 33 383153289
Email: m.daveni-piney@chru-nancy.fr

Abstract

Background: Complete blood count (CBC) and hemostatic screening tests are among the most commonly prescribed blood tests worldwide. All health care workers (nurse practitioners, pharmacists, dentists, midwives, and physicians) are expected to correctly interpret the results in their daily practice. Currently, the undergraduate hematology curriculum consists predominantly of lecture-based teaching. Because hematology combines basic science (blood cells and hemostasis physiology) and clinical skills, students report that they do not easily master hematology with only lecture-based teaching. Having interviewed students at the University of Lorraine, we considered it necessary to develop new teaching approaches and methods.

Objective: We aimed to develop and validate a serious game about CBC analysis for health care students. Our primary objective was to help students perceive hematology as being a playful and easy topic and for them to feel truly involved in taking care of their patients by analyzing blood tests. We considered that this game-based approach would be attractive to students as an addition to the classic lecture-based approach and improve their knowledge and skills in hematology.

Methods: We developed an adventure game called SUPER HEMO, a video game in which the player assumes the role of a protagonist in an interactive story driven by exploration and problem-solving tests. Following validation with beta testing by a panel of volunteer students, we used a novel, integrated teaching approach. We added 1.5 hours of gaming to the standard curriculum for a small group of volunteer students. Physician and pharmacy students in their third year at a single French university were invited to attend this extracurricular course. Pregame and postgame tests and satisfaction surveys were immediately recorded. Final hematology exam results were analyzed.

Results: A total of 86 of 324 physician students (26.5%) and 67 of 115 pharmacy students (58%) opted to participate. Median scores on the pre- and posttests were 6 out of 10 versus 7 out of 10, respectively, for the physician students, (P<.001) and 7.5 out of 10 versus 8 out of 10, respectively, for the pharmacy students (P<.001). At the final hematology evaluation, physician students who played SUPER HEMO had a slightly better median score than those who did not: 13 out of 20 versus 12 out of 20, respectively (P=.002). Pharmacy students who played SUPER HEMO had a median score of 21.75 out of 30; this was not significantly different from pharmacy students who did not play SUPER HEMO (20/30; P=.12). Among the participants who answered the survey (n=143), more than 86% (123/143) believed they had strengthened their knowledge and nearly 80% (114/143) of them had fun.

Conclusions: Feedback from this game session provided evidence to support the integration of interactive teaching methods in undergraduate hematology teaching. The development of SUPER HEMO is intended to be completed so that it can become a support tool for continuing education.

(JMIR Serious Games 2023;11:e40350) doi:10.2196/40350

KEYWORDS

educational technology; hematology; health care students; education; teaching; validation; methodological study; video support tool; continuing education; serious games; educational games

Introduction

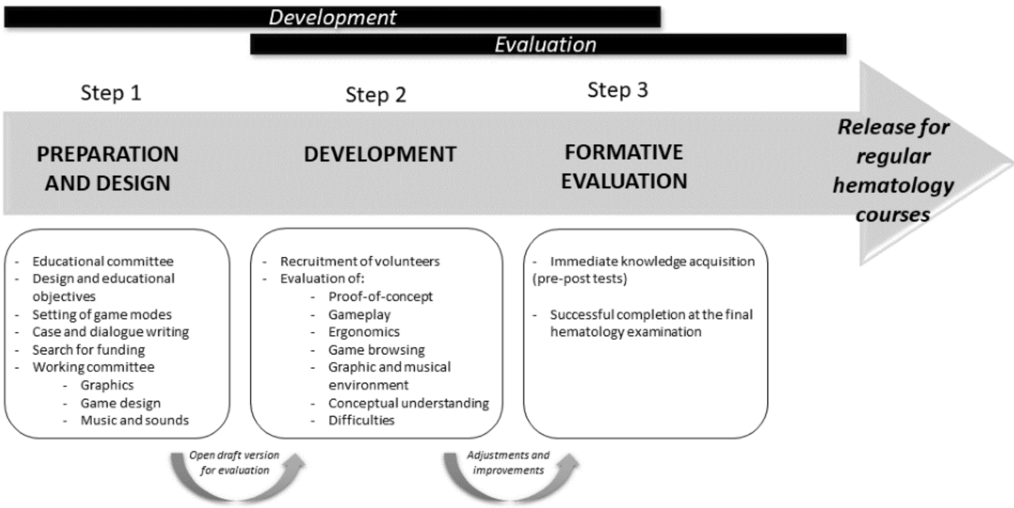
Numerous serious games (SGs) have been developed to improve nursing [1] and medical [2] knowledge and skills. The main subjects are surgery [3-5], emergency medicine [6,7], pharmacy [8] for health care students, and other subjects, such as preventive medicine for adolescents and young people [9-12]. Systematic reviews of SGs conclude that they seem to be at least as effective as other digital education modalities [13], but pedagogical effectiveness, participant behavior, and patient health outcomes have barely been evaluated [14-16].

In the context of the global COVID-19 pandemic, the demand for online learning increased worldwide. However, it has been reported that reduced peer and teacher interaction can cause motivation issues [17,18]. Recently, online learning has been described negatively, especially by health care students in clinical practice [19]. Many health care students see working in the health care setting as a vocation rather than a job, with patient-centered and compassionate care being the basis of this view [20]. Therefore, video games that enable specifically situated, experiential learning by introducing different unwell characters represent an attractive learning tool for today's students, who are very receptive to computer-based learning.

SGs for hematology education are rare and deal only with transfusion [21,22]. One important part of hematology education is complete blood count (CBC). CBC is a quantitative and qualitative evaluation of blood cells and stands as one of the most common laboratory tests in medicine, being indicated for a vast number of conditions. CBC interpretation is taught only with lecture-based courses in hematology. An internal survey among physician and pharmacy students at the University of Lorraine revealed that more than 50% of students considered CBC interpretation hard to master. Because correctly applying CBC knowledge to form patient diagnoses and make clinical decisions is a requirement for all health professionals, we decided to implement an SG for hematology education.

We developed an SG (Figure 1) named SUPER HEMO with a structured, 3-phase development framework that included preparation and design, development, and formative evaluation, as described previously [23].

Figure 1. SUPER HEMO development.



Methods

Preparation and Design

Framework

As a reference for the creation and development of the game, we took inspiration from role-playing and adventure games (eg, point-and-click games and visual novels), as these are commonly played at home by students. The game's contents, including a database with questions, answers, and feedback, were based on knowledge from the Collège national des enseignants en hématologie (the French national college of hematology teachers).

At first, we created an educational committee composed of 3 hematology experts (1 pharmacist and 2 medical doctors), a pharmacist with gamification expertise (with no expertise in hematology), and an instructional designer. Meetings took place every month for the first 6 months of the project. The goals of this committee were to define pedagogical objectives, game design, and game modes, and to write the clinical cases' dialogue. During the writing of the clinical cases, physician students volunteered to test some of the cases before their integration into the game. The committee also looked for funding. The raised funds were mainly used to hire a graphics designer and a game developer.

Then, a working committee was created with 2 medical doctors, a pharmacist with hematology expertise, a pharmacist with gamification expertise, an instructional designer, a graphics designer, and a game developer. Meetings occurred every 2 months to discuss practical issues arising from game conception.

Some members worked together outside of the meetings in groups, such as the graphics designer with the hematology expert or the game developer with the instructional designer and the hematology expert.

The project was then presented to the pedagogical council of each faculty.

Story

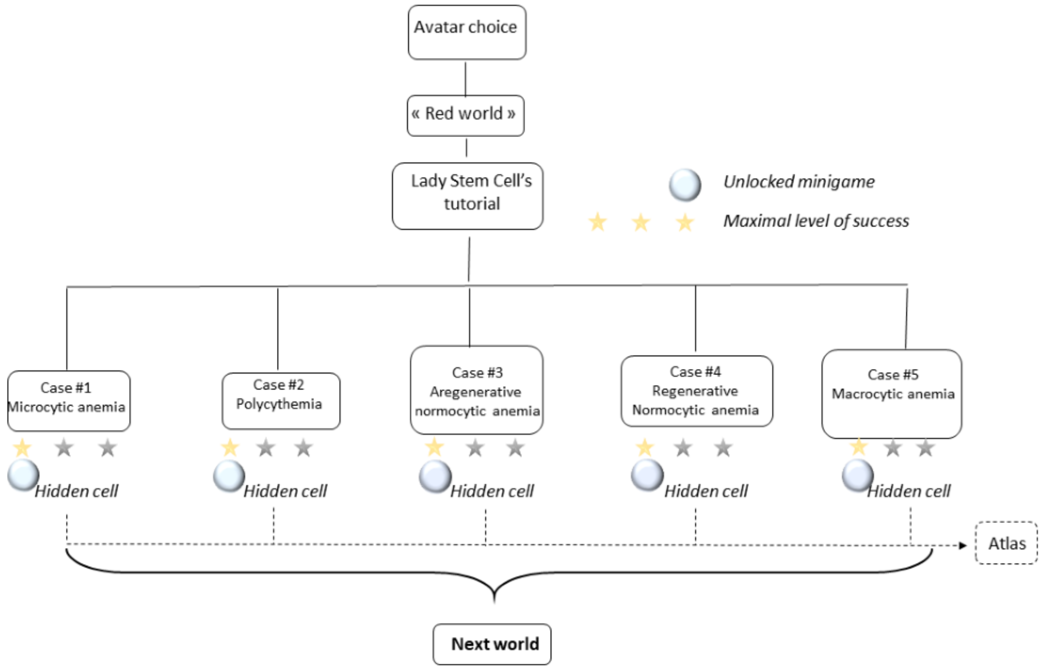
SUPER HEMO is set in a dreamlike "Red Cell World" (Multimedia Appendix 1), with red-blood-cell trees and depictions of the organs involved in erythropoiesis, including a "lung mountain," "medullar cave," "kidney rock," "spleen fortress," and "thyroid isthmus."

Players can choose a female or a male avatar on the home screen. They then complete the introduction, in which "Lady Stem Cell" explains the world and the game's settings and instructions and gives the player the "CBC asset," which is the power to check the blood parameters of the unwell characters encountered and interpret the corresponding results. Players assume the role of a hematology superhero named SUPER HEMO. SUPER HEMO can meet 5 unwell characters in 5 different steps. The player must answer their questions and find the best way to diagnose and cure them. "Magicians" (radiologists, pathologists, hematology-biologists, pharmacists, and geneticists) can be summoned to help the player find the right answer (Multimedia Appendix 2) in exchange for gold coins.

Mechanics

To complete the world's challenges (Figure 2), SUPER HEMO must explore 5 clinical cases.

Figure 2. "Red World" mechanics.



Each stop (represented by a light blue button) corresponds to the clinical case of an unwell character. Players choose to explore the clinical cases in the order that they decide. When SUPER HEMO successfully ends a case, players are rewarded with 1, 2, or 3 stars depending on the number of errors they made. Moreover, a hidden hematopoietic cell can be caught to unlock a minigame to earn gold coins. A wrong answer to a skill question makes SUPER HEMO lose the patient's trust and lose gold coins, and a wrong answer to a treatment question makes the hero lose the patient's trust. Lady Stem Cell gives immediate feedback to every question, thus maintaining the user's motivation and commitment to the game [24]. If all gold coins and the patient's trust are lost, Mister Insurance takes SUPER HEMO back to the beginning of the case, where the player can immediately play again if they have enough gold coins; otherwise, they can still earn gold coins in minigames before trying the case again. The hidden collected cells constitute an atlas of hematopoietic cells that contains a precise description and a real picture (taken by microscopy) of each blood cell. Minigames are always related to hematology in a fun way.

When SUPER HEMO reaches 80% success in the world's 5 clinical cases (and achieves a total of 12 stars of a possible 15) the player wins a new asset (a myelogram) and is thereby allowed to move on to a higher level, which corresponds to another hematopoietic world.

Throughout the game, to maintain the dreamlike atmosphere and immersion, different theme songs accompany the player (with the possibility to mute them). The player also has the option to reset the game on the home screen (not pictured).

Development

Technology

The game was programmed in January 2019 using C# in the Unity game engine, for computers only (ie, there was no mobile app). The invention was protected with an Inter Deposit Digital Number on September 9, 2020, for the University of Lorraine.

To date, the game is available in French only and is free of charge at the University.

Video Game Beta Tests

Three beta-test sessions were organized with small groups of undergraduate and graduate physician and pharmacy volunteer students. The goal was to obtain a primary evaluation of the game design and concept and to debug the game. The volunteers played the game for 1 hour and were then asked to fill in a questionnaire (Multimedia Appendix 3) about several aspects of the game, including the graphical interface, gameplay, use of multimedia, and educational content, and provide ideas for improvement and general comments. We collected the questionnaires and analyzed the answers to modify or improve the game and the teaching methods, if required.

Formative Evaluation

Ethics Approval

The study was conducted in accordance with the Helsinki Declaration and Resolution. The study was approved by the Pedagogic Committee of the Faculté de Pharmacie, Université de Lorraine (June 17, 2021) and Faculté de Médecine, Université de Lorraine (July 7, 2021).

Recruitment and Game Evaluation

Students in their third year of medicine and pharmacy courses were identified as the most appropriate study participants, since hematology is a regular and mandatory course unit during this academic year. These student cohorts were expected to benefit the most from additional exposure to clinical learning while using SUPER HEMO, as their upcoming final exams were planned to take place shortly after game exposure. The game evaluation was performed after 2 weeks of classical hematology teaching. The gaming course consisted of 1.5 hours of gaming (in the Red World) that covered the following standard red blood cell disorders: anemia and polycythemia. The game evaluation was split into 2 phases examining (1) the immediate knowledge acquisition of the players and (2) whether the players successfully completed their final hematology examination.

First, to evaluate the effectiveness of this teaching method, voluntary participants from each course were asked to complete a knowledge test consisting of 10 multiple-choice questions (Multimedia Appendix 4); one point was obtained for each correct answer. The participants completed the 10-question test before (pretest) and after playing the game for 1 hour (posttest). An online questionnaire was designed to assess playability and the students' understanding of SUPER HEMO. Students were also asked to rate their level of confidence after the gaming session on a questionnaire. Qualitative data considering the students' general feedback was also collected. All answers were anonymized.

Second, successful completion of the final hematology examination was extracted for students who had participated in SUPER HEMO and those who had not by the pedagogic committee, and mean results were compared.

Statistics

Statistical analyses were carried out using Prism (version 5.0; GraphPad). Comparisons of participation rates for the physician and pharmacy students, as well as the female to male ratio of the groups, were made with the Fisher exact test. Pre- and posttest scores and the final evaluation were expressed as median values, with the range and 25th to 75th percentiles. Pre- and posttest results were compared using a paired Wilcoxon signed-rank test in the 3 groups (ie, the overall population, the physician students, and the pharmacy students). Final evaluation results were compared using the Mann-Whitney test. As participation was on a voluntary basis, a post hoc power analysis of the final evaluation's scores was also performed.

Results

Beta Tests

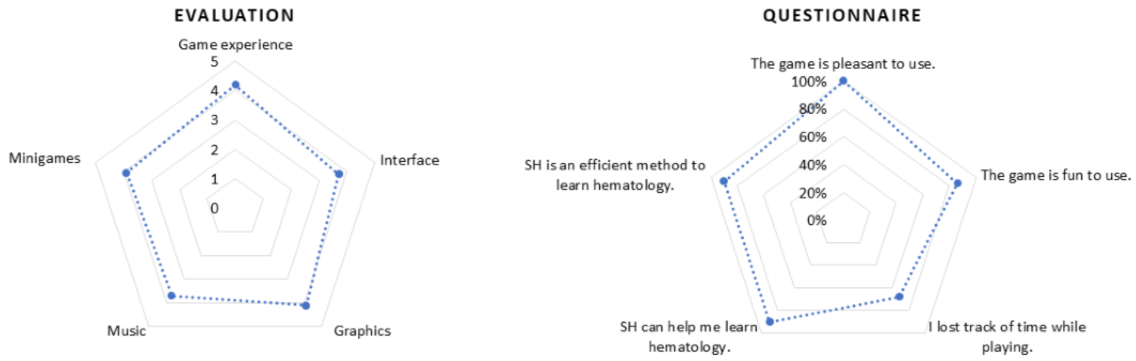
The results of the 3 beta tests (Figure 3) indicated a significant interest in this new SG.

The interface received a score of 3.7 of 5. As for the multimedia aspect, the graphics and music received scores of 4.1 and 3.7 of 5, respectively. All students stated that they enjoyed the game, 86% (19/22) found the game fun to use, and 68% (15/22) even lost track of time while playing. Regarding the educational content, 90% of the students (20/22) found that SUPER HEMO represented an efficient method to learn hematology.

The beta tests allowed us to detect a few points to improve SUPER HEMO and address issues encountered by the students. Some students had difficulties answering certain types of questions (for example, ones that used drag-and-drop), or they could not find the minigames. This led us to integrate tutorials at the beginning of each game, such as on how to answer questions encountered for the first time. We also modified some questions and minigame rules to better drive the players. Moreover, some players forgot the CBC results while talking to the unwell characters and frequently wanted to check them; therefore, we added a button to allow the players to check the CBC results as often as they wanted to. Finally, as the game tasks could be interrupted, we added a "log info" button to remind the students of dialogue text.

The free comments included mostly thanks for the initiative and anticipation for the sequels.

Figure 3. Beta-test results. SH: SUPER HEMO.



Integrated Teaching Approach in Addition to the Standard Hematology Undergraduate Curriculum

A total of 153 volunteer students were recruited, including 86 of 324 physician students (26.5%) and 67 of 115 pharmacy students (58%), who agreed to participate in this complementary session at the end of the standard lecture-based hematology course. Of note, the proportion of female students was higher in the participant group (Table 1).

Overall, the volunteer students were evaluated on a 10-point scale (Table 2 and Figure 4). They had a higher posttest score (median 7.5, range 2.5-10) than pretest score (median 6.5, range 1.5-9; *P*=.001), indicating that the game slightly improved their immediate knowledge acquisition. The median pre-and posttest scores were 6 (range 1.5-8) and 7 (range 2.5-10), respectively, for the physician students (*P*<.001) and 7.5 (range 3-9) and 8 (range 3.5-10), respectively, for the pharmacy students (*P*<.001).

At the final examination (Figure 4), we observed that the physician students who played SUPER HEMO obtained a slightly higher score (median 13/20, range 6-17) than those who did not play SUPER HEMO (median 12/20, range 5-17; *P*=.002), with a satisfactory study power (83%). The pharmacy students who played SUPER HEMO had a score (median 21.75/30, range 12.25-27.25) that was not statistically significantly different from those who did not play SUPER HEMO (median 19.8/30, range 9.5-26.75; *P*=.12). Unfortunately, the study power was low (64%) for this group.

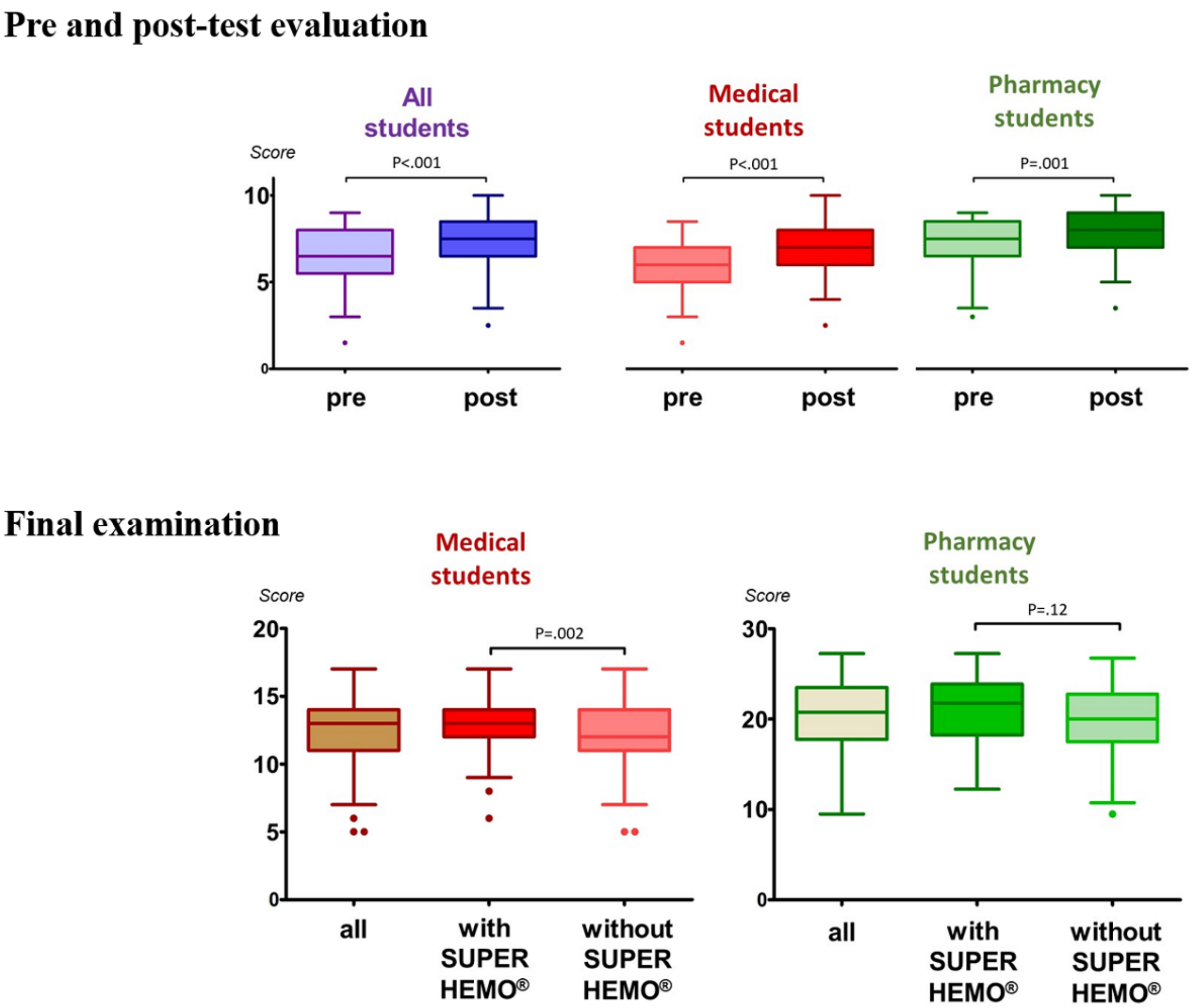
Table 1. Comparison of participants and nonparticipants in SUPER HEMO evaluation.

Characteristics	Participants, n	Nonparticipants, n	*P* value
All students (N=439)			<.001
Female	110	161	
Male	43	125	
Physician students (n=324)			.05
Female	60	136	
Male	26	102	
Pharmacy students (n=115)			.02
Female	50	25	
Male	17	23	

Table 2. Pre- and posttest evaluations (scores are on a 10-point scale).

	Pretest			Posttest			*P* value
	Median score	Range	25th-75th percentile	Median score	Range	25th-75th percentile	
All students	6.5	1.5-9	5.5-8	7.5	2.5-10	6.5-8.5	<.001
Physician students	6	1.5-8	5-7	7	2.5-10	6-8	<.001
Pharmacy students	7.5	3-9	6.5-8.5	8	3.5-10	7-9	.001

Figure 4. SUPER HEMO evaluation.

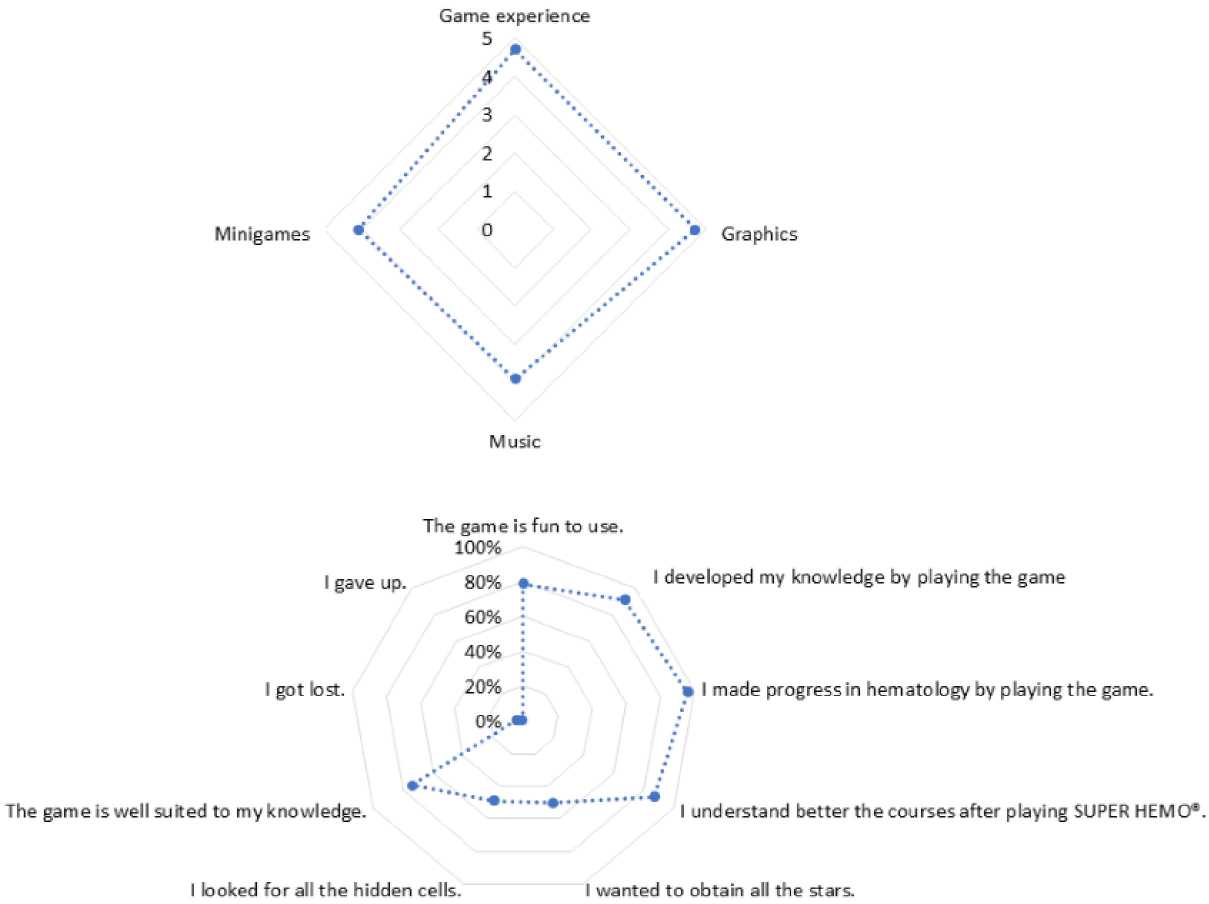


Gameplay Satisfaction

Among 153 volunteer students, 143 answered the questionnaire (93.4%). Game experience received a score of 4.7 out of 5, and 79% of the students (n=113) found the game fun to use. Regarding multimedia, graphics received a score of 4.7 out of 5, and music received 3.9 out of 5. The minigames were scored as attractive (4.1/5; Figure 5).

Concerning the educational content, most of the 153 students indicated that they had augmented their knowledge (n=130, 91%), had made progress in hematology (n=137, 96%), and better understood their courses (n=124, 87%) after playing SUPER HEMO. In addition, 71 students (50%) indicated that they specifically aimed to obtain the top 3 stars at the end of each case in the game, and 70 students (49%) dedicated specific effort to collect all the hidden cells. While the effect of rewards on memory appears well documented, it has recently been reported that incentives can also have counterproductive effects on memory [25]. Our videogame reward system was, however, developed to create a realistic game environment with well-known reinforcement and reward schedules. Of the 153 participants, 106 (74%) indicated that the flow of the game suited their knowledge, zero indicated they were bored by the game, 5 (3%) became lost in the game, and only 1 gave up.

Figure 5. Gameplay satisfaction.



Discussion

Principal Findings

SUPER HEMO was developed to increase students' motivation for learning hematology. In fact, as previously described, when students feel involved, they are more likely to achieve educational goals [26]. But with only 4 hematology teachers at the university, bedside (for clinical symptoms) and laboratory (for cell recognition) teaching in undergraduate medical education could not be fully accomplished for that year's 324 physician and 115 pharmacy students. Consequently, SUPER HEMO was developed to confront students with different clinical situations, improve their cell observation skills, and supplement the classical teaching model. Because players may have different skills, we developed the pedagogic content concomitantly with gamification [27]. Special characters, such as Lady Stem Cell, were created to regularly debrief the players on wrong or right answers to questions [28]. SUPER HEMO level 1 (the Red World) was developed and beta tested over a 2-year period. Subsequently, SUPER HEMO's approach was integrated to the standard hematology undergraduate curriculum of third-year physician and pharmacy students and the SG was evaluated.

In health care education, studies comparing SGs to other teaching methods with prospective evaluations are scarce [29,30]. We assumed that this prospective evaluation might be useful to justify SUPER HEMO's integration with the standard hematology curriculum. The satisfaction questionnaire clearly showed that most students enjoyed playing SUPER HEMO (113/142, 80%) and felt that they learned from it (123/142, 86%). These results demonstrate the students' strong commitment to the game. This result was reinforced by the free comments (eg, "I find the interface truly attractive; it really makes me want to do well" and "A good experience, dialogs or context are quite funny but still remain consistent!"). Several students inquired about playing the rest of the game (eg, "We're looking forward to the white and yellow worlds' release" and "I hope I can play again soon!"). Students highlighted the link between the game and seriousness (eg, "It allowed me to study in a fun way" and "Fun way to learn hematology or to practice without the feeling that I have studied").

Knowledge improvement with this complementary method to the standard course was more difficult to evaluate. If a positive effect of SUPER HEMO was clearly observed for short-term knowledge (ie, the results of the pre- and posttests), the measurement of learning outcome (ie, the results of the final examination) should also be discussed. First, the first SUPER HEMO session ran through the COVID-19 pandemic, when restrictions were in place on attending courses. Therefore, we could not evaluate the effectiveness of this SG with a randomized controlled trial. After discussion with the pedagogic committee during the pandemic, courses were transmitted virtually to students who wanted to stay at home; less than 10% of students attended on site. In order not to penalize medically or psychologically fragile students, we decided to invite students to participate as they chose to do so. We can hypothesize that volunteer students who came to the SUPER HEMO session were the most motivated in the class, thus biasing the results of the final exams. Second, we observed that pharmacy students were more likely to attend the SUPER HEMO session than the physician students. Of note, the pharmacy students were probably more motivated, as their final exam took place a few days after the gaming session, whereas the physician students had their final exam 1 month after the gaming session. For the pharmacy students, although the participation rate was satisfactory, the study was underpowered, suggesting that follow-up studies (within the next few years) with more students might confirm that playing SUPER HEMO allowed students to obtain a better score in the final hematology evaluation (as was observed for the physician students). Third, our conclusions on interest in SUPER HEMO should be moderated by consideration of the SUPER HEMO session design. The session had a time limit of 90 minutes and was based only on the available "Red World," which dealt with anemia and polycythemia, while the final evaluation contained questions on red blood cells, white blood cells, and platelets. We therefore propose that in the future (1) three worlds corresponding to the three lineages of hematopoietic cells in the CBC be made available to encompass the whole hematology program, (2) game-based learning should have no time restrictions, and (3) new evaluations with more participants should be organized with other universities.

Currently, we consider that our research contributes to the literature by providing a new game for teaching hematology and an investigation of the effectiveness of the SG context for hematology learning. This first experiment with SUPER HEMO commits us to develop this SG for hematology in future academic years. Future work will focus on developing levels 2, 3, and 4, the "White World," "Yellow World," and "Complex World," respectively, with all parameters varying in the latter. We propose an evolving game that covers the entire program of hematology and is accessible on the digital platform of the University of Lorraine. SGs have been poorly developed for hematology education. Tan et al [21] were the first to report an SG, developed for nurses in Singapore, that dealt with the safe administration of blood transfusions. This SG was prospectively tested with 103 second-year undergraduate nursing students randomized into control or experimental groups. Posttest knowledge and mean scores for confidence improved significantly in the experimental group ($P<.001$) after the SG intervention compared to mean pretest scores and mean posttest scores for the control group ($P<.001$). However, no significant differences ($P=.11$) were found between the experimental and control groups for mean posttest performance scores. Four years later, the participants evaluated the SG positively as an innovative and stimulating learning tool; however, more rigorous efforts to improve the interface and alleviate technical issues were suggested as ways to make the SG more accessible and intuitive for all levels of nursing staff [22]. To our knowledge, SUPER HEMO is the first SG developed for CBC interpretation to be used by teachers of hematology for students in medicine, pharmacy, dentistry, and midwifery. During the COVID-19 pandemic, education was suddenly disrupted, and universities were mandated to switch to online teaching. The game-based computer app that we designed represents a potentially effective teaching tool for health care students.

Conclusion

This study has provided evidence that SUPER HEMO met our primary objective: to develop an SG for hematology that was playable and acceptable overall. The usability of SUPER HEMO was demonstrated beyond the initial beta-testing pilot study; we obtained preliminary evidence that SUPER HEMO might be a useful educational tool. We will use it as a supplement to lecture-based courses and trace the time and frequency of logins to SUPER HEMO. Last, we propose to correlate this continuous training to student results for the third-year final exams, final graduation exams (at the end of the fifth year), and for the student's specialty choice.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Red Cell World.
[PPTX File , 1365 KB - games_v11i1e40350_app1.pptx]

Multimedia Appendix 2
SUPER HEMO avatars speaking with different characters.
[PPTX File , 1345 KB - games_v11i1e40350_app2.pptx]

Multimedia Appendix 3

Beta-test questionnaire.
[PDF File (Adobe PDF File), 52 KB - games_v11i1e40350_app3.pdf]

Multimedia Appendix 4
Pre and post tests.
[PDF File (Adobe PDF File), 76 KB - games_v11i1e40350_app4.pdf]

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Abbreviations

CBC: complete blood count
SG: serious game

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Original Paper

A Software Engineering Framework for Reusable Design of Personalized Serious Games for Health: Development Study

Stéphanie Carlier[1,2], MSc; Vince Naessens[1], MSc; Femke De Backere[1,2], PhD; Filip De Turck[1,2], PhD

[1]Internet Technology and Data Science Lab, Faculty of Engineering and Architecture, Ghent University, Ghent, Belgium

[2]Interuniversity Microelectronics Centre, Ghent, Belgium

Corresponding Author:
Stéphanie Carlier, MSc
Internet Technology and Data Science Lab
Faculty of Engineering and Architecture
Ghent University
Technologiepark-Zwijnaarde 126
Ghent, 9052
Belgium
Phone: 32 9 331 49 38
Email: stephanie.carlier@ugent.be

Abstract

Background: The use of serious games in health care is on the rise, as these games motivate treatment adherence, reduce treatment costs, and educate patients and families. However, current serious games fail to offer personalized interventions, ignoring the need to abandon the *one-size-fits-all* approach. Moreover, these games, with a primary objective other than pure entertainment, are costly and complex to develop and require the constant involvement of a multidisciplinary team. No standardized approach exists on how serious games can be personalized, as existing literature focuses on specific use cases and scenarios. The serious game development domain fails to consider any transfer of domain knowledge, which means this labor-intensive process must be repeated for each serious game.

Objective: We proposed a software engineering framework that aims to streamline the multidisciplinary design process of personalized serious games in health care and facilitates the reuse of domain knowledge and personalization algorithms. By focusing on the transfer of knowledge to new serious games by reusing components and personalization algorithms, the comparison and evaluation of different personalization strategies can be simplified and expedited. In doing so, the first steps are taken in advancing the state of the art of knowledge regarding personalized serious games in health care.

Methods: The proposed framework aimed to answer 3 questions that need to be asked when designing personalized serious games: Why is the game personalized? What parameters can be used for personalization? and How is the personalization achieved? The 3 involved stakeholders, namely, the domain expert, the (game) developer, and the software engineer, were each assigned a question and then assigned responsibilities regarding the design of the personalized serious game. The (game) developer was responsible for all the game-related components; the domain expert was in charge of the modeling of the domain knowledge using simple or complex concepts (eg, ontologies); and the software engineer managed the personalization algorithms or models integrated into the system. The framework acted as an intermediate step between game conceptualization and implementation; it was illustrated by developing and evaluating a proof of concept.

Results: The proof of concept, a serious game for shoulder rehabilitation, was evaluated using simulations of heart rate and game scores to assess how personalization was achieved and whether the framework responded as expected. The simulations indicated the value of both real-time and offline personalization. The proof of concept illustrated how the interaction between different components worked and how the framework was used to simplify the design process.

Conclusions: The proposed framework for personalized serious games in health care identifies the responsibilities of the involved stakeholders in the design process, using 3 key questions for personalization. The framework focuses on the transferability of knowledge and reusability of personalization algorithms to simplify the design process of personalized serious games.

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KEYWORDS

serious game; health care; personalization; domain knowledge; framework; eHealth; cocreation

Introduction

Background

Serious games have a primary objective other than pure entertainment as they seek to educate or train, among others [1,2]. In many domains of health care, serious games have shown positive effects and are increasingly used to motivate treatment adherence, reduce treatment costs, and educate patients and their families on a specific pathology [3-7]. For example, serious games are used for the treatment of mental health disorders, such as anxiety disorders or depression [5,8-10], physical [11-14] or cognitive rehabilitation [15-17], or the education of health professionals and patients [18-22]. Multiple reviews exist on this emerging field that state that serious games can be an effective tool for health, but the research remains in its infancy, limited by design and evaluation challenges [5,10,20,21,23-25].

One of these challenges is the long-term and continuous support of the targeted users. The user's abilities will not only evolve but also based on the user's current context, a different configuration or approach might be called for. Many researchers have indicated the need for a personalized approach in serious games, abandoning the *one-size-fits-all* approach [26-31]. Serious games often fail to sustain long-term retention and treatment adherence if gamification mechanisms are not adaptive and cannot dynamically reengage the user [32,33]. Users lose motivation and games become predictable. Although the primary objective of a serious game is not entertainment, it remains crucial that the game is entertaining to retain user engagement [34]. To create long-term engagement in serious games, a balance between challenge and skill, leading to a state of flow, must be achieved [35].

Games tailored to the user generally result in better performance outcomes for the user, making personalization a key aspect of a successful serious game [36-39]. Different terms, such as adaptability, adaptivity, personalization, contextualization, and customization, are used in the literature to indicate the tailoring of serious games to users. Sajjadi et al [26] introduced the overarching term *individualization* when no distinction between these concepts is necessary. Adapting a serious game to the needs of a user can be done at design time, before starting the game (ie, static personalization), or while playing the game (ie, dynamic personalization).

Adaptability is defined by multiple researchers as the possibility to change an environment based on the user's changing needs, whereas *adaptivity* is the dynamic or automatic adjustment of game elements to the individual's actions or performance [26,29]. *Personalization* is characterized by the, often automatic, adaptation of the game based on the profile or context information of a specific individual user, such as heart rate or age [26]. *Customization* can be seen as changing the system based on the needs of a user group or an individual user, manually or automatically, and is often related to changes in appearance and content [26,40]. Streicher and Smeddinck [29] considered personalization as a specific form of customization, while they saw adaptability and adaptivity as a means to achieve personalization or customization. These concepts refer to the tailoring of the game at run time (ie, before or during gameplay), which differs from the player-centered design in which decisions are made during the design of the game based on the needs of a specific target group [41].

Not only do people learn in different ways and paces and perceive the difficulty level of the game differently, but the game itself is also experienced differently by different people, and not all game elements will work for everyone. In addition, the specific skills of the user might vary and develop over the course of playing the game [26,35,42,43]. The game should therefore be able to respond by adapting to the user, that is, ensuring a state of flow [4,35].

Flow theory models the relationship between the level of challenge in the game and the skill level of the user [44,45]. According to the Flow Model, the user is in a state of flow (ie, total immersion with maximized focus and performance) when the game has a clear goal and the user receives direct feedback on their performance related to this goal [45]. More importantly, to enter this state of flow, or the flow channel, the goal and related challenge level of the game should match the skill level of the user [4,29]. Frustration occurs when the game is too difficult for the perceived skill level and boredom sets in if the user is not challenged sufficiently by the game. Therefore, a serious game should maintain a balance between these parameters, even as the skill level of the users increases throughout the course of the game, to ensure that a state of flow is achieved, as shown in Figure 1. Because people differ and learn at different rates, the serious game should be able to detect and respond to the changing context and skill level of the user [4].

Another disadvantage of current gamified health applications is that the level of customization is often lacking, resulting in gamification that does not take health purposes, changes, or target groups into account [32]. Entertainment games already include different preferences among users by identifying player types using models such as the Bartle Model [46]. However, these models cannot be generalized to serious games because they are too limited. More context or player aspects need to be considered for the personalization of serious games, such as anxiety, stress, learning style, engagement, performance, skill level, and so on [26]. In contrast to the audience of entertainment games, the target audience of serious games is larger, including nongamer types.

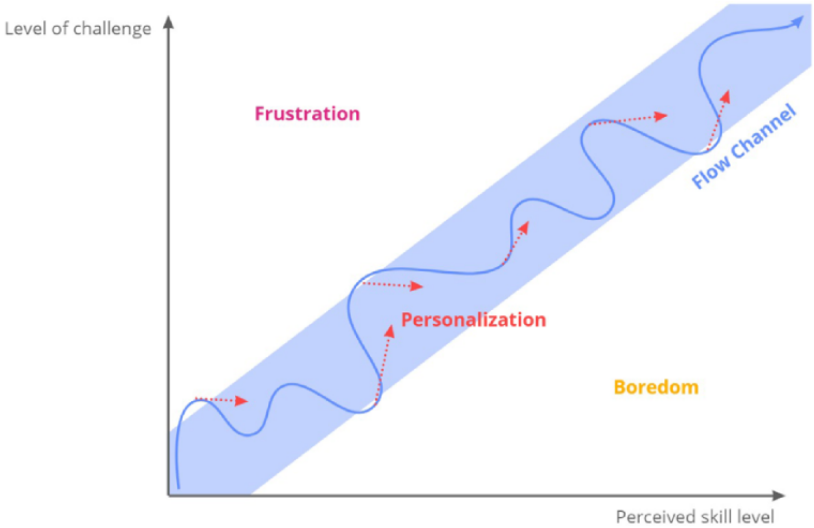
Serious games and gamification, with a user-centered, adaptive, and personalized approach, show promise in increasing treatment adherence and boosting engagement with interventions [3]. Creating a personalized serious game from scratch for each type of user is a costly and challenging operation for developers and domain experts [17,29]. To create a serious game, expert knowledge of relevant domains is necessary. Often, therapists and domain experts are continuously involved in this design process in various ways [28,47]. Some examples are as follows: the involvement of a team of therapists in the design process of a serious game for anxiety reduction in children with autism spectrum disorder [8]; conducting in-depth interviews with occupational therapists for a serious game for cognitive impairment [15]; and validating the content of an informational serious game on COVID-19 by consulting a specialized team of physicians, professors, and medical students [48].

Different methods exist to include personalization in serious games. Some approaches focus on classifying the user according to a certain player type [41,49,50], whereas others focus on changing game aspects [33,35,51]. Rule-based adaptation defines rules that, when satisfied, lead to predefined actions that determine the further course of the game. However, this can lead to a less effective game because adaptation options are limited by the predefined rules [4]. Plan-based adaptation can be considered as a collection of state machines. Each plan is a state machine of which each state is an executable action in the game. If a condition is met, the active states can be selected to determine the course of the game. This adaptation method can, for example, be used in games containing several storylines, unlocking different aspects of the story depending on the user's current physiological state (eg, relaxed vs stressed states) [4]. Model-based adaptation allows the creation of models for various game elements. These models can dynamically change based on the changing user information. This method allows for more complex analysis and adaptation techniques such as the use of artificial intelligence to predict the progression of the user in the future [4,52]. Studies exist on how gamification and serious games can be personalized and which factors influence these decisions [53]. However, it remains unclear how this information can be integrated into the design and implementation of a fully personalized and adaptive serious game.

Research exists on frameworks for the design of serious games; however, these are often designed for specific health care domains, such as physical [13,54-56] or cognitive rehabilitation [15,57,58], or focus on specific technologies, such as emotion recognition and gamification patterns [59,60]; only a few focus on the development of serious games in general [28,61]. Nevertheless, these frameworks often remain vague on how personalization can be achieved, use one specific model for personalization, or do not target personalized serious games [13,60,61]. Moreover, only one study reported the need for reusable serious games components and proposed a serious game framework for reusable intelligent software components (eg, emotion recognition and learning algorithms) [62]. However, this study is limited to the implementation of software components and does not state how domain knowledge and intelligent personalization algorithms can be integrated into the multidisciplinary design process of serious games.

Owing to the lack of standardized frameworks for the design of a (personalized) serious game, the challenging nature of the design process, and the focus on using case-specific guidelines, the evaluation of serious games is often limited and varies widely as different approaches are taken. Research should aim to evaluate the effectiveness of serious games more rapidly and in a controlled setting, focusing on comparing approaches using the same environment [10,17].

Figure 1. The Flow Model states that to enter the flow channel, that is, a state of total immersion and maximized focus and performance, the goal and related challenge should match the skill level of the user [46].



Objective

Overall, when creating a personalized serious game, 3 questions need to be asked:

- Why is the game personalized?
- What parameters can be used for personalization?
- How is the personalization achieved?

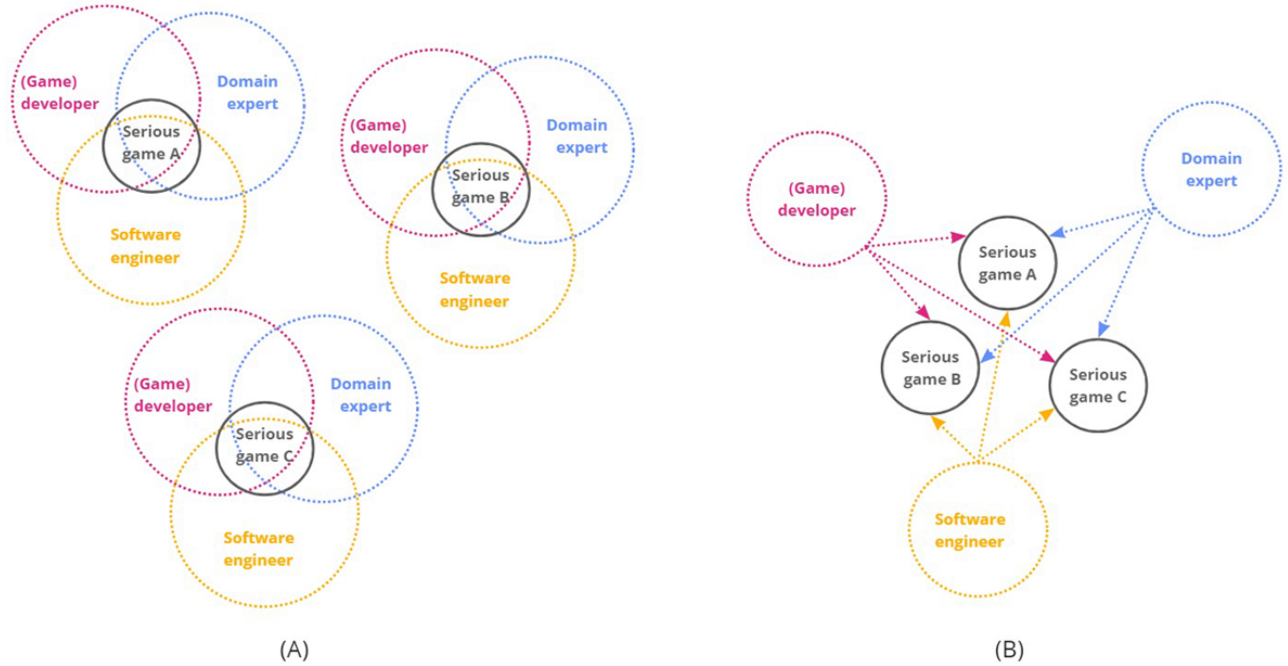
In this study, we aimed to answer these questions by proposing a software engineering framework that streamlines the design process of personalized serious games and facilitates the reuse of domain knowledge and personalization algorithms to reduce development costs.

Currently, the development of personalized serious games is a costly and complex process that requires the continuous involvement of different stakeholders, such as (game) developers, domain experts, and software engineers. Furthermore, this process must be completely repeated for each serious game and is often use-case specific. This means that each stakeholder should share their expertise throughout the design process of each new serious game, irrespective of the subject of the game, as their knowledge is never formalized or transferred to new serious games. This results in a complex process with many dependencies and redundancies between different stakeholders and serious games, which can be visualized as shown in Figure 2A. This approach complicates the evaluation of serious games and personalization strategies. With that many different parameters, such as design approach, target audience, or personalization algorithms, the comparison and evaluation of different personalization strategies are limited. Moreover, very little is known about how personalization strategies can be applied to serious games, as research is focused on the development of serious games for specific use cases, without attention to reusability.

This study aims to reduce these disadvantages by proposing a framework to simplify this process. The framework streamlines the development process of personalized serious games by considering the value of cocreation with different stakeholders, as shown in Figure 2B. However, by focusing on the reusability and formalization and transferability of expert knowledge, the dependencies between the stakeholders can be decoupled, thereby reducing the development cost of a personalized serious game.

The following paragraphs are structured as follows. The *Methods* section describes the *Use and Design of the Software* engineering framework, followed by the *Generic Framework*, which discusses the software engineering framework and the responsibilities of the involved stakeholders. To assess the proposed framework, a simple proof of concept was implemented, that is, an existing game was first transformed into a serious game, which is explained in the *Methods* section in *A Serious Game for ShoulderRehabilitation.* Next, the possibilities of the framework were illustrated by transforming this framework into a personalized serious game in the section *Proof of Concept: an Adaptive and Personalized SeriousGame*, followed by a discussion of the evaluation of the resulting serious game in the *Results* section. Finally, the conclusions of this study are discussed in the *Discussion* section.

Figure 2. (A) A conceptual schematic visualization of the currently complex and redundant dependencies between stakeholders during the development of multiple personalized serious games. (B) Schematic visualization of decoupling these dependencies by implementing reusable components that can be used for multiple serious games, thereby removing the tedious and repetitive effort of the stakeholders.



Methods

Use and Design of the Software Engineering Framework

The proposed framework provides a software engineering perspective on how the design process of serious games can be made more efficient by focusing on personalization and reusability. It can be used to transform existing (serious) games into personalized serious games as well as when designing new personalized serious games. As the proposed framework is a software engineering framework, it acts as an intermediate step between conceptualization and implementation, thereby aiming to close the gap between serious game design and implementation.

The Mechanics, Dynamics, and Aesthetics framework is widely accepted in game design as a formal approach for conceptualizing the dynamic behavior of game systems [63]. It approaches a game from the perspective of the player and discerns mechanics (ie, the actions, goals, and rules of the game), dynamics (ie, the behavior followed by the player's interaction with the mechanics), and the aesthetics (ie, the desired emotional responses of the player when playing the game). The Mechanics, Dynamics, Aesthetics, and Outcomes (MDAO) framework is an extension of the Mechanics, Dynamics, and Aesthetics framework for the conceptualization of serious games [64], and it introduces the concept of outcomes, that is, the behavioral or intellectual responses of the player after playing the game. The MDAO framework approaches a game from the player's perspective by first defining the outcomes and aesthetics, followed by dynamics and mechanics. To define the necessary concepts, a domain expert (outcomes and aesthetics) and a game developer (dynamics and mechanics) are needed. The results of the MDAO framework can then be used in the process of answering the 3 questions the framework poses: Why is the game personalized? What parameters are used for personalization? and How is personalization achieved?

Furthermore, the proposed framework is an extended version of the adaptive experience engine proposed by Bellotti et al [65]. They proposed an architecture that decouples the content of educational tasks from the game aspects in sandbox serious games, that is, games that encourage free play, to standardize the development of educational serious games and increase the efficiency by focusing on the reusability of educational tasks. The adaptive experience engine of Bellotti et al [65] uses educational content or tasks, defined by pedagogical experts, and stores these tasks in a common repository for reuse in different games. A game author is then responsible for specifying the requirements of the delivery of such a task at run time, that is, determining the type of task and time it is relevant during gameplay.

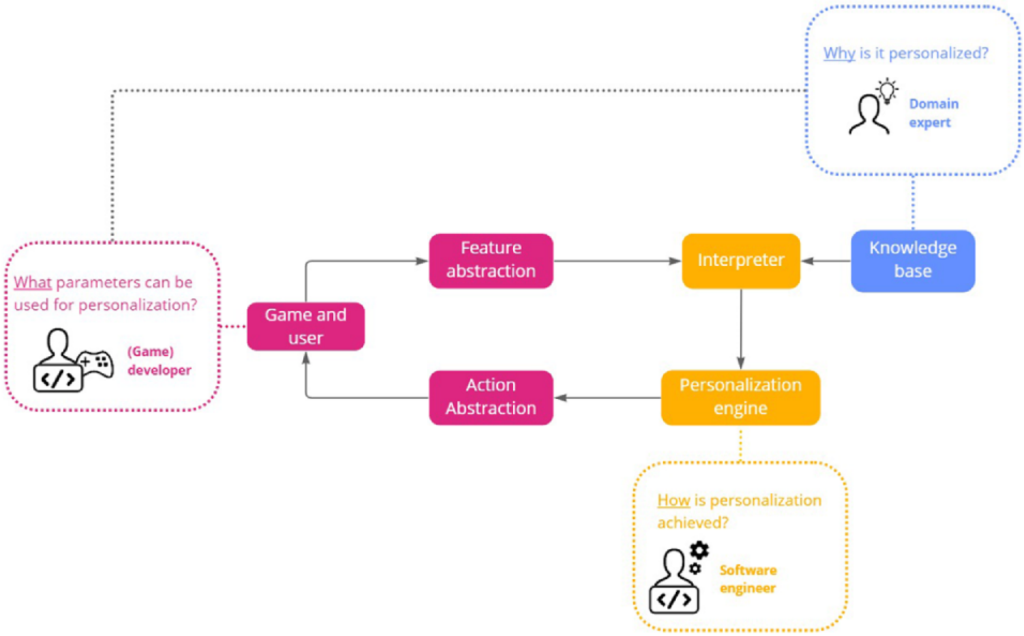
We proposed an extension of this framework for the personalization of serious games for health (SGH). We defined the necessary building blocks to increase the reusability of the different components and assign stakeholder responsibilities to these components. Instead of a repository of educational tasks, a knowledge base, which was designed according to the requirements of the domain experts, was included to model the necessary domain knowledge of a serious game. Furthermore, a personalization engine allows for the inclusion and evaluation of multiple personalization algorithms. The proposed framework was evaluated by implementing a proof-of-concept serious game to validate that the framework meets the expectations of the authors.

Generic Framework

Overview

The framework decoupled the domain knowledge from the personalizable variables in the serious game and personalization algorithms. This allowed the modification or addition of expert knowledge and game concepts independently of each other and the exploration of different personalization strategies without altering the structure of the game itself. The generic architecture discerned 6 modules through which a personalization loop flowed, moving through the different modules to translate user and game data into a specific knowledgeable game task that resulted in the adaptation of the game, as shown in Figure 3.

Figure 3. The generic framework consists of 3 types of modules. The Knowledge Base module formalizes the knowledge of the domain expert. The game-specific modules are the responsibility of the (game) developer and contain the personalized parameters. The final module, the Independent Personalizer, is the responsibility of the software engineer, who implements the algorithms for personalization.



Domain Knowledge

The *Knowledge Base* module is at the heart of the framework and aims to answer the question, *Why is there a need for personalization?* More specifically, this module is responsible for modeling the knowledge of the domain experts that gives insight into the serious aspect of the game. Serious games are defined as games that have objectives other than pure entertainment. For example, in the case of a rehabilitation scenario, this component will contain certain information regarding rehabilitation exercises and the conditions under which they can be executed, for example, injury type, skill level, and rehabilitation progress. For this example, the expert knowledge would indicate that personalized support during rehabilitation is necessary to accommodate different injury types, different phases of the rehabilitation process, skill levels, or more, thereby answering why there is a need for personalization. Such expert knowledge can be modeled or computerized using different approaches, for example, simple approaches such as databases or functions or more complex constructs such as ontologies. The goal of the *Knowledge Base* module is to allow the transferability of knowledge, and the module can thus be reused or replaced based on the domain in which the serious game is situated.

Game-Specific Modules

The 3 modules are game specific, namely, the *Game and User* module, which contains the game itself, and the *Feature Abstraction* and *Action Abstraction* modules, which function as a layer of abstraction between the game and the rest of the system. In consultation with the domain expert, the (game) developer can identify the necessary parameters for personalization, answering the question, *What needs to be personalized?* Two sets of parameters, namely, features and actions, are discerned at design time. First, the information that triggers personalization is defined as a feature. These features can be game information, such as scores, or physiological information collected using wearables (eg, heart rate). These features, which trigger the personalization, introduce a feedback loop in the system to ensure that it is adapted according to the needs of the user. For example, when a score or heart rate is too high, the game might be too exhausting, which should result in the adaptation of the system. In addition, when the user continues to score badly, the game might be too difficult, which in turn will result in the adaptation of the difficulty level. Second, the actions are a set of game parameters that are personalizable based on the context information, such as speed and difficulty level, or more complex constructs, for example, to personalize a storyline. At run time, the features are then periodically sent to the *Feature Abstraction* module, where they are abstracted to a generic format that can be interpreted by the game-independent modules. Existing player-type frameworks, such as the Hexad Framework, can be used to identify the parameters for personalization [64].

Independent Personalizer

Two modules, namely, the *Interpreter* module and the *Personalization Engine*, are game and domain independent and can thus be replaced or reused for the personalization of new or existing games. The software engineer aims to answer the question, *How is personalization achieved?* in these modules without the need to interact with the game itself. The *Interpreter* module interacts with the *Knowledge Base* and the game-specific modules to fetch the necessary information to understand the data it has just received. The module then interprets and translates the data into a format that can be understood using the *Personalization Engine*. This value contains the necessary information for the *Personalization Engine* to determine whether personalization is necessary and the degree of personalization without the need for context information. For example, if the user has an extremely high heart rate in a relaxation game, the *Interpreter* will understand, based on the context and domain knowledge that it receives, that the user's heart rate needs to be lowered and personalization has to be applied accordingly. Next, the *Personalization Engine*, containing one or more models for personalization, applies the action and sends it to the *Action Abstraction* module, a game-specific module that knows the game task that this action maps (eg, changing the speed of the game). In turn, the *Action Abstraction* module sends a game-specific task order to the game, which can then adapt accordingly and complete the personalization loop.

Different approaches for personalization exist, for example, intelligent algorithms such as reinforcement learning or recommender systems. By decoupling the personalization task from the game and domain knowledge, opportunities to explore the utility of different personalization models arise. Within one game, different approaches can be used to process or compare triggers for personalization. Furthermore, existing models can be reused for the development of new serious games, which simplifies and reduces the cost of creating a serious game.

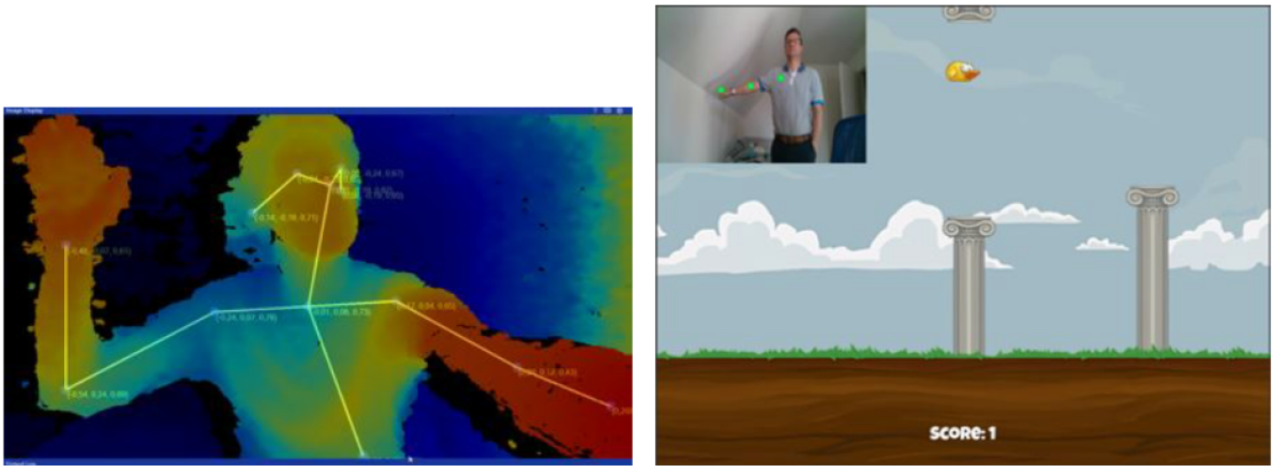
A Serious Game for Shoulder Rehabilitation

In physical rehabilitation, where patients need to repeat exercises regularly to train their mobility or balance, serious games can provide a welcome distraction from the repetitiveness of the treatment. Patients often lack the incentive to complete the time-consuming exercises at home or start rushing through, resulting in a decline in progress and exercise completion and once again demotivating the patient to correctly adhere to the treatment. Serious games for physical rehabilitation aim to motivate patients to increase their treatment adherence and effectiveness.

As a proof of concept, an existing game was transformed into a serious game and then used to illustrate how the proposed framework can be used to personalize existing serious games as well as when designing new serious games. The game was simple and contained a character that could be controlled by pressing a single button to make the character move upward and avoid upcoming obstacles, similar to the well-known game Flappy Bird (Gears). For this research, the game was transformed into a shoulder rehabilitation exercise that was suitable for physical rehabilitation after injury. As mentioned previously, in physical rehabilitation, it is important for patients to perform their exercises regularly and correctly.

The mechanics of the chosen game set the users up for failure, as they must continue controlling the character until it hit an obstacle and the game was over. This seems contradictory, as rehabilitation patients should not be rushed when performing their exercises, and this thus indicates the need for personalization by adapting the difficulty of the game to the capabilities of the user. Instead of controlling the character with a button, the user could control it by lifting their outstretched arm to the shoulder level and moving the character upward. The Intel RealSense Camera (Intel) [66] and the Cubemos skeleton (Intel) tracking SDK [67] were used to track the movement of the arm of the user and control the upward movement of the bird, as shown in Figure 4. The user earned a score based on how long they manage to keep the bird in the air without hitting any obstacles; otherwise, the game ended.

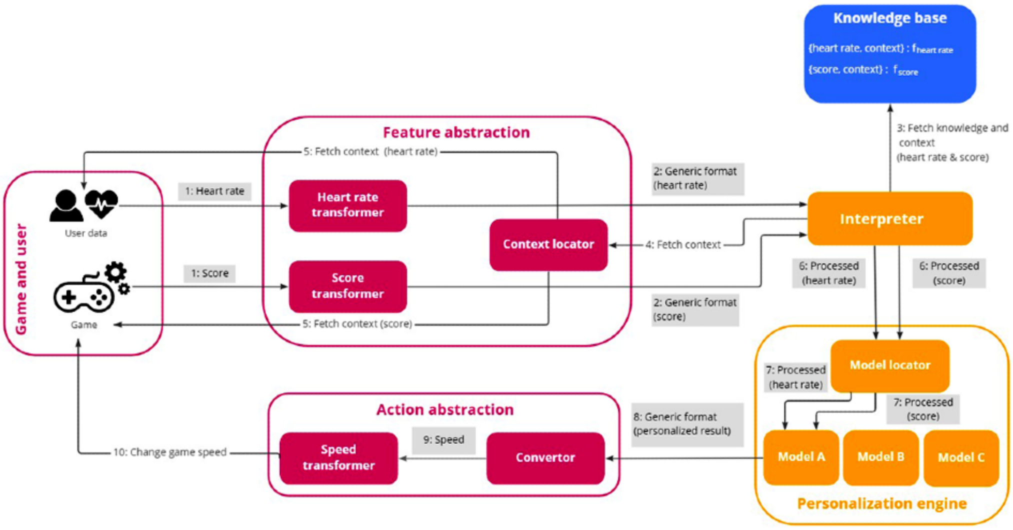
Figure 4. Using the Intel RealSense Camera and the Cubemos skeleton tracking (left), the arm movements of the user are tracked to control the game character (right).



Proof of Concept: an Adaptive and Personalized Serious Game

The following paragraphs discuss the different components of the generic framework in detail, using the implementation of the serious game for shoulder rehabilitation as an illustration of how the framework works. Figure 5 provides an overview of the implemented proof of concept using the proposed framework.

Figure 5. The implementation of the proof of concept using the proposed framework indicates that 2 features have been identified, namely, heart rate and game score. The Knowledge Base contains the necessary expert knowledge and respective context parameters that are necessary to interpret these features. After the Interpreter has interpreted this information, using the Context Locator to fetch the context values, the Personalization Engine is responsible for the adaptation, using the implemented models. Finally, this is again translated to an action of the game, namely, speed.



Domain Knowledge

As mentioned in the section *Generic Framework*, the *Knowledge Base* models the knowledge that is relevant for the specific serious game. This can be achieved using a simple database, storing values, or more complex constructs such as ontologies that are capable of modeling complex relationships between concepts in a computer-readable format. The responsibilities of the domain expert consist of (1) defining or reusing the necessary domain knowledge and, together with the (game) developer, (2) identifying the personalizable parameters of the serious game, that is, features and actions.

For this proof of concept, the *Knowledge Base* was kept simple. The *Knowledge Base* stored 2 functions, one for each identified feature, namely, f_{heart_rate} and f_{score}. The function f_{heart_rate} calculated the highest accepted heart rate for the given context information, whereas the function f_{score} looked at previous N scores, given the necessary context to evaluate the performance of the user. This means that, based on the game and its objective, 2 features were identified, namely, heart rate and game score.

Game-Specific Modules

As previously mentioned, for the game, 2 features were identified, namely, heart rate and game score. These data were collected by the *Game and User* component and were used to trigger the start of the personalization loop as they were periodically sent to the *Feature Abstraction* module, which sent them to the independent personalization modules for evaluation. As patients cannot rush their rehabilitation exercises but should perform them correctly to increase their mobility, the speed of the game was identified as a personalizable action. If the heart rate of the user increased or their game score decreased, the speed of the game should be lowered to continue to ensure good shoulder exercise performance.

Personalization of the game can occur both online (ie, in real time) and offline. For offline personalization, the feature data were only sent after a gaming session, adapting the game for the next session, whereas for real-time personalization, the game was personalized during the gaming session, based on the data received up to that point. One game session was considered to be a level of the game. Both types of personalization have their benefits: real-time personalization allows the game to quickly respond to the user's currently changed context, whereas offline personalization facilitates a more complex analysis that considers the overall performance and progress of the user, instead of just a moment in time.

For each feature, the *Feature Abstraction* module contains its respective *Transformer* module, responsible for translating the data to a generic format, which can be interpreted by the independent personalization modules. Using this generic format, the features can be interpreted by the rest of the system without the need for game-specific information. Nonetheless, these features had very little meaning without the necessary context information. For example, it was difficult to interpret a heart rate of 100 without any additional information. However, given the knowledge that this was the resting heart rate of a 25-year-old male, it was possible to interpret the importance if this heart rate. Therefore, the *Context Locator* module was responsible for providing the relevant context information to the personalization modules when needed. The *Context Locator* knew which context mapped to what features and fetched this information from the *Game and User* module.

This decoupling reduced the integration of a new serious game for personalization to the following steps: (1) identifying the features, (2) identifying the actions, (3) implementing or reusing the respective *Transformer* modules, and (4) creating a *Context Locator* that fetched the relevant context information for the correct feature.

Independent Personalizer

After the *Interpreter* receives the feature data in a generic format, it contacts the *Knowledge Base* to fetch the information to interpret the received value. This information includes the expert knowledge and context parameters that are linked to a specific feature. For the game, the knowledge linked to the heart rate feature was f_{heart_rate} and the relevant context parameters were age, sex, and game intensity. For the score feature, the linked knowledge was f_{score} and the relevant context parameters were the previous N scores.

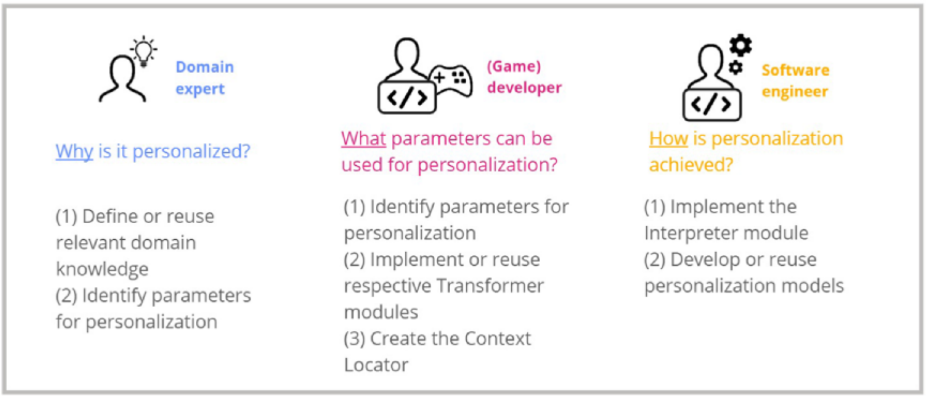
Next, the *Interpreter* module contacts the *Context Locator* to fetch the values of these context parameters for each feature. After receiving all the required information, the *Interpreter* can give meaning to the feature data and transform it into a processed value that contains the necessary information for the *Personalization Engine*, that is, the degree of the needed personalization, but is devoid of any game- or domain-specific knowledge. Continuing the example, the feature data, a heart rate of 100, and the associated context, the resting heart rate of a 25-year-old male, can be interpreted as an unusually high heart rate that should be reduced.

The *Personalization Engine* receives this processed value, and its *Model Locator* sends it to the correct model. As mentioned in the previous section, multiple types of models exist; however, for the proof of concept, only simple rule-based models were implemented to illustrate the framework. The first model receives the processed score as input and is used as an offline adaptation model, that is, the score after each gaming session is processed and used for the adaptation of the speed for the next gaming session. The second model takes the processed score and heart rate as input and is used for offline adaptation, whereas the third model receives the same input but is used for real-time adaptation.

The output of these models is a personalized value that is sent to the *Action Abstraction* module. This module, more specifically, the *Speed Transformer*, performs the reversed action of the *Feature Abstraction* module, as it transforms this generic format into a game-specific format, namely, to an action of the game, that is, speed.

As the *Interpreter* processes these input values, and the *Action Abstraction* module processes the output values, the software engineer does not have to have any domain- or game-specific knowledge to implement personalization algorithms. This reduces the responsibilities of the software engineer in (1) implementing the *Interpreter* module and (2) developing or reusing personalization models. Figure 6 presents an overview of the responsibilities of each of the involved stakeholder.

Figure 6. An overview of the responsibilities of the involved stakeholders.



Results

Simulation of Game Scores

To evaluate the proposed framework, the implementation of a personalized game is assessed using several simulations. First, the response of the system was evaluated when only game scores were used as features. Each score represents the score obtained after a single game. The difficulty level at the start of a gaming session was always 0.8. Adaptation of the speed would only occur after a completed game, that is, offline personalization.

The first series of scores was simulated to show a near-horizontal trend; that is, the user achieved, on average, a constant score for each game. The system used the previous scores of the user to decide whether the difficulty, that is, the speed of the bird, must be personalized. Thus, the difficulty was expected to be increased if this trend continued. Figure 7 shows the simulated scores that were fed to the system (top panel) and the response of the system regarding the adaptation of the difficulty (bottom panel). The gaming scores from the first 10 games showed a more diverging scoring pattern, indicating some drops in the score, and the system responds accordingly by lowering the difficulty. Game 14 showed a substantial increase in the gaming score, followed by a nearly constant score. As shown in the figure, the system reacted to this trend as expected by continuously increasing the difficulty of the game.

A second simulation showed continuously improving game scores, that is, on average, upward trend, as illustrated in Figure 8. As the user continued to improve their previous score, the game was most likely to become too easy for the user. The expected response of the system was to increase the difficulty of the game more visibly during this upward trend than during a nearly constant trend. As of game 16, after a brief drop, the user significantly improved their game scores, upholding an upward trend. As expected, the system countered this by increasing the difficulty significantly faster than during the first 13 sessions, when the user achieved a constant score.

The final simulated game series illustrated the situation in which the performance of the user continued to drop, that is, a downward trend in the game scores, as illustrated in Figure 9. Such behavior might indicate that the game is too difficult for the user and the game should respond by significantly decreasing the difficulty. As of the 16th game, the score of the user kept dropping, to which the system responded, as expected, by decreasing the speed of the game. By game 27, the user reached a new local maximum, which was answered by the system by again a slow increase in difficulty.

Figure 7. The first 10 games show a diverging score (top), which responds to a near-constant difficulty (bottom). The score of the user drops as of game 10, to which the system responds with a drop in difficulty. After game 14, the user achieves, on average, a constant score, which is, as expected, responded to by the system with a slow increase in difficulty.

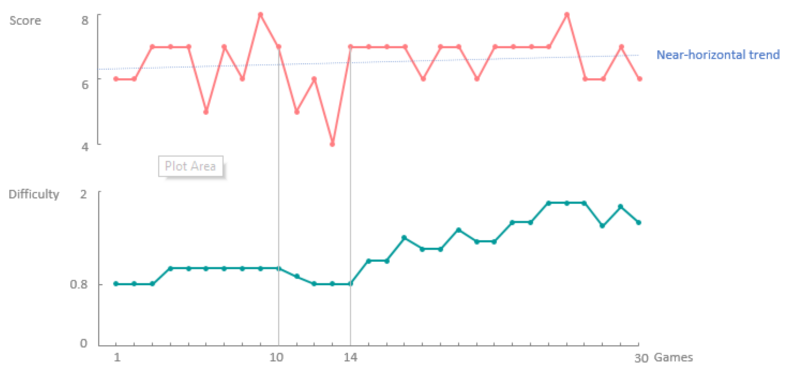


Figure 8. The score of the user is, on average, constant during the first 13 games (above), to which the system responds with a slight increase in difficulty (below). After a brief drop in scores, the user's score indicates an upward trend as of game 16. The system responds by significantly increasing the difficulty of the game as long as this upward scoring trend continues.

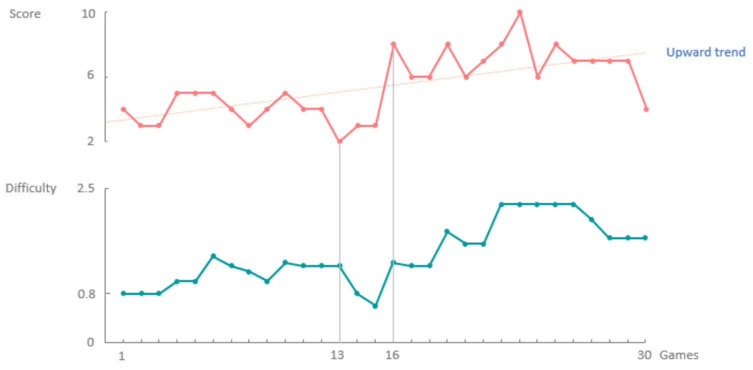
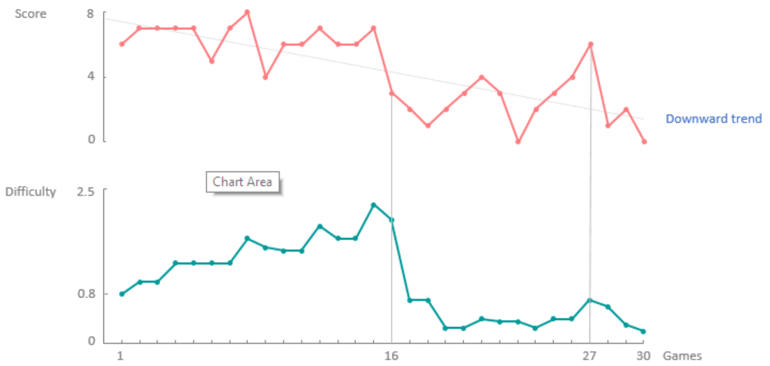


Figure 9. In the first 15 games, the user reaches, on average, a constant score (above), to which the system again responds by slowly increasing the difficulty (below). As of game 16, the score keeps dropping, showing a downward trend, to which the system responds by significantly lowering the difficulty.



Simulation of Game Scores and Heart Rate

For a second evaluation of the system, game scores and a rising heart rate, which at some point would exceed the set maximum heart rate of 180, were simulated. For this particular use case, where the user should perform a simple arm exercise, an elevated heart rate could indicate that the patient was distressed or experiencing pain, which would negatively affect the obtainable goal, that is, increasing the mobility of the arm. Therefore, the system should respond to this elevated heart rate by adapting to the game. The response of the system was compared for both offline, that is, after a gaming session, and real-time personalization, that is, during a gaming session.

For this simulation, we expected that a high heart rate would have a greater impact on the personalization of the game than the gaming score. If a rising heart rate was detected and the heart rate approached the maximum threshold heart rate of 180, the system should respond by immediately reducing the speed of the game. However, for offline personalization, the system was only able to respond if the average heart rate of the last completed game session exceeded 180. Therefore, the system could only reduce the speed of the game after a completed game session. For real-time personalization, the system was expected to respond much sooner and decrease the speed of the game from the moment the real-time heart rate exceeds the threshold value during the gaming session.

For this evaluation, the constant gaming score from the first simulation (Figure 7) was reused. Figure 10 illustrates the simulated gaming score (above), simulated average heart rate per gaming session (middle), and response of the system for both offline adaptation and real-time adaptation (below). For offline adaptation (green), the difficulty during a gaming session remained constant and was adapted only after the game has been completed. For real-time adaptation (purple), the difficulty could vary during a gaming session as real-time adaptations occurred. The difficulty values illustrated in Figure 10 correspond to the difficulty level at the end of each gaming session.

In the first simulation of a constant game score, the expected behavior was an increase in the difficulty. However, the system then also had to consider a rising heart rate, which resulted in more or less constant difficulty as long as the heart rate continued to rise. For offline adaptation, as soon as the average heart rate of a game session crossed the threshold value, which was the case for game 27, the system responded by decreasing the difficulty. Because offline adaptation introduced a certain delay, the game could only respond by game 28. The figure shows that this delay was not visible in the case of real-time adaptation, as the difficulty had already decreased for game 26.

Figure 11 provides a detailed overview of how the system reacted (below) to the real-time heart rate (above) during games 26 to 30. Here, it is clear that the user's heart rate already exceeded the threshold value during game 26, and thus the system could immediately reduce the difficulty of the game in the case of real-time adaptation. Because of the rigidity of offline adaptation, that is, one set speed for an entire game, the difficulty also decreased more slowly compared with real-time adaptation. The minimum difficulty for offline personalization of the entire exercise session was reached in game 30, whereas this minimum was already reached in game 27 using real-time personalization, reaching an even lower speed by the end of game 30.

Figure 10. For an, on average, constant score (above) and a constantly increasing heart rate (middle), the system responds differently for real-time personalization compared with offline personalization (below). If the system is updated after the game (offline personalization), the maximum threshold heart rate of 180 bpm is exceeded in game 27, of which the average heart rate is 182 bpm. The system thus starts decreasing the difficulty as of game 28. When the system is updated during the game (real-time personalization), the system already decreases the difficulty as of game 26, therefore achieving a much lower speed much faster. bpm: beats per minute.

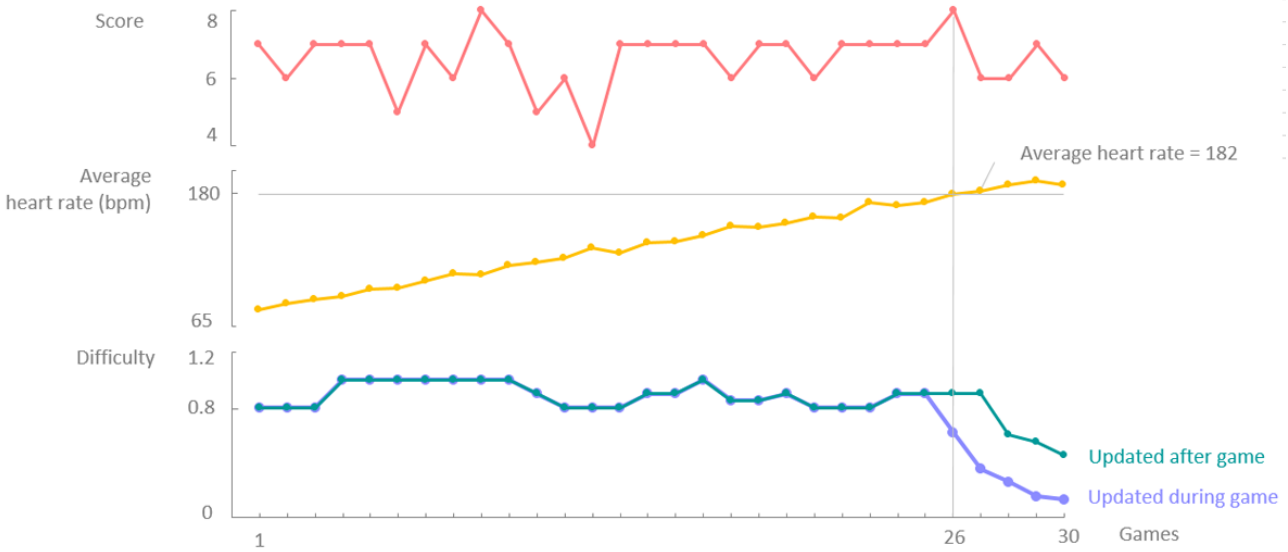
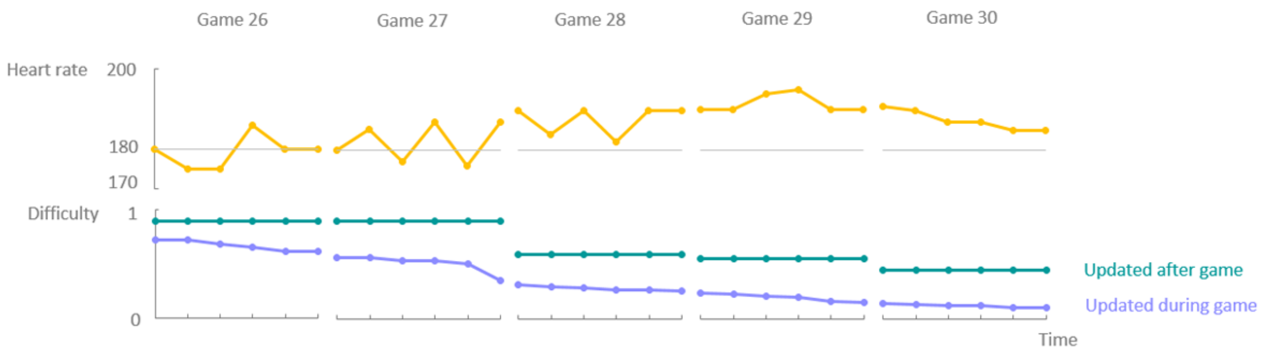


Figure 11. This detailed overview of the heart rate of the user starting from game 26 (top) indicates that the system can reduce the difficulty of the game (bottom) much faster in the case of real-time adaptation as the maximum threshold of 180 is already exceeded in game 26. Because the average heart rate of a gaming session only exceeds 180 in game 27, a delay is introduced in the version using offline adaptation. Real-time adaptation, therefore, allows the system to respond much faster to critical values than when offline personalization is used.



Discussion

Principal Findings

This study proposes a framework to standardize and simplify the design of personalized SGH. The process of designing a serious game is challenging and involves multiple stakeholders. The proposed framework identifies the responsibilities of the involved stakeholders using 3 key questions. The framework focuses on the reusability, formalization, and transferability of the expertise of these stakeholders to simplify this process. As a proof of concept, a simple game was transformed into a serious game for shoulder rehabilitation. The game was implemented according to the proposed framework to illustrate how it can streamline the design and implementation of personalized serious games. Several simulations were conducted to evaluate the personalization mechanics of the resulting personalized serious game.

The integration of the framework introduces several advantages for the design of personalized serious games. First, by assigning responsibilities to the stakeholders involved, the cocreation of the serious game is still respected, but the complicated process is simplified. Each stakeholder knows what is expected of them and with whom they need to communicate to receive specific information. By introducing 3 types of modules, namely, domain knowledge, game-specific modules, and an *Independent Personalizer*, and defining the communication between these modules, the reusability of these modules becomes possible, introducing a sort of “plug-and-play” structure of the components. Domain knowledge can be formalized using complex structures, such as ontologies or a simple information database, and can be reused or extended to multiple serious games. Over time, researchers can gather an extensive knowledge base covering one or more domains, each time reducing the effort needed to integrate their knowledge into a new serious game. A similar approach can be adopted for the other modules.

Furthermore, this framework allows for the integration of multiple personalization algorithms or approaches. As discussed in the *Introduction* section, different methods exist for the personalization of serious games, but very little is known about their effectiveness. Using this framework, software engineers can focus on further developing and evaluating these personalization approaches without the need to repeat the entire process from scratch. Thus, more effort can be directed toward developing more complex and intelligent algorithms. However, the framework allows not only the reusability of algorithms but also multiple algorithms to be used simultaneously for one serious game, as the *Personalization Engine* can contain multiple models for the identified features. This can be interesting when both real-time and offline personalization needs to be considered. Serious games in the health care domain often deal with gathering time-sensitive information, collecting health sensor data, or monitoring the performance of the user, and wrong movements can have detrimental effects. The framework allows the integration of specialized personalization models that monitor these data and intervene instantaneously when needed without the need to interrupt the rest of the personalized game mechanics, as these models can exist independently of one another.

Finally, the literature has shown that the evaluation of the effectiveness of serious games is often inadequate because of sparse evaluation results, lack of standardized evaluation approaches, and high cost of designing serious games. This framework takes the first steps toward a more accessible and standardized evaluation procedure for serious games. The framework easily allows the control of different parameters by interchanging the components under evaluation, such as personalization algorithms, and reusing other components. Moreover, because of the reusability of components, different personalization strategies for serious games can be tested and evaluated at a much faster pace.

Future Work

Although this study offers many contributions, it has some limitations that will be addressed in future work. First, the complexity of the proof of concept is limited to illustrating the functioning of the framework. Second, the resulting personalized serious game was evaluated using simulations. Therefore, future work will focus on implementing a more complex knowledge base and intelligent algorithms. Using this framework will facilitate the evaluation and comparison of different artificial intelligence algorithms, such as recommender systems or machine learning algorithms. The resulting serious game will be assessed using large-scale evaluations with end users to ensure that the personalization strategies used fit the needs of the target audience. To this end, questionnaires such as the System Usability Scale [68] and the Gameplay Scale [69] will be essential for thorough evaluation.

Conclusions

We proposed a framework for the design of personalized SGH. The aim of this framework is to offer guidelines that streamline the complex cocreation process of serious games. Moreover, the implementation of this framework facilitates the transferability of domain knowledge and reusability of personalization algorithms, thereby taking the first steps to the state of the art concerning personalization in SGH. Complex models of specific domain knowledge can be reused and extended, while different personalization strategies can be easily compared and evaluated.

Authors' Contributions

SC, VN, and FDB conceptualized the study. SC and VN designed the methodology; were responsible for validation, formal analysis, investigation, and curation; and wrote the original draft. VN procured the software. SC visualized the data. SC, VN, FDB, and FDT reviewed and edited the manuscript. FDT supervised the study. All the authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

MDAO: Mechanics, Dynamics, Aesthetics, and Outcomes
SGH: serious games for health

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Original Paper

Vertical Integration of Electronic Health Records in Medical Consortiums: Dynamic Modeling Approach Based on the Evolutionary Game Theory

Shenghu Tian[1,2], PhD; Yu Chen[2], PhD

[1]Business School, Yunnan University of Finance and Economics, Kunming, China

[2]School of Management and Economics, Kunming University of Science and Technology, Kunming, China

Corresponding Author:
Yu Chen, PhD
School of Management and Economics
Kunming University of Science and Technology
Number 727, Jingming South Road, Chenggong District
Kunming, 650504
China
Phone: 86 0871 6517 ext 2836
Email: Ychen@kust.edu.cn

Abstract

Background: China has continuously issued policies to speed up the interconnection, mutual recognition, sharing of medical information systems, and data integration management across regions and institutions. However, the vertical integration of electronic health records (EHRs) within the medical consortium is hampered by "poor mechanism and insufficient motivation" and the phenomenon of "free riding" among participating medical institutions, which makes the integration less effective.

Objective: We hope to clarify the game mechanism of stakeholders in the vertical integration of EHRs, and put forward targeted policy suggestions for improvement.

Methods: We constructed the "government-hospital-patient" tripartite evolutionary game model based on the detailed analysis of the research problems and their assumptions. We then simulated the game strategies and outcomes of each participant using the system dynamics approach to reveal the long-term strategy evolution mechanism of the core participants in the vertical integration of EHRs in the medical consortium, as well as the influencing factors and action mechanisms of each party's strategy evolution to provide references for improving relevant policies.

Results: The evolutionary game system could eventually reach an optimal equilibrium, but in areas where the government was required to be in a dominant position, patient supervision was necessary to have a positive role, while a reasonable reward and punishment mechanism can promote active participation of hospitals.

Conclusions: The effective way to achieve the goal of vertical integration of EHRs in the medical consortium is to build a multiagent coordination mechanism under the guidance of the government. Meanwhile, it is necessary to establish a scientific integration performance evaluation mechanism, a reward and punishment mechanism, and a benefit distribution mechanism to promote the healthy development of vertical integration of EHRs in medical consortiums.

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KEYWORDS

medical consortium; EHRs; evolutionary game; system dynamics; medical information resources

Introduction

The construction of a medical consortium is an important institutional innovation to deepen medical reform and a specific practical path to achieve graded diagnosis and treatment, which plays a vital role in the reform and development of medical and health undertakings in China. It is generally believed that a medical consortium is a medical service community with high-level medical institutions (tertiary hospitals) as the core institution (also named the leading unit) and other medical and health institutions at various levels in the region united as participating units (also known as member units) to vertically integrate medical and health resources, thereby eliminating fragmentation of medical services and achieving integration of services, responsibilities, benefits, and management [1]. The accessibility, continuity, and radiation of medical services are enhanced, and the quality and efficiency are improved, via the integration of cross-regional and cross-level medical services, resources, technologies, and information [2]. Since the promulgation of the "Pilot Work Plan for the Construction of Urban Medical Consortium" [3], relevant policies have repeatedly emphasized strengthening the integrated management of medical consortiums, realizing the continuous recording of electronic health records (EHRs) and electronic medical records, and gradually realizing the effective sharing of medical and health information within the medical consortium, to improve the efficiency of treatment and reduce medical costs. The "14th Five-Year Plan for the Implementation of Quality and Efficient Medical and Health Services," released in July 2021 [4], also includes accelerating the interconnection, mutual recognition, and sharing of cross-regional and cross-institutional information systems, as well as data integration and management as key projects. The construction of a medical consortium has thus become an important strategic measure to build an integrated medical and health service system in China.

EHRs refer to the systematic digital record of health information, such as disease treatment, immunization, chronic disease management, genetic history, throughout the life cycle of individual citizens through a variety of collection channels. The existing EHRs are scattered in different medical and health institutions at all levels, which seriously restricts the healthy and orderly development of a medical consortium. The vertical integration of EHRs refers to the collection, sorting, and ordering of EHRs among medical institutions at different levels within a medical consortium [5]. The purpose of EHRs is to break the decentralized pattern, promote the collaboration and hierarchical diagnosis and treatment within the medical consortium, promote the in-depth cooperation and organizational collaboration within the medical consortium, and help the development of the medical consortium from loose to compact. The integration of medical information resources has always been the core of medical and health information research. Although existing studies focused on the integration of diagnosis and treatment information resources within medical institutions, attention given to the integration and sharing of EHRs across institutions is far from adequate. The reasons for this are as follows: (1) the policies related to the integration of medical consortium and EHRs have not been proposed for a long time, and the policy effect has not been fully manifested; and (2) the shackles of "poor mechanism and insufficient motivation" are deeply rooted in the integration of medical resources across institutions, and the phenomenon of "free riding" by participating medical institutions is prominent, which makes the integration ineffective.

The game theory is suitable for the study of multiagent behavior. Evolutionary game is favored because its bounded rationality assumption of game players is more realistic, which is widely used in various fields, such as multiple governance, organizational coordination, and information behavior. Cross-institutional information resource sharing often involves many stakeholders, and it could gradually approach the evolutionary stable state after repeated games. Some studies have tried to use the evolutionary game method to perform relevant research in the medical and health field, such as studying doctor-patient disputes under government regulation [6], evolutionary game of a 2-way referral mechanism [7], emergency management of public emergencies [8], knowledge sharing in online health communities [9], drug safety and public health quality supervision [10,11], and integrated health care systems [12]. Some studies also use evolutionary game and simulation methods to explore the willingness of medical data sharing, but these only consider the 2 parties of patients and medical service institutions [13], and fail to consider the willingness and influence mechanism of cross-agency data sharing of the government and other multiparties under the organization mode of the medical consortium. The government, hospitals, and patients are the 3 direct stakeholders involved in the vertical integration of EHRs. To make all parties act in a unified manner in order to achieve the collective goal of resource integration, it is necessary to understand the long-term game strategy and its evolutionary stability of all parties. In addition, most previous studies used qualitative analysis methods such as speculative reasoning, expert interviews, or text analysis, and few studies used mathematical methods to discuss the issues shared by EHRs across institutions.

The essence of cross-organizational EHRs integration within a medical consortium is not a technical implementation but an organizational synergy problem, the core of which is the progressive evolutionary game problem of multiple stakeholders. In particular, participating medical institutions and patients have more evolutionary characteristics of progressive learning, and government behavior affects the development direction of EHRs integration. In this paper, we used evolutionary game analysis to incorporate the government, hospitals, and patients into a system model to explore the long-term strategy evolution of the 3 parties in the vertical integration of cross-organizational EHRs within a medical consortium, as well as the influencing factors and mechanisms of each party's strategy evolution. Finally, we proposed corresponding countermeasures based on data simulation using system dynamics. The findings of the study can provide a reference basis for the smooth implementation of vertical integration of EHRs within a medical consortium.

Methods

Construction of an Evolutionary Game Model

Problem Statements and Assumptions

From the perspective of stakeholders, the core participants involved in the vertical integration of EHRs are mainly the government, hospitals, and patients. As the main driving force of the hierarchical diagnosis and treatment system, the government has made every effort to promote the vertical integration of EHRs in the medical consortium through top-level design and the introduction of relevant policies to optimize the allocation of medical resources. However, local governments may make every effort to promote it or treat it negatively, due to the impact of protectionism, high costs, human resources, and complexity of implementation. Therefore, the behavior strategies of the local government are either "trying to promote it" or "treating it negatively."

Hypothesis 1

For local governments, if they try their best to promote the integration of EHRs, the income, such as social value, public praise, superior rewards, will be R_g and the cost will be C_g; when the local government takes a negative attitude, it will neither give subsidies or rewards to the hospitals and patients nor impose penalties. The cost is K_g (C_g>K_g) in such cases, and the local government will be punished as F_g (including the accountability of the superior government, government credibility, and reputation loss). When the hospital actively participates in the information integration under the policy effect and achieves good results in practice, the boundary between the local government's "efforts to promote" and "negative treatment" will become very vague. Therefore, the local government will not be held accountable by the superior government, nor will there be potential punishment such as loss of credibility and reputation.

As the owner of EHRs, hospitals' participation attitude directly affects the success or failure of the vertical integration of EHRs. Existing research shows that the leading large hospitals worry about weakening the absolute dominant position of medical resources, while the small hospitals participating in the medical consortium may negatively treat the integration of information resources to maintain their own economic interests and social reputation [14]. However, both the leading hospitals and member units may actively respond to national policies, abandon "free riding" opportunism, and actively participate in the vertical integration project of EHRs. Therefore, the behavior strategies of the hospital are active participation or passive participation.

Hypothesis 2

For the hospital, the revenue under normal operation is R_h. If the hospital actively participates in the sharing and utilization of cross-institutional EHRs, the reward subsidy from the superior government is F_h, and the cost is C_h. If the hospital chooses a negative strategy, its cost is K_h (C_h>K_h), and the resulting damage to the overall social interests is R_p, which will be borne by the public (especially patients). When patients find that their EHRs cannot be shared and utilized across institutions, if they complain to the superior supervision organization, the hospital will be punished as M_h. If the patients do not choose to complain, no supervision cost will be incurred.

As the biggest beneficiary of the hierarchical diagnosis and treatment system, the patients have the right and obligation to supervise and complain about the interconnection and availability of EHRs in the medical consortium. The patients may supervise hospital behaviors to protect their own rights and interests and complain to the medical and health supervision department, but they may also give up their right to supervision because of negative ideas such as "It's better to save trouble" and "supervision is the same as non-supervision" or because they think that the supervision cost is too high. Therefore, the behavior strategy space of patients is participating in supervision or giving up supervision.

Hypothesis 3

For patients, the cost of active participation in supervision is C_p, and the reward from the government is F_p; if patients give up supervision, they will neither incur costs nor receive government incentives.

The behaviors of local governments, hospitals, and patients all conform to the bounded rationality hypothesis of the evolutionary game theory. In the game process, each party continuously adjusts its own strategies through the behaviors of the other 2 parties, and finally reaches a stable state after repeated games.

Construction of a Tripartite Profit Matrix

Assuming that the ratio of local government choosing to promote is x, the ratio of its negative treatment is $1 - x$. If the rate of active participation is y, the rate of passive participation is $1 - y$. If the rate of patients choosing supervision complaints is z, the rate of giving up supervision is $1 - z$, and $x, y, z \in [0, 1]$. The relevant parameter settings and their meanings are shown as Table 1.

According to the aforementioned analysis and assumptions, the game payoff matrix of the 3 core players in the vertical integration of EHRs in the medical consortium under different strategic combinations is shown in Table 2.

Table 1. Relevant parameters setting and their meanings.

Parameters	Meanings
R_g	Benefits when the local government tries to promote EHR[a] integration
C_g	Costs when the local government pushes hard
K_g	Costs when the local government treats EHR integration negatively
F_g	Punishment received when the local government treats EHR integration negatively
R_h	Revenue when the hospital is in normal operation
C_h	Costs when hospitals are actively involved in EHR integration
K_h	Costs when hospitals are passively involved in EHR integration
F_h	Government subsidies when hospitals actively participate in EHR integration
M_h	Punishment when the hospital participates passively in EHR integration
F_p	Rewards received when patients actively participate in supervision
C_p	Costs when patients actively participate in supervision
R_p	Social damage caused by negative hospital participation

[a]EHR: electronic health record.

Table 2. Evolutionary game payoff matrix of the local government, hospital, and patient.

Game players	Local governments	
	Push hard (x)	Negative treatment ($1 - x$)
Hospital		
Actively participation (y)		
Patient		
Participation in supervision (z)	$R_g - C_g - F_h - F_p, R_h - C_h + F_h, F_p - C_p$	$-K_g, R_h - C_h, -C_p$
Waiver of supervision ($1 - z$)	$R_g - C_g - F_h, R_h - C_h + F_h, 0$	$-K_g, R_h - C_h, 0$
Passive participation ($1 - y$)		
Patient		
Participation in supervision (z)	$R_g - C_g + M_h, -K_h - M_h, F_p - C_p - R_p$	$-K_g - F_g, -K_h, -C_p$
Waiver of supervision ($1 - z$)	$R_g - C_g + M_h, -K_h - M_h, -R_p$	$-K_g - F_g, -K_h, -R_p$

Behavior Equilibrium Analysis of Evolutionary Game

Expected Profit of Game Players

Let E_{g1} be the expected return when the government pushes hard, E_{g2} be the expected return when the government treats EHR integration negatively, and E_g be the average return under the 2 strategies of the government pushing hard and treating negatively, then:

$$E_g = xE_{g1} + (1 - x)E_{g2} \quad \textbf{(1)}$$

$$E_{g1} = yz(R_g - C_g - F_h - F_g) + y(1 - z)(R_g - C_g - F_h) + z(1 - y)(R_g - C_g + M_h) + (1 - y)(1 - z)(R_g - C_g + M_h) \quad \textbf{(2)}$$

$$E_{g2} = yz(-K_g) + y(1 - z)(-K_g) + z(1 - y)(-K_g - F_g) + (1 - y)(1 - z)(-K_g - F_g) \quad \textbf{(3)}$$

Let E_{h1} be the expected benefit when the hospital actively participates, E_{h2} be the expected benefit when the hospital passively participates, and E_h be the average benefit in both cases of active and passive hospital participation, then we have:

$$E_h = yE_{h1} + (1 - y)E_{h2+} \quad \textbf{(4)}$$

$$E_{h1} = xz(R_h - C_h + F_h) + x(1 - z)(R_h - C_h + F_h) + z(1 - x)(R_h - C_h) + (1 - x)(1 - z)(R_h - C_h) \quad \textbf{(5)}$$

$$E_{h2} = xz(-K_h - M_h) + x(1 - z)(-K_h - M_h) + z(1 - x)(-K_h) + z(1 - x)(-K_h) + (1 - x)(1 - z)(-K_h) \quad \textbf{(6)}$$

Let E_{p1} be the expected benefit when the hospital actively participates, E_{p2} be the expected benefit when the hospital passively participates, and E_p be the average benefit in both cases of active and passive hospital participation, then we have:

$$E_p = zE_{p1} + (1 - z)E_{p2} \quad \textbf{(7)}$$

$E_{p1} = xy(F_P - C_P) + y(1 - x)(-C_P) + x(1 - y)(F_P - C_P - R_P) + (1 - x)(1 - y)(-C_P)$ **(8)**

$E_{p2} = x(1 - y)(-R_p) + (1 - x)(1 - y)(-R_p)$ **(9)**

Replication Dynamic Equation of Game Players

Replication dynamic equations can not only reflect the speed of evolution, but also determine the direction of decision evolution of game players. According to the calculation method proposed by Friedman [15], we constructed the replication dynamic equation under the active state of each game player.

Combining equations 1-3, we could construct the replication dynamic equation when the government tries to promote EHR integration as follows:

$F(x) = dx/dt = x(E_{g1} - E_g) = x(1 - x)(Eg_1 - E_{g2})$

$= x(1\text{-}x)\{[yz(R_g - C_g - F_h - F_p) + y(1 - z)(R_g - C_g - F_h) + z(1 - y)(R_g - C_g + M_h) + (1 - y)(1 - z)(R_g - C_g + M_h)] - [yz(-K_g) + y(1 - z)(-K_g) + z(1 - y)(-K_g - F_g) + (1 - y)(1 - z)(-K_g - F_g)]\}$

$= x(1 - x)[(R_g + F_g + M_h + K_g - C_g) - y(zF_p + F_g + F_h + M_h)]$ **(10)**

Combining equations 4-6, the replication dynamic equation for active hospital participation could be constructed as follows:

$F(y) = dy/dt = y(Eh_1 - E_h) = y(1 - y)(Eh_1 - Eh_2)$

$= y(1 - y)\{[xz(R_h - C_h + F_h) + x(1 - z)(R_h - C_h + F_h) + z(1 - x)(R_h - C_h) + (1 - x)(1 - z)(R_h - C_h)] - [xz(-K_h - M_h) + x(1 - z)(-K_h - M_h) + z(1 - x)(-K_h) + (1 - x)(1 - z)(-K_h)]\}$

$= y(1 - y)[(R_h + K_h - C_h) - x(F_h + M_h)]$ **(11)**

Similarly, combining equations 7-9, the replication dynamic equation could be constructed when the patient is actively supervised as follows:

$F(z) = dz/dt = z(Ep_1 - E_p) = z(1 - z)(Ep_1 - Ep_2)$

$= z(1 - z)\{[xy(F_p - C_p) + y(1 - x)(-C_p) + x(1 - y)(F_p - C_p - R_p) + (1 - x)(1 - y)(-C_p)] - [x(1 - y)(-R_p) + (1 - x)(1 - y)(-R_p)]\}$

$= z(1 - z)[x(F_p - R_p - yR_p)+(1 - y)R_p - C_p]$ **(12)**

Equilibrium Analysis of the Evolutionary Game System

Combining equations 10-12, we can get the 3D dynamic system of the game participants (ie, the government, hospitals, and patients), which is given as follows:

$F(x) = dx/dt = x(1 - x)[(R_g + F_g + M_h + K_g + C_g) - y(zF_p + F_g + F_h + M_h)]$

$F(y) = dy/dy = y(1 - y)[(R_h + K_h - C_h) + x(F_h + M_h)]$

$F(z) = dz/dt = z(1 - z)[x(F_p - R_p + yR_p) + (1 - y)R_p - C_p]$ **(13)**

By making the 3 replicated dynamic equations in equation (13) equal to 0, we can obtain 8 pure strategies Nash equilibrium solutions of the evolutionary game system, namely, (0, 0, 0), (0, 0, 1), (0, 1, 0), (0, 1, 1), (1, 0, 0), (1, 0, 1), (1, 1, 0), and (1, 1, 1). Existing studies in the field have proved that only the stability of the aforementioned 8 local equilibrium points can be considered in the analysis of a 3-party evolutionary game [16], and that it is not necessary to consider the Nash equilibrium solution *E* (*x**, *y**, *z**) of the mixed strategy. The sign of Jacobian matrix can be used to judge whether the aforesaid 8 local equilibrium points are the evolutionary stability strategy of the system, and the condition is det(*J*)>0 and tr(*J*)<0. The Jacobian matrix can be obtained by solving the partial derivatives of the 3 equations in equation (13) with respect to *x*, *y* and *z*, respectively:

$J_{11} = (1 - 2x)[(R_g + F_g + M_h + K_g - C_g) - y(zF_p + F_g + F_h + M_h)];$

$J_{12} = -x(1 - x)(zF_p + F_g + F_h + M_h);$

$J_{13} = -xy(1 - x)F_p;$

$J_{21} = y(1 - y)(F_h + M_h);$

$J_{22} = (1 - 2y)[(R_h + K_h - C_h) + x(F_h + M_h)];$

$J_{23} = 0;$

$J_{31} = z(1 - z)(F_p - R_p + yR_p);$

$J_{32} = -z(1 - z)(1 - x)R_p;$

$J_{33} = (1 - 2z)[x(F_p - R_p + yR_p) + (1 - y)R_p - C_p];$

$\det(J) = J_{11}J_{22}J_{33} + J_{12}J_{23}J_{31} + J_{13}J_{21}J_{32} - J_{13}J_{22}J_{31} - J_{12}J_{21}J_{33} - J_{11}J_{23}J_{32} = xzy^2(1 - x)^2(1 - y)(1 - z)(F_h + M_p)F_pR_p + xyz(1 - x)(1 - 2y)(1 - z)(F_p + yR_p - R_p)[-C_h + K_h + R_h + x(F_h + M_h)]F_p + xy(1 - x)(1 - y)(1 - 2z)(F_h + M_h)[(-C_p + (1 - y)R_p + x(F_p + yR_p - R_p)](F_g + F_h + zF_p + M_h) + (1 - 2x)(1 - 2y)(1 - 2z)[-C_p + (1 - y)R_p + x(F_p + yR_p - R_p)][-C_h + K_h + R_h + x(F_h + M_h)][-C_g + F_g + K_g + M_h + R_g - y(F_g + F_h + zF_p + M_h)]$ **(14)**

$\text{tr}(J) = J_{11} + J_{22} + J_{33} = (1 - 2x)[-C_g + F_g + K_g + M_h + R_g - y(F_g + F_h + zF_p + M_h)] + (1 - 2y)[-C_h + K_h + R_h + x(F_h + M_h)] + (1 - 2z)[-C_p + (1 - y)R_p + x(F_p + yR_p - R_p)]$ **(15)**

The det(*J*) and tr(*J*) values of 8 local equilibrium points can be calculated from equations 14 and 15 and judgment conditions, as shown in Table 3.

So far, the evolutionary game system has achieved the stable state under certain conditions. However, it can be seen from Table 3 that the det(*J*) and tr(*J*) values are determined by the values of many parameters. The existing conditions and calculation methods make it difficult to determine whether the aforesaid 8 equilibrium points are the evolutionary stability strategy, which indicates that it is not clear whether there are equilibrium points in the evolutionary game system. System dynamics can analyze the complex dynamic evolution process of evolutionary game models under the conditions of bounded rationality and asymmetric information [17], and can explore and reveal the potential mechanism of problems and seek key strategies to solve problems [18]. Therefore, we further use the system dynamics tool to simulate the impact of uncertainty factors on the stability of the evolutionary game system, so as to provide decision-making reference for formulating relevant policies and optimizing the dynamic mechanism of EHRs integration.

Table 3. The det(J) and tr(J) of the Jacobian matrix.

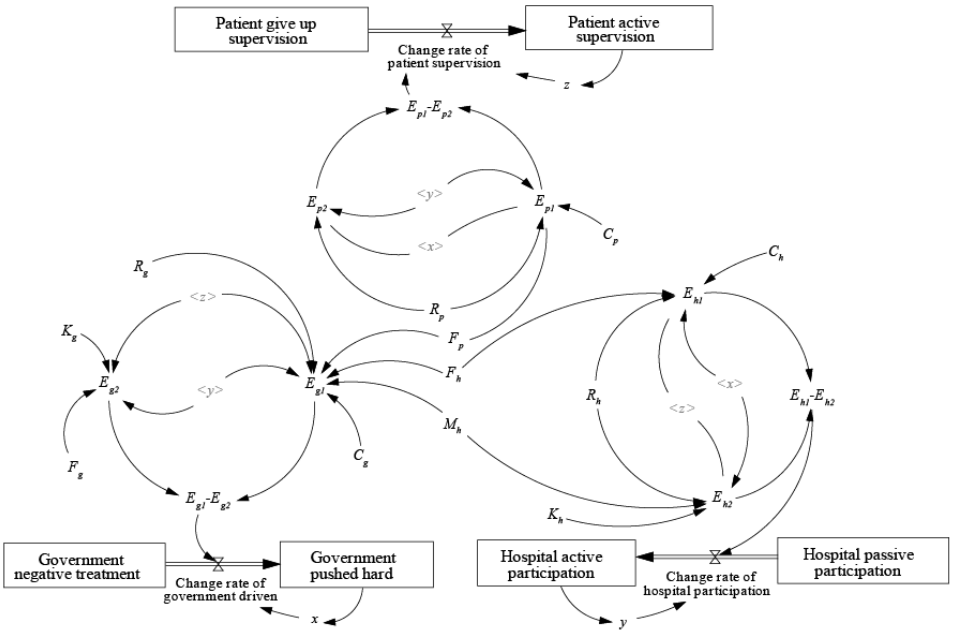
Equilibrium point	Det(J)	Tr(J)
(0, 0, 0)	$(R_p - C_p)(K_h + R_h - C_h)(F_g + K_g + M_h + R_g - C_g)$	$F_g + K_g + K_h + M_h + R_g + R_h + R_p - C_g - C_h - C_p$
(0, 0, 1)	$(C_p - R_p)(K_h + R_h - C_h)(F_g + K_g + M_h + R_g - C_g)$	$C_p + F_g + K_g + K_h + M_h + R_g + R_h - R_p - C_g - C_h$
(0, 1, 0)	$-C_p(C_h - K_h - R_h)(K_g + R_g + C_g - F_h)$	$C_h - C_p - F_h + K_g - K_h + R_g - R_h - C_g$
(0, 1, 1)	$C_p(C_h - K_h - R_h)(K_g + R_g - C_g - F_h - F_p)$	$C_h + C_p - F_h - F_p + K_g - K_h + R_g - R_h - C_g$
(1, 0, 0)	$(F_p - C_p)(C_g - F_g - K_g - M_h - R_g)(F_h + K_h + M_h + R_h - C_h)$	$C_g - C_h - C_p - F_g + F_h + F_p - K_g + K_h - R_g + R_h$
(1, 0, 1)	$(C_p - F_p)(C_g - F_g - K_g - M_h - R_g)(F_h + K_h + M_h + R_h - C_h)$	$C_g - C_h + C_p - F_g + F_h - F_p - K_g + K_h - R_g + R_h$
(1, 1, 0)	$(F_p - C_p)(C_g + F_h - K_g - R_g)(C_h - F_h - K_h - M_h - R_h)$	$C_g + C_h - C_p + F_p - K_g - K_h - M_h - R_g - R_h$
(1, 1, 1)	$(C_p - F_p)(C_g - F_h + F_p - K_g - R_g)(C_h - F_h - K_h - M_h - R_h)$	$C_g + C_h + C_p - K_g + K_h - M_h - R_g - R_h$

Construction of the System Dynamics Simulation Model

According to the aforementioned analysis, we used Vensim PLE (Ventana Systems, Inc) to build a system dynamics model of the evolutionary game among the government, hospitals, and patients in the vertical integration of EHRs in the medical consortium, as shown in Figure 1. In the figure, x, y, and z are 3 stocks, representing the time integration of 3 rate variables, namely, the change rate of government promotion, the change rate of hospital participation, and the change rate of patient supervision, expressed by their respective replication dynamic equations; E_{g1}, E_{g2}, E_{h1}, E_{h2}, E_{p1}, and E_{p2} are 6 intermediate variables, which respectively represent the expected return of each entity under different strategic states. The remaining 12 parameters are external factors outside the system boundary that may affect stock changes. The arrow lines indicate the causal relationship between 2 elements. The interaction of cause and effect acts as a causal feedback loop.

The purpose of system dynamics simulation is to reveal the law of development and change of things. The model construction focuses on the consistency, adaptability, and effectiveness of its overall structure. Therefore, the design of a system dynamics model does not require the authenticity and accuracy of parameter setting [19]. In this paper, common assignment methods are used for reference in parameter setting, and finally determined according to the experience of the interviewed experts. The specific parameter settings are as follows: initial time=0 years, final time=20 years, time step=0.125 years; R_g=30; C_g=6; K_g=3; F_g=4; R_h=50; C_h=7; K_h=5; F_h=8; M_h=10; C_p=1; F_p=2; and R_p=6. It should be noted that different initial values of each parameter will not change the simulation conclusion [20].

Figure 1. The system dynamics simulation model of the 3-party evolutionary game.



Ethical Considerations

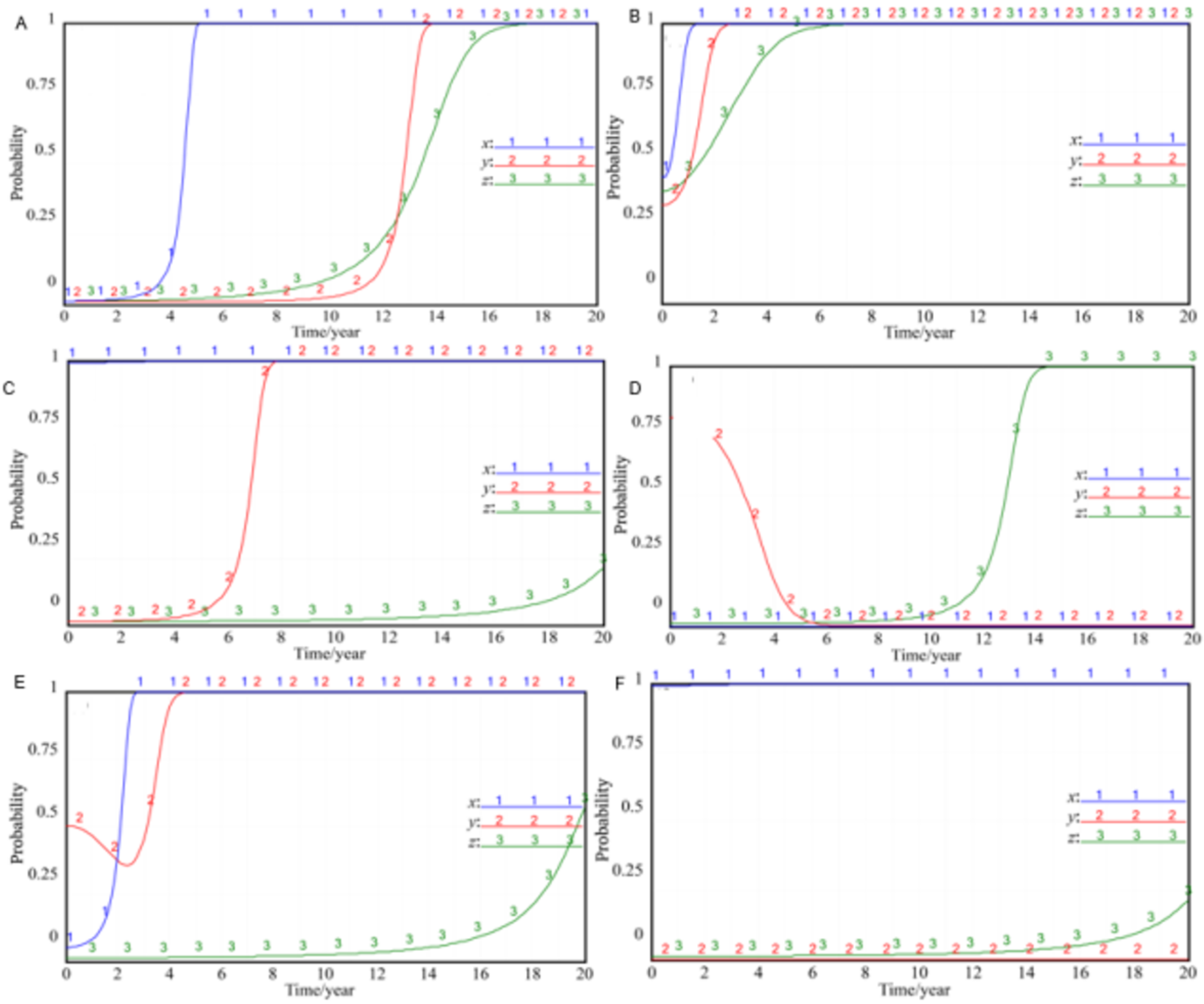
Because no specific people or animals are involved in the research and no individual privacy is involved, academic ethics review is not required.

Results

Holistic Simulation Analysis of the Evolutionary Game Model

The initial state of the government, the hospital, and the patient in the evolutionary game is pure strategy, that is, each party's strategy choice is 0 or 1, but the 8 possible equilibrium states formed by this are unstable. As long as one party's strategy is slightly adjusted, the other parties will learn to imitate and then choose strategies with higher returns, and the whole game system will evolve into a new equilibrium state. Taking the (0, 0, 0) combination strategy as an example, the evolutionary game process under different values of *x*, *y*, and *z* is shown in Figure 2 (the ordinates in the figure represent the probability of strategy selection of the government, hospitals, and patients in the corresponding state).

Figure 2. Process of the evolutionary game in the case of combined values of *x*, *y*, and *z*. (A) *x*=0.01, *y*=0.01, *z*=0.01; (B) *x*=0.45, *y*=0.35, *z*=0.4; (C) *x*=0.99, *y*=0.01, *z*=0.01; (D) *x*=0, *y*=0.8, *z*=0.01; (E) *x*=0.05, *y*=0.5, *z*=0.01; (F) *x*=0.99, *y*=0, *z*=0.01.



Comparing Figure 2A-C, we can see that as long as the government's strategy evolves in the direction of vigorous promotion, no matter how much the initial probability of active participation of hospitals and patients is, the strategy of active participation and supervision will be adopted eventually, that is, as long as X evolves from 0 to 1, the whole system will develop into a stable state of (1, 1, 1), and it shows that the evolution speed of the government's strategy is faster than that of the hospital's strategy. The evolution speed of the hospital's strategy is faster than that of the patient's strategy. At the same time, when the government's strategy changes from 0 to 0.01 or from 1 to 0.99, it will eventually evolve into the strategy of trying to promote, showing that the strategy of trying to promote is always the best strategy of the government. During the vertical integration of cross-agency EHRs in the medical consortium, the government has always been and should be in the leading position. In specific practice, the government should take the initiative to promote rather than completely transfer the responsibility to the hospital.

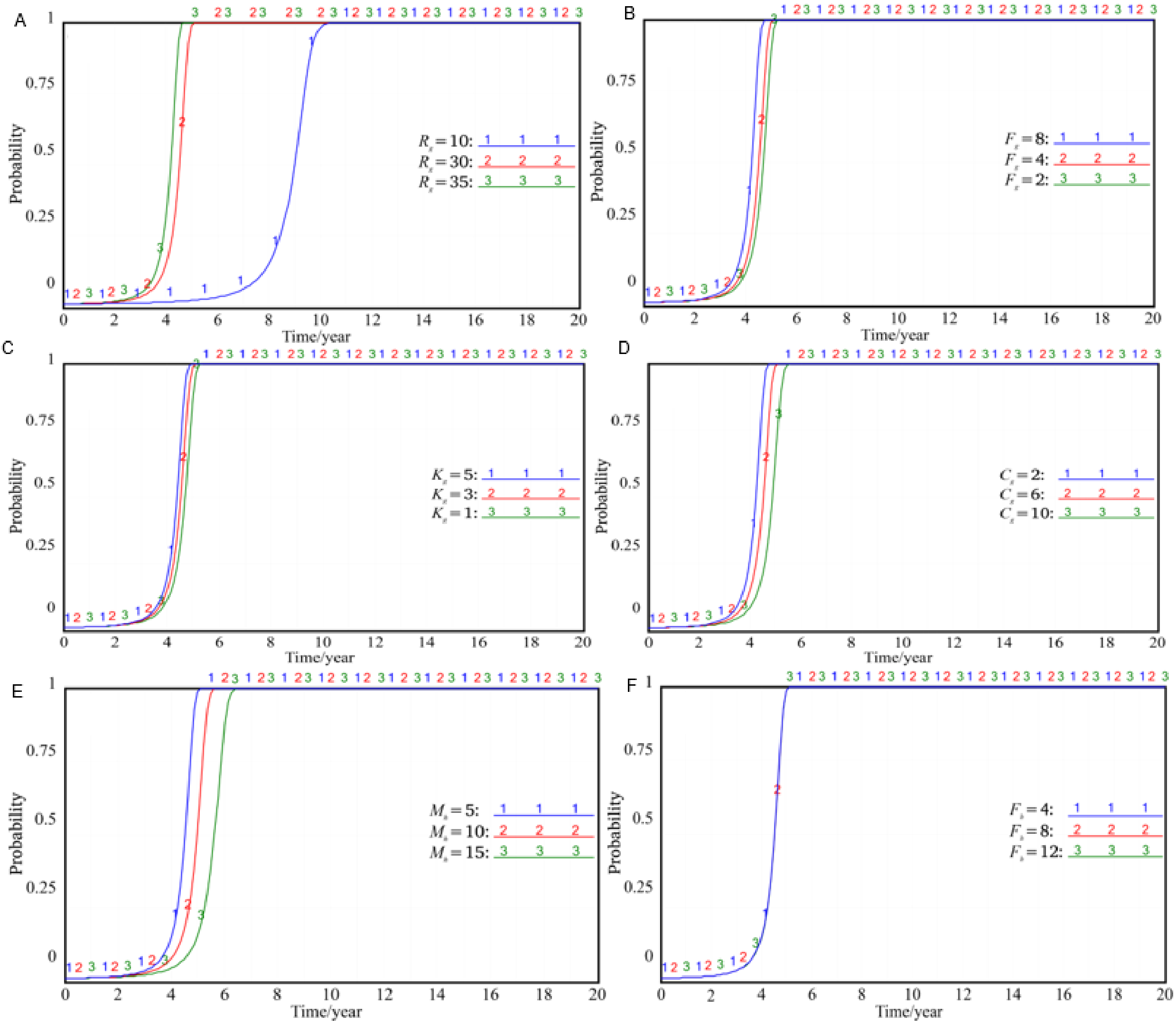
When the government chooses to promote the strategy, the hospital will always reach the status of 1 before the patients. However, comparing Figure 2D,E, it can be found that when the government chooses the negative treatment strategy, even if the hospital has high enthusiasm to participate in the vertical integration of EHRs at the beginning, it will gradually choose the negative participation strategy as time goes on; however, when the hospital completely chooses the passive participation strategy, even if the government adopts the promotion strategy again, it will be difficult to promote the hospital from the passive strategy to the active participation in a short time. The enlightenment from this conclusion is that the local government should do a good job in the overall design and development planning at the beginning, or it will be difficult to achieve the national goal of vertical integration of EHRs.

It can be seen in Figure 2 that the patients were the slowest to choose the active supervision strategy, but this is always the best strategy for patients. At the same time, it was also found that once patients choose the active supervision strategy, no matter how the strategies of the government and hospital change, the patients will tend to the active supervision strategy. Through the overall simulation analysis, it can be seen that the evolutionary game system will finally reach the equilibrium state at (1, 1, 1) after the 3 parties' strategy mutation, learning imitation, and strategy adjustment in the game process.

Factors Influencing the Government's Strategy Selection

According to the model simulation, 7 external variables such as the revenue R_g and cost C_g when the local government tries to promote, the cost K_g and punishment F_g when the local government treats the hospital negatively, the government subsidy F_h to the hospital, the supervision reward F_p to the patients, and the punishment M_h when the local government participates in the hospital negatively will affect the local government's strategy choice (Figure 3). It can be seen from Figure 3A-C that R_g, F_g, and K_g have similar effects on the government's strategy selection. In the initial value state, increasing the values of the 3 parameters will make the government's promotion probability x reach 1 earlier, which means increasing the revenue when the government is trying to promote. By contrast, increasing the cost and punishment of the government's negative treatment of the integration of EHRs will enhance the government's enthusiasm for trying to promote. Comparatively, income has a greater impact on the choice of the government's strategy. Comparing Figure 3D,E, it can be seen that C_g and M_h have similar effects on the government's strategy. Increasing the values of the 2 parameters respectively will prolong the period for the government to choose the strategy of trying to promote, which indicates that the higher the promotion cost, the lower the probability of the government trying to promote. It is worth mentioning that when the punishment M_h for passive participation in the hospital is increased to a certain extent, the government will slow down its efforts to promote the stability of the strategy, which indicates that the government cannot blindly increase its revenue by increasing the punishment. It also means that the government revenue R_g pays more attention to the social value after the integration of EHRs rather than punishing the hospital. The change of F_h and F_p has no obvious impact on the government's strategy. The curve trend after the change of the 2 parameters is basically the same, as shown in Figure 3E, which means that as long as the goal of integrating medical resources to improve medical efficiency can be achieved, the local government is likely to be willing to grant subsidies and supervise incentives. In other words, whether to give subsidies to hospitals or reward patients for supervision is not the main factor affecting the government's choice of strategies.

Figure 3. Impact of external variables on government's strategy selection. (A) The impact of R_g on the choice of government's strategy. (B) The impact of F_g on the choice of government's strategy. (C) The influence of K_g on the choice of government's strategy. (D) The influence of C_g on the choice of government's strategy; (E) The impact of M_h on the choice of government's strategy; (F) The impact of F_h on the choice of government's strategy.

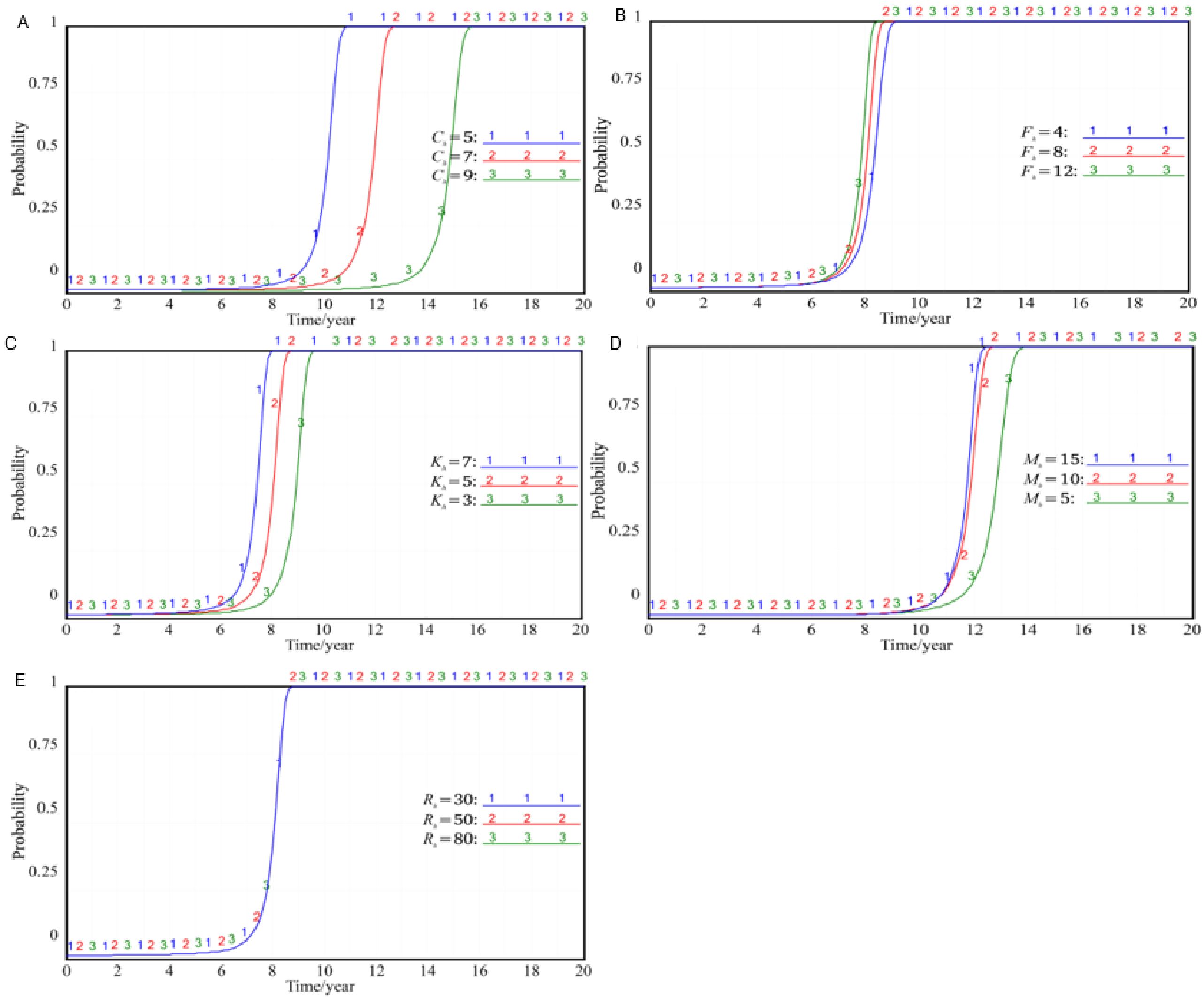


Factors Influencing the Hospital's Strategy Selection

Through simulation, it can be found that 4 external variables, namely, the cost C_h when the hospital actively participates, the cost K_h when the hospital passively participates, the government subsidy F_h when the hospital actively participates, and the punishment M_h when the hospital passively participates, will affect the choice of the enterprise strategy (Figure 4). When the value of C_h is smaller or the values of K_h, F_h, and M_h are larger, the probability of hospitals choosing the active participation strategy will be greatly increased. According to the analysis in Figure 4D, when the punishment M_h for the government's passive participation in the hospital increases to a certain extent, the marginal utility of the punishment measures will be greatly weakened, that is, when the punishment is increased to a certain extent, the incentive effect of the punishment itself will be weakened. A consistent conclusion has been reached in the analysis of the influencing factors of the government's strategy choice.

It was also found in the simulation that the hospital's revenue R_h under normal conditions will not affect its strategy choice (Figure 4E). This shows that neither large hospitals that occupy an absolute dominant position in medical information nor small hospitals with limited resources will refuse the vertical integration of EHRs because of the amount of their own information resources. In other words, both large hospitals and small hospitals have the potential willingness to act collectively to achieve the vertical integration of EHRs. This finding is of great significance for the government to vigorously promote the vertical integration of EHRs (eg, electronic medical records).

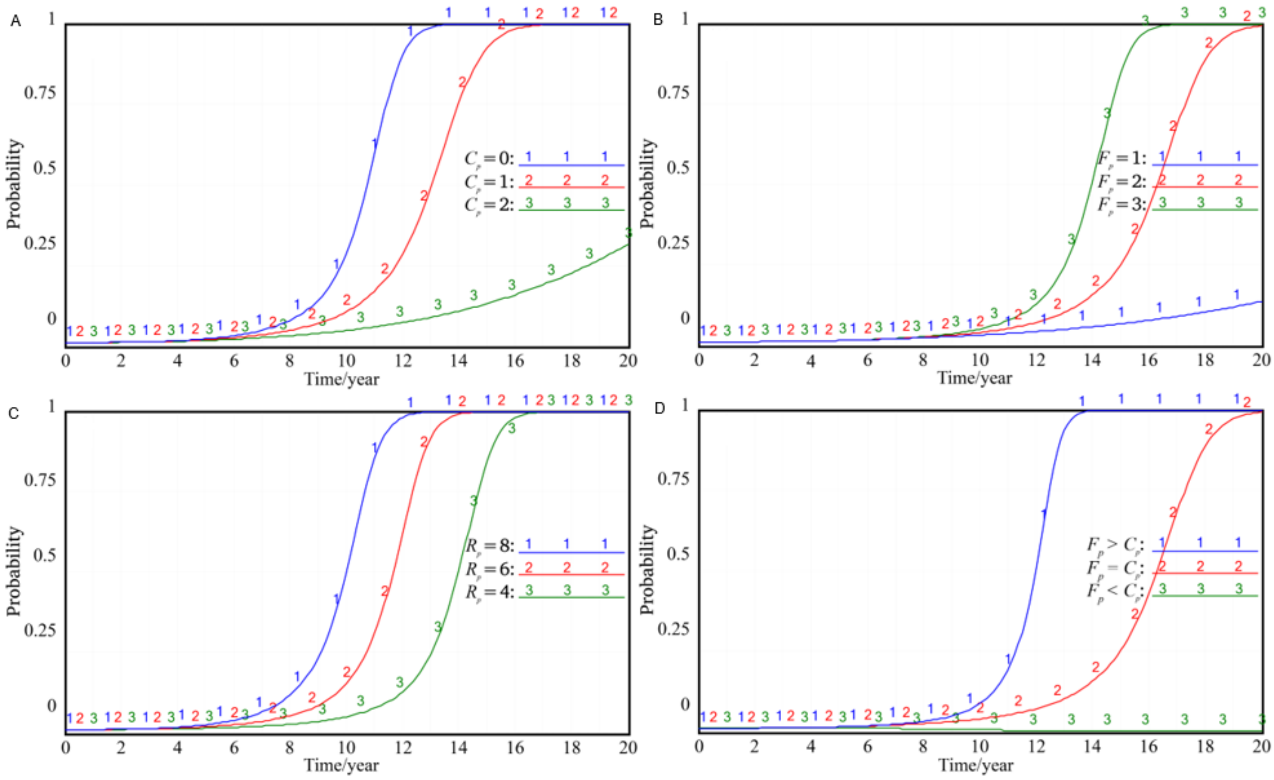
Figure 4. Impact of external variables on the hospital's strategy selection. (A) Impact of C_h on the hospital's strategy selection. (B) Impact of F_h on the hospital's strategy selection. (C) Impact of K_h on the hospital's strategy selection. (D) Impact of M_h on the hospital's strategy selection. (E) Impact of R_h on the hospital's strategy selection.



Factors Influencing the Patient's Strategy Selection

The factors that affect the patient's strategy selection mainly include the cost C_p and the reward F_p when the patient actively participates in the supervision, as well as the social damage R_p caused by the hospital's negative participation (Figure 5). We can see in Figure 5A,B that when the patient's supervision cost C_p becomes larger or the government reward F_p becomes smaller, the probability of patients choosing the active supervision strategy will obviously decrease. It can be seen from the simulation that the probability of patients choosing the active supervision strategy is determined by the difference between F_p and C_p, as shown in Figure 5C. When $F_p>C_p$, patients tend to choose active supervision. However, when $F_p=C_p$, the probability of patients choosing active supervision will significantly decrease. At this time, an increasing number of patients will take the "free riding" behavior and give up supervision, but when $F_p<C_p$, the probability of patients choosing active supervision is very low, and they will finally give up supervision. Therefore, to achieve the goal of vertical integration of EHRs, the government should provide some incentives for patient supervision and try to reduce the cost of patient supervision. When the social damage R_p caused by the hospital's negative participation is greater, the patients are more inclined to adopt the active supervision strategy, but this is not what we expect (Figure 5D). Therefore, the government is required to firmly choose and strive to promote the strategy to guide and encourage hospitals to choose the active participation strategy, so as to reduce the overall social damage.

Figure 5. Impact of external variables on the patient's strategy selection. (A) Effect of C_p on the patient's strategy selection; (B) Effect of F_p on the patient's strategy selection; (C) Joint effect of F_p and C_p on the patient's strategy. (D) Impact of R_p on the patient's strategy selection.



Discussion

Principal Findings

Using evolutionary game analysis and system dynamics simulation methods, we analyzed the evolution process of long-term strategies of the government, hospitals, and patients in the vertical integration of EHRs, and the influencing factors and mechanisms of each party's strategy choice. The principal findings are described below.

The choice of strategies of the 3 parties is jointly determined by a variety of external factors. Increasing the benefits of the government's efforts to promote and increasing the costs and penalties of the government's negative treatment have a greater impact on the government's strategic choice, while subsidies to hospitals and incentives to patients only have a little impact on the government's strategic choice. The following scenarios would motivate hospitals to choose an active participation strategy: lower cost of active participation, higher cost of passive participation, higher government subsidies, and reasonable penalties. The revenue of hospitals under normal circumstances have a little impact on the choice of hospital's strategies. Whether patients choose the active supervision strategy is mainly determined by the difference between the government reward and the supervision cost. Only when the patient supervision reward is higher than its cost can the purpose of encouraging patients to actively supervise be achieved.

The vertical integration of EHRs within the medical consortium has practical feasibility. In the model simulation, it is found that the strategies of the government, hospitals, and patients finally reach the optimal equilibrium state at (1, 1, 1), and both large and small hospitals have the potential willingness to take unified action to achieve the vertical integration of EHRs. However, this requires the government to be in a leading position and make every effort to promote it. It is difficult to achieve the goal of vertical integration of EHRs if the integration responsibility is fully delegated to the hospital.

Constructing a multiagent coordination mechanism under the guidance of the government is the only way to achieve the goal of vertical integration of EHRs in the medical consortium. The research shows that the government's strategy is influenced by strategies of both hospitals and patients. Patient's strategy is also influenced by the strategies of both the government and the hospital; the hospital's strategy choice is mostly directly affected by the government's strategy, and the patient's strategy can only indirectly affect the hospital's strategy choice through the impact on the government's strategy. Establishing a good cooperation mechanism can not only improve the cooperation efficiency, but also reduce the participation cost, so as to accelerate the realization of the integration goal. Therefore, it is necessary to build a multibody coordination mechanism led by the government and fully mobilize the enthusiasm of all parties so that the medical consortium can achieve the goal of vertical integration of EHRs.

The simulation results revealed that the appropriate increase of government subsidies for active participation and penalties for passive participation can enhance the enthusiasm of hospitals, while the improvement of supervision incentives can also encourage patients to choose active supervision strategies. Therefore, the government should establish a reasonable reward and punishment mechanism, and design a detailed implementation plan. The government should also build a reasonable benefit distribution mechanism among medical institutions to ensure the mutual use performance after the vertical integration of EHRs. Performance evaluation plays an important role in guiding, supervising, and promoting the vertical integration, and is also the main basis for establishing a reward and punishment mechanism and a benefit distribution mechanism. Therefore, the government should independently design the performance evaluation mechanism of information resource integration in the evaluation system of medical consortium construction, to reduce "free riding" opportunistic behavior and improve the enthusiasm of hospitals and patients to participate.

Limitations

Admittedly, there are limitations in this study. First, only the 3 core participants (the government, hospitals, and patients) were considered, while other stakeholders (eg, technology providers) were not considered. Second, because of the constraints of research conditions, real data available for prediction and simulation were not obtained. In the future, we will consider a wider range of stakeholders and seek to obtain real data for empirical studies to further improve the reliability of our findings.

Conclusions

We should build a multiagent coordination mechanism. As discussed in the preceding sections, strategies of the government, hospitals, and patients are intertwined and each is influenced by multiple external factors. Achieving the goal of vertical integration of EHRs requires the participation of multiple parties, with the government in a leading position. Establishing a good coordination mechanism can improve the efficiency of collaboration and reduce the cost of participation, thus accelerating the achievement of integration goals. Therefore, it is imperative to establish a government-led multiparticipant collaborative mechanism.

We should set up a reward and punishment mechanism and a benefit distribution mechanism. Simulation results show that appropriately increasing government subsidies when hospitals are actively involved and penalties when they are negatively involved can increase hospital motivation. Increasing monitoring rewards can also motivate patients to choose active monitoring strategies. Therefore, the government should establish a reasonable reward and punishment mechanism and design a detailed reward and punishment implementation plan. It should also build a reasonable benefit distribution mechanism among medical institutions to ensure the interoperability performance of vertically integrated EHRs.

We should establish a scientifically integrated performance evaluation mechanism. Performance evaluation aims to compare, measure, and judge the gap between the real development status and the predefined expectation standard. The evaluation results have an important role in guiding, supervising, and promoting the development of EHRs toward verticality, and are also the main basis for setting up reward and punishment mechanisms and benefit distribution mechanisms. Therefore, the government should independently design the performance evaluation mechanism of information resource integration in the evaluation system of medical consortium construction, so as to reduce the opportunistic behavior of "free riding" and increase the enthusiasm of hospital participation.

Acknowledgments

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Authors' Contributions

SHT contributed to model construction and simulation analysis, and wrote the original draft. YC reviewed and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record

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Original Paper

Games in Times of a Pandemic: Structured Overview of COVID-19 Serious Games

Tjaša Kermavnar[1], MD, PhD; Valentijn T Visch[1], PhD; Pieter M A Desmet[1], PhD

Human-Centered Design, Industrial Design Engineering, Delft University of Technology, Delft, Netherlands

Corresponding Author:
Tjaša Kermavnar, MD, PhD
Human-Centered Design
Industrial Design Engineering
Delft University of Technology
Landbergstraat 15
Delft, 2628 CE
Netherlands
Phone: 31 648921936
Email: T.Kermavnar@tudelft.nl

Abstract

Background: The COVID-19 pandemic introduced an urgent need for effective strategies to disseminate crucial knowledge and improve people's subjective well-being. Complementing more conventional approaches to knowledge dissemination, game-based interventions were developed to create awareness and educate people about the pandemic, hoping to change their attitudes and behavior.

Objective: This study provided an overview and analysis of digital and analog game-based interventions in the context of the COVID-19 pandemic. As major pandemics and other large-scale disruptive events are expected to increase in frequency in the coming decades, this analysis aimed to inform the design, uptake, and effects of similar future interventions.

Methods: From November 2021 to April 2022, Scopus, Google, and YouTube were searched for articles and videos describing COVID-19–themed game-based interventions. Information regarding authorship, year of development or launch, country of origin, license, deployment, genre or type, target audience, player interaction, in-game goal, and intended transfer effects was extracted. Information regarding intervention effectiveness was retrieved where possible.

Results: A diverse assortment of 23 analog and 43 digital serious games was identified, approximately one-third of them (25/66, 38%) through scientific articles. Most of these games were developed by research institutions in 2020 (13/66, 20%) and originated in Europe and North America (38/66, 58%). A limited number (20/66, 30%) were tested on relatively small samples, using a diversity of research methods to assess the potential changes in participants' knowledge, attitudes, and behaviors as well as their gameplay experience. Although most of the evaluated games (11/20, 55%) effectively engaged and motivated the players, increased awareness, and improved their understanding of COVID-19–related issues, the games' success in influencing people's behavior was often unclear or limited.

Conclusions: To increase the impact of similar future interventions aimed at disseminating knowledge and influencing people's attitudes and behaviors during a large-scale crisis, some considerations are suggested. On the basis of the study results and informed by existing game theories, recommendations are made in relation to game development, deployment, and distribution; game users, design, and use; game design terminology; and effectiveness testing for serious games.

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KEYWORDS

COVID-19; serious game; game-based intervention

Introduction

Background

The outbreak of the novel coronavirus causing COVID-19 was declared a pandemic in March 2020 [1]. With increasing restrictions and uncertainty, a growing number of studies have reported troubling large-scale psychological effects of the COVID-19 pandemic, including worry, fear, anxiety, boredom, frustration, irritability, anger, sadness, and depression [2-7]. On a collective level, health anxiety, collective disorientation, community panic, crisis fatigue, and social isolation fatigue have been observed [3,4,8]. These effects seem to be perpetuated by *doomsurfing* or *doomscrolling*, which refers to the tendency to continually search for bad news on the web even though it is saddening, disheartening, or depressing [9]. An increase in additional dysfunctional behaviors such as panic purchasing of essential household items, increased consumption of psychoactive substances, weight gain because of stress-induced eating, and complete social withdrawal has suggested an imbalance between increased environmental demands and the efficacy of people's resilience and coping. Experts have advised that people adhere to daily routines and maintain a strong degree of social connectedness to improve communication and reduce boredom [10-12]. Less conventional means to maintain or improve people's subjective well-being have also been investigated, including digital health interventions (ie, telemedicine, eHealth, and mobile health) [13-15], exergames [16], arts-based interventions [10], bibliotherapy [17], and the company of pet animals [18].

Playing games has been a popular coping strategy during the pandemic [19,20]; it has even been recommended by the World Health Organization (WHO) as an effective way to stop the spread of COVID-19 [21]. Kleinman et al [22] reported that people resorted to games to maintain their mental well-being (eg, to cope with loneliness, escape from the troubling real world, or replace the loss of routines because of quarantine), connect with others (eg, with distanced friends and family, people confined to the same household, or new people), or substitute reality (eg, using game characters as a substitute for real interactions and hosting internet-based events). Some people have also found solace in creating games or gamifying everyday activities to cope with distress during quarantine [22].

During the pandemic, an increased interest specifically in pandemic-themed games such as the board game *Pandemic*, which was developed after the 2003 severe acute respiratory syndrome epidemic, was observed [23]. In 2020, over 50 global game industry leaders launched the campaign *#PlayApartTogether* to encourage gamers to follow the WHO guidelines as well as incorporate COVID-19 prevention messages into their games [24,25]. Thus, in addition to *entertainment* games intended to be played primarily for amusement purposes, a considerable number of *serious* games were developed to educate people about the COVID-19 pandemic, influence their behavior, and improve their well-being in terms of increased life satisfaction and decreased negative affect. These games drew upon the proven positive effect that (serious) games can have on increasing health literacy [26,27]. Although the entertainment in playing games can in itself benefit one's psychological well-being, our study focuses on *serious* games that were intentionally designed to spread awareness and knowledge of COVID-19, promote healthy behaviors, and increase people's resilience during the pandemic.

Serious games (hereinafter referred to as *games*) often use entertainment qualities to increase player motivation to learn and change their attitudes or behavior in the real world (ie, to facilitate *transfer effects* such as contagion-preventive behavior) [28]. They can increase people's understanding of complex situations and equip them with the knowledge and skills that are required in real life [24], especially when immersive simulations of threatening new or unusual situations are used in a safe environment that players can explore to prepare for the possible consequences of a real disaster [29]. Although multiple theories on the motivational effects of game and play (starting in 1938 with *Homo Ludens* by Huzinga [30,31]) have been developed, it is very difficult to specify the exact game elements that cause games' transfer effects [32,33]. Some theorists have stated that games are ideal candidates for optimally responding to universal motivational needs (cf the relationship between games and self-determination theory [34]), whereas other theorists [35] have claimed that games provide a safe space to explore and play along the dimensions of rule-based games (*ludus*) and spontaneous play (*paidia*). In addition to the motivational effects of game elements, such as rewards, challenges, or imagination [36], games can motivate people by offering an alternative world that is fun, safe, and engaging. Huizinga [30] dubbed this (experienced) game world "the magic circle," defining it as "a temporary world within the ordinary world with specific time- and space-boundaries." Several theories, such as the theory of narrative transportation [37] and make-believe [38], describe why people tend to be attracted to these alternative worlds. Serious games make use of the motivational aspects of (entertainment) games to intentionally achieve effects in the *ordinary* or *real* world. These can involve effects on awareness (cf health risk awareness [39]), health knowledge [40], health attitudes [41], and health behaviors [42].

Objectives

Recent reports such as that by Metabiota [43] have warned that the risk of another major pandemic during our lifetimes is higher than many expect—they estimate the likelihood of another pandemic occurring within the next 25 years to be 47%-57%. Similarly, Marani et al [44] predicted up to a 3-fold increase in the yearly probability of extreme epidemics in the coming decades. This implies that the games developed in response to the recent pandemic could potentially serve as a basis for future games, indicating a need to explore the landscape of COVID-19–themed games. Apart from a recent analysis of 5 studies that evaluated 4 games in total [45], to date, no comprehensive reviews that could help evaluate the various game design decisions for this specific context have been published. Thus, the overview presented in this paper aims to inform the design of similar game-based interventions by showcasing the diversity of intentions and design strategies.

Methods

Search and Selection of COVID-19 Games

In November 2021, we performed a search of Scopus to identify scientific articles that described the development or testing of COVID-19–themed games. The search was limited to articles and conference papers published in English after 2018 that included the keyword "game*" and any of the keywords "covid*," "sars-cov*," "pandemic*," or "lockdown*" in the title. To further reduce the number of irrelevant results, we excluded those where the word *game* was used in relation to *game changer* or the Olympic and Paralympic games. The search was then repeated in April 2022 to include the most recent studies. Titles and abstracts of the identified 181 results were screened to exclude publications that did not focus on games developed to educate the general public on the COVID-19 pandemic. In total, 34 full texts describing 25 different games were included in the review.

An important consideration that informed the literature review was that games are not necessarily disseminated through or discussed in scientific publications. To avoid excluding relevant games that had only been disseminated through nonscientific media, Google and YouTube were also searched using the aforementioned keywords. This search, which was performed from November 2021 to April 2022, identified 42 additional games developed by private citizens, studios, and profit and nonprofit organizations. Owing to the overwhelming number of prototypes of digital games developed primarily for game jams (eg, International Festival of Independent Games "JAMMING THE CURVE: COVID-19 Game Jam") or competitions (eg, the 2021 Institute of Electrical and Electronics Engineers Conference on Virtual Reality and 3D User Interfaces contest "Challenging Pandemics"), these were not included in this study.

Data Extraction

The identified games were analyzed and categorized based on the Comprehensive Taxonomy for Serious Games by De Lope and Medina-Medina [46]. This taxonomy builds on a series of concepts from existing partial classification systems to collect and organize a large number of game features when developing new games or when analyzing or comparing existing ones [46]. Information regarding the games' authorship, license, deployment, genre or type, target audience, player interaction, in-game goal, and intended transfer effects was extracted. Information regarding the year of development or launch, country of origin, and user testing was also obtained where possible.

Results

COVID-19 Games

Overview

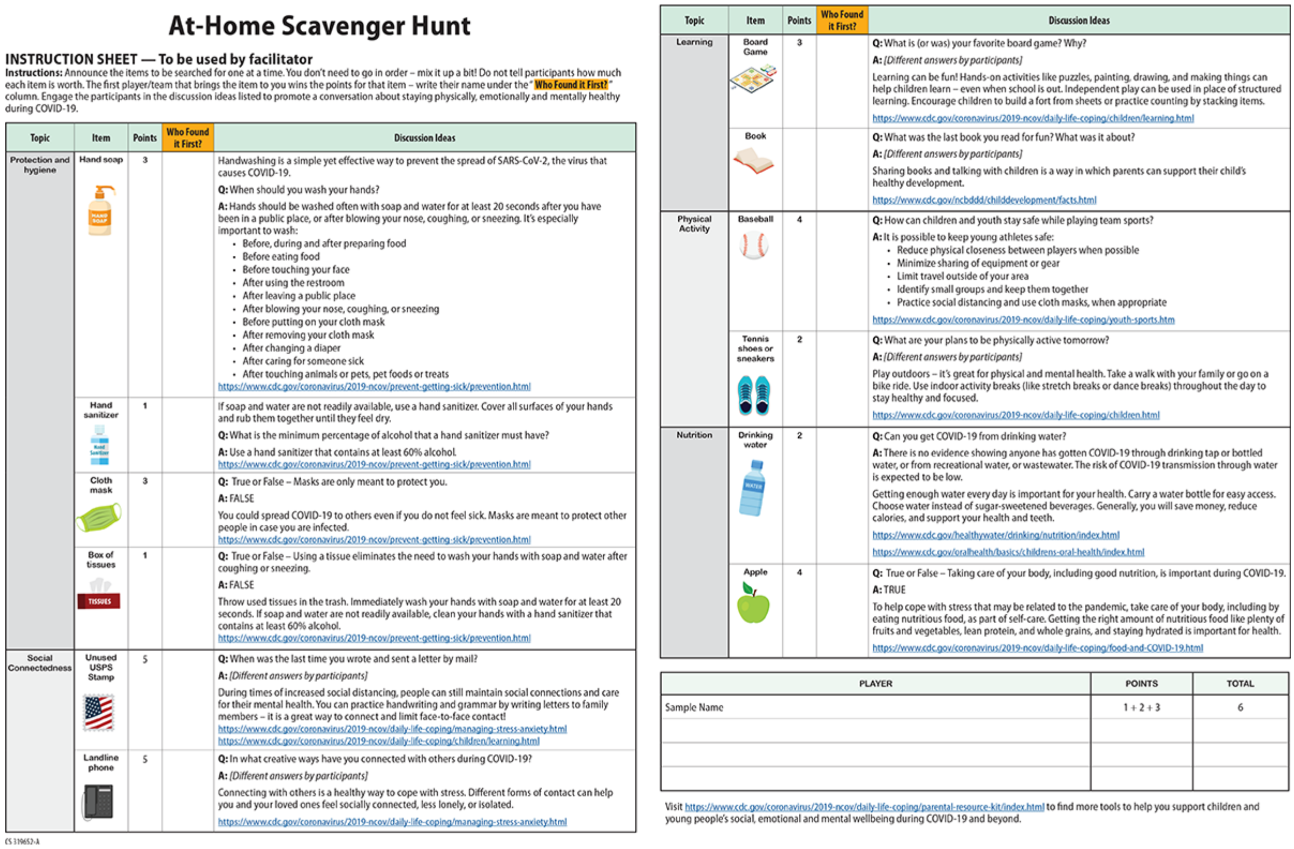
By January 2022, a total of 66 COVID-19–themed games—23 (35%) analog and 43 (65%) digital—were identified. Detailed overviews of analog and digital games are provided in Multimedia Appendix 1 [47-52] and Multimedia Appendix 2 [53-70], respectively; Figures 1-10 show 10 game examples. The general findings are presented in the following sections.

Figure 1. Clinic Deluxe Edition: CoVid_19 variant (image reproduced with permission from Alban Viard [71]).

Figure 2. Plague Inc.: The Cure (image reproduced with permission from Ndemic Creations [72]).

Figure 3. Antidote COVID-19 (image reproduced with permission from Psyon Games [73]).

Figure 4. At-Home Scavenger Hunt [47]. Materials developed by the Centers for Disease Control and Prevention (CDC). Reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the US Government, Department of Health and Human Services, or Centers for Disease Control and Prevention.



At-Home Scavenger Hunt

INSTRUCTION SHEET — To be used by facilitator

Instructions: Announce the items to be searched for one at a time. You don't need to go in order – mix it up a bit! Do not tell participants how much each item is worth. The first player/team that brings the item to you wins the points for that item – write their name under the "**Who Found it First?**" column. Engage the participants in the discussion ideas listed to promote a conversation about staying physically, emotionally and mentally healthy during COVID-19.

Topic	Item	Points	Who Found it First?	Discussion Ideas
Protection and hygiene	Hand soap	3		Handwashing is a simple yet effective way to prevent the spread of SARS-CoV-2, the virus that causes COVID-19. **Q:** When should you wash your hands? **A:** Hands should be washed often with soap and water for at least 20 seconds after you have been in a public place, or after blowing your nose, coughing, or sneezing. It's especially important to wash: • Before, during and after preparing food • Before eating food • Before touching your face • After using the restroom • After leaving a public place • After blowing your nose, coughing, or sneezing • Before putting on your cloth mask • After removing your cloth mask • After changing a diaper • After caring for someone sick • After touching animals or pets, pet foods or treats https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
	Hand sanitizer	1		If soap and water are not readily available, use a hand sanitizer. Cover all surfaces of your hands and rub them together until they feel dry. **Q:** What is the minimum percentage of alcohol that a hand sanitizer must have? **A:** Use a hand sanitizer that contains at least 60% alcohol. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
	Cloth mask	3		**Q:** True or False – Masks are only meant to protect you. **A:** FALSE You could spread COVID-19 to others even if you do not feel sick. Masks are meant to protect other people in case you are infected. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
	Box of tissues	1		**Q:** True or False – Using a tissue eliminates the need to wash your hands with soap and water after coughing or sneezing. **A:** FALSE Throw used tissues in the trash. Immediately wash your hands with soap and water for at least 20 seconds. If soap and water are not readily available, clean your hands with a hand sanitizer that contains at least 60% alcohol. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
Social Connectedness	Unused USPS Stamp	5		**Q:** When was the last time you wrote and sent a letter by mail? **A:** *[Different answers by participants]* During times of increased social distancing, people can still maintain social connections and care for their mental health. You can practice handwriting and grammar by writing letters to family members – it is a great way to connect and limit face-to-face contact! https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/managing-stress-anxiety.html https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/learning.html
	Landline phone	5		**Q:** In what creative ways have you connected with others during COVID-19? **A:** *[Different answers by participants]* Connecting with others is a healthy way to cope with stress. Different forms of contact can help you and your loved ones feel socially connected, less lonely, or isolated. https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/managing-stress-anxiety.html
Learning	Board Game	3		**Q:** What is (or was) your favorite board game? Why? **A:** *[Different answers by participants]* Learning can be fun! Hands-on activities like puzzles, painting, drawing, and making things can help children learn – even when school is out. Independent play can be used in place of structured learning. Encourage children to build a fort from sheets or practice counting by stacking items. https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/learning.html
	Book			**Q:** What was the last book you read for fun? What was it about? **A:** *[Different answers by participants]* Sharing books and talking with children is a way in which parents can support their child's healthy development. https://www.cdc.gov/ncbddd/childdevelopment/facts.html
Physical Activity	Baseball	4		**Q:** How can children and youth stay safe while playing team sports? **A:** It is possible to keep young athletes safe: • Reduce physical closeness between players when possible • Minimize sharing of equipment or gear • Limit travel outside of your area • Identify small groups and keep them together • Practice social distancing and use cloth masks, when appropriate https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/youth-sports.htm
	Tennis shoes or sneakers	2		**Q:** What are your plans to be physically active tomorrow? **A:** *[Different answers by participants]* Play outdoors – it's great for physical and mental health. Take a walk with your family or go on a bike ride. Use indoor activity breaks (like stretch breaks or dance breaks) throughout the day to stay healthy and focused. https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children.html
Nutrition	Drinking water	2		**Q:** Can you get COVID-19 from drinking water? **A:** There is no evidence showing anyone has gotten COVID-19 through drinking tap or bottled water, or from recreational water, or wastewater. The risk of COVID-19 transmission through water is expected to be low. Getting enough water every day is important for your health. Carry a water bottle for easy access. Choose water instead of sugar-sweetened beverages. Generally, you will save money, reduce calories, and support your health and teeth. https://www.cdc.gov/healthywater/drinking/nutrition/index.html https://www.cdc.gov/oralhealth/basics/childrens-oral-health/index.html
	Apple	4		**Q:** True or False – Taking care of your body, including good nutrition, is important during COVID-19. **A:** TRUE To help cope with stress that may be related to the pandemic, take care of your body, including by eating nutritious food, as part of self-care. Getting the right amount of nutritious food like plenty of fruits and vegetables, lean protein, and whole grains, and staying hydrated is important for health. https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/food-and-COVID-19.html

CS 319652-A

PLAYER	POINTS	TOTAL
Sample Name	1 + 2 + 3	6

Visit https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/parental-resource-kit/index.html to find more tools to help you support children and young people's social, emotional and mental wellbeing during COVID-19 and beyond.

Figure 5. GO VIRAL! (image reproduced with permission from Tilt Studio and Professor Sander L van der Linden from the University of Cambridge [66]).

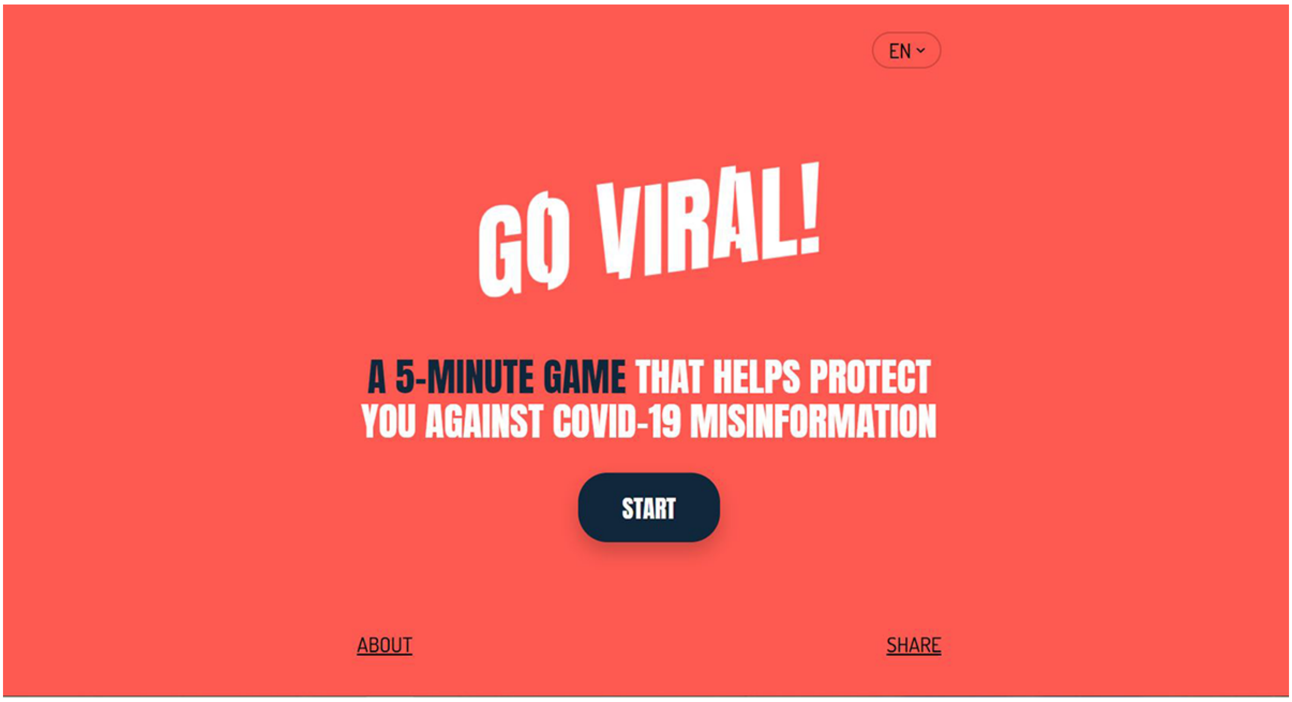


Figure 6. You Make Me Sick! (image reproduced with permission from The Partnership in Education [52]). The game was created by The Partnership in Education, a project supported by the National Institute of General Medical Sciences of the National Institutes of Health under award R25GM132910.

Figure 7. Lockdown! (image reproduced with permission from Yann Boucher [76]).

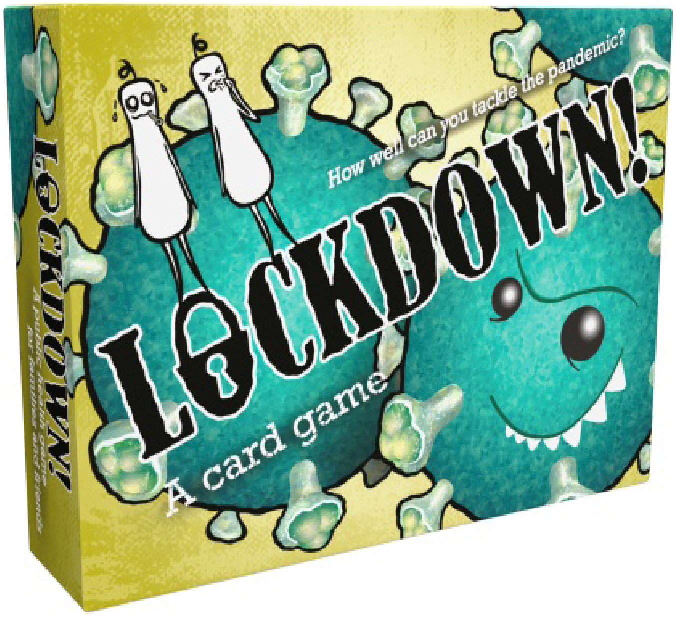


Figure 8. Corona Bee (image reproduced with permission from Focus Games [56]).

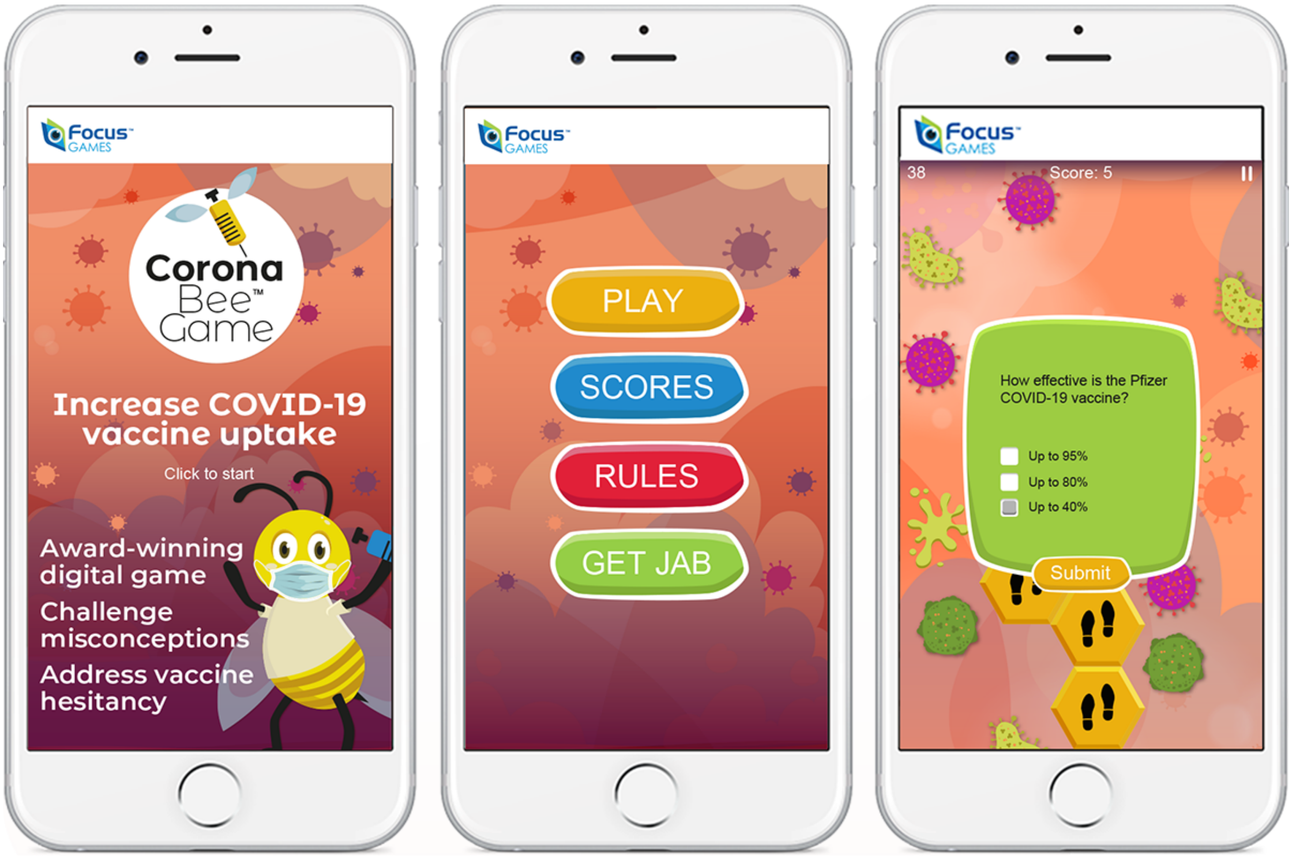


Figure 9. Heroes of Covid-19 (image reproduced with permission from GRM Digital [67]).

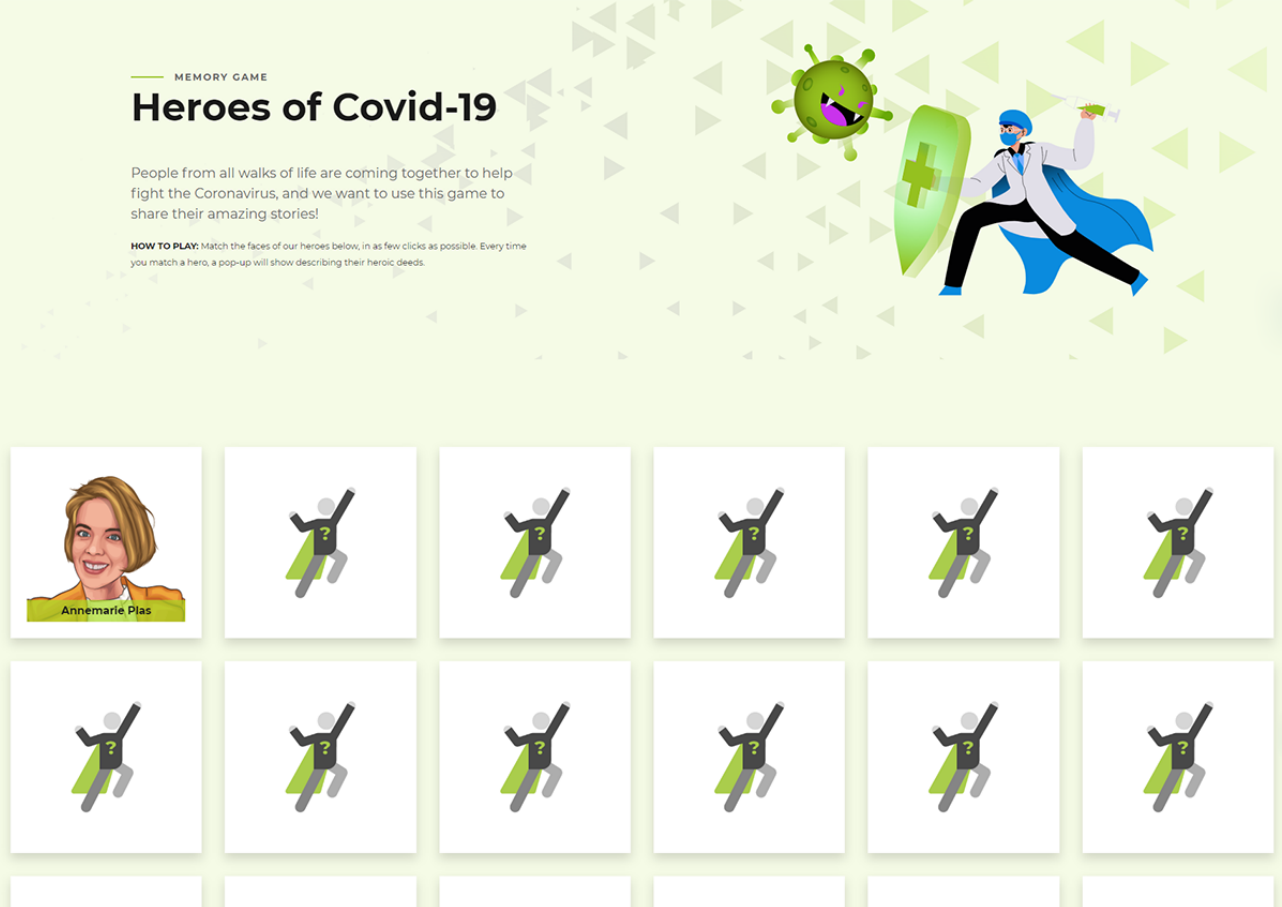


Figure 10. Destroy COVID (image reproduced with permission from Kristóf Horváth [74]).

Release Year and Location

The vast majority of the identified games were developed or launched in 2020 (41/66, 62%); the rest were developed or launched in 2021. The largest number of games originated in the United States (10/66, 15%), India (9/66, 14%), and the United Kingdom (7/66, 11%). The countries of origin of other games included Denmark, the Netherlands, and Switzerland (3/66, 5% of the games each); Canada, Czech Republic, Finland, Germany, Morocco, Portugal, and South Africa (2/66, 3% of the games each); and Australia, Bangladesh, Belgium, Brazil, China, France, Hungary, Indonesia, Poland, Saudi Arabia, Singapore, and Taiwan (1/66, 2% of the games each). For 8% (5/66) of the games, the country of origin could not be determined.

Authorship

The lead developers were research institutions (31/66, 47% of the games), game development studios (17/66, 26% of the games), or private individuals (13/66, 20% of the games). A total of 9% (6/66) of the games were developed by children aged 10 to 17 years (*Better than Hugo, Corona – Mit Eifer ins Geschäft, Corona Yuga, COVID-19: A Race to the Vaccine, Go Corona Go,* and *Infected!*). Governmental and nongovernmental organizations (eg, ministries, educational institutes, the WHO, the Centers for Disease Control and Prevention [CDC], the United Nations Children's Fund, and Médecins Sans Frontières) were involved in the development of 22% (5/23) of the analog games and 16% (7/43) of the digital games.

License

In total, 65% (15/23) of the analog games were commercial (price: US $6.54-33.77), 30% (7/23) were available for free (6/7, 86% of these as *Print & Play* games), and 9% (2/23) were Kickstarter prototypes. In contrast, the vast majority of digital games were free to play (20/43, 47%) or prototypes (20/43, 47%); 5% (2/43) were commercial (price: US $4.36-9.80), and 2% (1/43) were developed for internal use at a company.

Target Audience

Most games (38/66, 58%) targeted younger audiences, including children as young as 3 years old, teenagers, and university students. Analog games were often designed to be engaging for the entire family, whereas 36% (24/66) of all digital games did not have a defined target audience. Certain other games targeted very specific user groups, such as gamers, active social media users, health care workers, health enthusiasts, employees of certain enterprises, and the African population.

Game Types and Genres

Practically all games identified were simulations of the COVID-19 pandemic. Some were set in the players' immediate environment, such as the classroom (eg, *Fighting COVID-19 at Purdue University*), the office (eg, *Social Distancing – The Game*), or the supermarket (eg, *Dino-Store*), or more broadly in a village, town, or city (eg, *Clinic Deluxe Edition: CoVid_19 variant* [Figure 1], *COVID Dodge, SurviveCovid-19,* and *VRS Fight Club*); a country (eg, *Better than Hugo* and *Korona hra*); or the world (eg, *Plague Inc.: The Cure*; Figure 2), where the players were tasked with controlling the spread of the disease. Others were set in a microscopic environment of the human body, where the players assumed the role of immune cells in fighting off the infection (eg, *Antidote COVID-19* [Figure 3] and *Infekcja*) or of the virus in spreading the disease (eg, *Viruscape*). Other interesting approaches were used in games such as *At-Home Scavenger Hunt* by the CDC (Figure 4), which required the players to find relevant physical items in their actual environment; the location-based game *MeetDurian*, where virtual items could be collected in the player's physical environment (similar to *Pokémon GO*) if the player was wearing a face mask, the presence of which was detected by face recognition software; and *GO VIRAL!* (Figure 5), which was set in the environment of a simulated social media platform.

The vast majority of analog games were board games (15/23, 65%) or card games (6/23, 26%). The most common analog game types or genres were strategy games (11/23, 48%; eg, *Lockdown!*; Figure 7) and race-to-the-end games (6/23, 26%; eg, *You Make Me Sick!*; Figure 6), whereas most digital games were primarily strategy (15/43, 35%; eg, *Plague Inc.: The Cure*), action (14/43, 33%; eg, *COVID Dodge*), and trivia (12/43, 28%; eg, *Corona Bee*; Figure 8) games. Some less common game types such as meditation or Zen (*CovidShield*), hidden object (*Help to stop the COVID-19 coronavirus* and *At-Home Scavenger Hunt* by the CDC), memory (*Heroes of Covid-19*; Figure 9), and escape room–type puzzles (*COVID-19 [CORONA VIRUS]* and *Destroy COVID*; Figure 10) were also identified.

Deployment

Most digital games (23/43, 53%) were web-based and playable on PCs, mobile devices, consoles, or a combination of these. An additional 21% (9/43) were deployed for mobile platforms, 7% (3/43) were deployed for desktop and mobile platforms, 2% (1/43) were deployed for desktop only, 2% (1/43) were deployed for desktop and consoles, and 2% (1/43) were deployed for consoles only. Analog games mainly took the form of physical objects (eg, game boards with figures and dice, play money or tokens, playing cards, and puzzle pieces) or free electronic files that were designed to be printed at home (*Print & Play*).

Player Interaction

Of the 43 digital games, 37 (86%) were single-player, 4 (9%) were multiplayer (up to 7 players), and 2 (5%) were single- and multiplayer. Of the 6 multiplayer digital games, 5 (83%) were co-operative, and 1 (17%) was competitive. In contrast, all analog games (23/23, 100%) were multiplayer (up to 100 players), although single-player versions were also available in 26% (6/23) of the cases. Of these 23 games, 18 (78%) were competitive, 4 (17%) were co-operative, and 1 (4%) involved only teams or partnerships.

Gameplay Duration

Information retrieved from 15 analog games showed that gameplay duration ranged from 5 to 180 minutes—3 (20%) games required up to 15 minutes, 5 (33%) games required up to 30 minutes, 2 (13%) games required up to 45 minutes, 2 (13%) games required up to 60 minutes, and 3 (20%) games required >1 hour. The estimated duration could only be retrieved for 7% (3/43) of the digital games, which were substantially shorter than most analog games and lasted 5 to 15 minutes.

Intended Transfer Effects

Overview

In addition to a mostly entertaining *in-game goal*, serious games explicitly add a more *serious, out-game goal* [75], which refers to the intended effect of the game in the *real world* [28]; such an effect can be observed after playing the game and may include increased knowledge and awareness, skill development, and changes in attitudes or behaviors. Such serious games aim for impact that is typically long-term, in contrast to more short-term or direct forms of impact such as interactions, actions, and experiences while playing the game (for discussion on human impact–centered design, refer to the study by Fokkinga et al [77]). This repertoire of COVID-19 games covers this diversity of purposes, as summarized in Table 1 (extracted from the games' descriptions; for details, refer to Multimedia Appendix 3).

Table 1. Intended transfer effects of COVID-19–themed games (listed according to the hierarchy of effects model originally developed for advertising and recommended by McGuire [78] for use in public health campaigns [79]; N=66).

Intended transfer effect	Games, n (%)	Examples
Awareness-oriented effects	11 (17)	
Need for vaccination Preventive measures Need for well-being		• Antidote COVID-19 • Beat Corona • Corona – Mit Eifer ins Geschäft • COVID Challenge • Heroes of Covid-19 • Social Distancing – The Game
Education-oriented effects	38 (58)	
Virus Policy Vocabulary Personal care Information assessment		• Antidote COVID-19 • Clinic Deluxe Edition: CoVid_19 variant • Corona Bee • COVID Safety Simulation: CAMPUS LIFE • Govid • You Make Me Sick!
Attitude-oriented effects	12 (18)	
Improving empathy Sense of collective responsibility Critical reflection		• Better than Hugo • Breaking the Magic Circle • Corona Game • Essential Workers • GO VIRAL! • SurviveCovid-19++
Behavior-oriented effects	8 (12)	
Executing preventive measures Social conversation Staying healthy Entertainment Maintaining well-being		• At-Home Scavenger Hunt • Corona Yuga • CovidShield Game Suite • Fighting COVID-19 at Purdue University • MeetDurian • The Magic Soldier of the Human Body

Increasing Awareness and Spreading Knowledge

Overall, the games reviewed in this study aim to educate the players on the COVID-19 pandemic in an entertaining way. Practically all games (66/66, 100%) were developed to spread general awareness about COVID-19 (eg, *Is COVID-19 caused by bacteria or a virus?*; *Name one symptom of COVID-19 that affects the respiratory system*; and *What does the "19" in COVID-19 stand for?*). Some (6/66, 9%) were intended to educate people about the means and mechanisms of virus spread, the immune response, or both (eg, *True or False: COVID-19 can only be spread from person-to-person* and *Can you get COVID-19 from drinking water?*), whereas others (34/66, 52%) focus more on safety precautions to avoid catching and spreading the infection (eg, *True or False: Wearing a face mask can help stop the spread of COVID-19 to others*; *When should you wash your hands?*; and *What is the minimum percentage of alcohol that a hand sanitizer must have?*). Still others (5/66, 8%) specifically address vaccination (eg, *True or False: The COVID-19 vaccines can give you COVID-19*; *True or False: The vaccine will damage my DNA*; *I'm healthy and I'm never ill, should I still get vaccinated?*; and *Should a pregnant woman have the vaccine?*).

Influencing Attitudes

Several games (11/66, 17%) aim to cultivate people's sense of empathy and collective responsibility (eg, *Clinic Deluxe Edition: CoVid_19 variant*, *Fighting COVID-19 at Purdue University*, and *Essential Workers*) as well as encourage critical reflection on policy makers' dilemmas (eg, *Better than Hugo* and

Lockdown!) or the spread of misinformation (eg, *CoronaChampion* and *GO VIRAL!*). *Heroes of Covid-19* may be the only game to focus on positive aspects of the pandemic, raising awareness of people's noble deeds during this period (eg, "Quinn Callandar, a boy scout from Canada, used his 3D printing skills to create ear guards for people who feel pain from wearing masks all day"; "Intensive care nurse Molly Watts created a book entitled 'Dave the Dog is worried about coronavirus' to help tackle anxiety in children amid the Covid-19 outbreak"; and "Annemarie Plas from Brixton, London united the nation and gave the NHS frontline a boost with her 'Clap for our Carers' initiative.").

Influencing Behavior

Some games were designed to promote adherence to safety precautions in real-life settings. For example, *Fighting COVID-19 at Purdue University* aims to encourage students to clean their university laboratories, and *MeetDurian* encourages players to wear protective masks in public. Other games aim to stimulate behavior that can directly improve the players' well-being, such as mindfulness breathing (*CovidShield Game Suite*) and immunity-increasing nutrition (*The Magic Soldier of the Human Body*).

In most cases, the players were to adopt the positive role of a *hero* fighting the virus or protecting their avatar from infection in a simulated environment. An interesting yet less common alternative was to teach people about undesirable or unsafe behaviors by putting them in the negative role of, for example, the virus (*Viruscape*), an infected customer at a store (*Instructional remote multiplayer VR game*), or a misinformation spreader (*GO VIRAL!*).

Testing of Effectiveness in Promoting Transfer Effects

A relatively small number of scientific studies that investigated the effectiveness of the individual COVID-19–themed games (20) have been published (Multimedia Appendix 4 [80-101]). In total, 3 categories of effects were most frequently tested: the change in participants' knowledge of COVID-19 and infection prevention measures, their gameplay experience, and the games' potential to facilitate players' attitude or behavior change. The studies used various research methods and tools, including heuristic evaluations by experts, surveys composed of custom or standardized questionnaires and administered before or after gameplay, observations during gameplay, semistructured interviews, self-reports, or game log analysis after gameplay. A total of 15% (3/20) of the studies assessed the players' changes in knowledge [80-82] and attitudes [80,83,84] by comparing their pre- and postgameplay responses. One study involved a control group that watched an educational video about COVID-19 for comparison with a test group that played the game [80], whereas another used comparative analysis with other similar games [85]. With the exception of 30% (6/20) of the studies, which involved larger numbers of participants or instances of gameplay, testing was performed on relatively small samples (2-30 participants).

At this point, it is important to emphasize the diversity of methods used to assess the effectiveness of the games as these can greatly limit the comparability of the results. Nevertheless, most of the studies considered (11/20, 55%) found that the games succeeded in engaging and motivating the players [80,81,83,84,87,91,94,99,101], increasing awareness, and facilitating teaching COVID-19 hygienic knowledge [80-83,89,91]. Improved understanding led to positive changes in players' attitudes toward COVID-19 preventive measures [80,82,83,87,89,91,94,97,102]. A study reported that health anxiety remained relatively unchanged in response to playing 1 game [80].

Certain limitations of these studies have been acknowledged, especially in relation to the games' capacity to change players' behaviors. A proper assessment of the games' capacity to influence behavior was found to be particularly challenging as different sources of information may have contributed to people's adherence to safety measures [90,103] and as other factors—most notably, the players' ages—also affected the games' effectiveness [87,94]. The effectiveness of the reviewed games was often unclear or limited [98,103], and Suppan et al [92] explicitly stated that a longitudinal trial would be necessary to accurately assess their behavioral impact.

In addition, the studies recruited participants to play the games and evaluate their impact as opposed to surveying people who had already obtained and played the games through their own initiative. Information regarding the number of times the games were downloaded or played also does not appear to be structurally documented or made available; thus, it remains unclear to what extent the games were able to motivate people to play them in the first place. However, this information is of key importance as a game cannot be effective if it is not played.

Discussion

Principal Findings

This study aimed to provide an overview of games that were developed during the COVID-19 pandemic to disseminate crucial knowledge and enhance people's subjective well-being. In general, we observed an extensive proliferation of games—especially digital games—in 2020, when the pandemic was declared. Most (31/66, 47%) were developed by research institutions in Europe and North America—some in collaboration with health authorities. All efforts notwithstanding, the overall frequency of use and impact of these games seem to have been modest at most.

To effectively influence people's attitudes and behavior, design interventions need to be tailored to each situation, considering the environmental demands—as perceived by the target group—and their personal resources to meet these demands. On the basis of the findings of this study, we provide recommendations for the design of games aimed at improving people's well-being in future global health crises similar to the COVID-19 pandemic.

Game Development, Deployment, and Distribution

Overview

A game only has an impact if it is played. It is noteworthy that we only became aware of the multitude of COVID-19–themed games when we started actively searching for them. Although our experience is anecdotal, it does suggest the importance of investing time and effort in the dissemination of serious games.

Develop a Dissemination Plan

In the context of a pandemic, game developers should carefully consider their target audience. In many cases, this is probably the broadest audience possible, making it crucial to plan for the effective dissemination of the game. Most of the reviewed analog games (15/23, 65%) were commercially available physical objects, whereas most digital games (20/43, 47%) were freely accessible web-based applications. Each of the various forms of dissemination has advantages and disadvantages, but deployment strategy and cost may influence game accessibility to the greatest extent. Commercial games, for example, have an advantage in that they have access to professional dissemination channels and are often designed to be intriguing and esthetically appealing to attract people's attention. However, the cost and effort necessary to obtain such games can preclude them from reaching a broader audience. For analog games, *Print & Play* games tend to be the most convenient to access, especially when freely available on the web. Such games have a relatively low threshold for access in that buying them is not necessary.

When social distancing is required, as was the case during the pandemic, playing analog games is typically only possible for members of the same household. In contrast, digital games are easy to obtain and play remotely provided that the users have access to electricity and the internet. To maximize reach, Hill et al [82] advised that COVID-19–themed games must be platform-independent and playable with minimal hardware.

Collaborating with health authorities, the media, nongovernmental organizations, educational institutions, (local) governments, and social media influencers can also help spread awareness of a game's existence, although this may not always be the case. The designers of *Escape COVID-19*, for example, conducted a retrospective analysis to investigate the reasons for their limited success in recruiting participants for their study [104]. Specifically, they aimed to assess the effect of 3 different dissemination strategies on game account creation over a period of 6 months. In the first period (53 days), the game was disseminated by a part-time worker; following this was a press release (15 days); and in the final stage, the game was officially announced by the Swiss Federal Office of Public Health (15 days). Their findings suggested that the press release was the most successful and the official communication was the least successful. Nonetheless, the sequence and duration of communication interventions should also be considered.

Ensure the Reliability of Information

For games that aim to inform and share recommendations during a pandemic, a prominent challenge is that such recommendations are inherently dynamic. Although some information might be fixed (eg, what a virus is), other information may likely change after a game is introduced. The use of reliable sources such as the WHO, the CDC, and local governments can assure people that the communicated knowledge is factual. Practically all the reviewed games based their learning objectives on such sources. However, as guidelines may differ among different institutions and game developers may have different opinions on which information is correct, it is recommended that players be explicitly informed about the sources of the communicated knowledge. In addition, the credibility of the aforementioned sources can be subject to change, as seen with the rapidly waning trust in the CDC in the United States.

Real-time updates can be especially helpful in tackling confusion when guidelines change rapidly owing to the evolving understanding of health crises. It is critical that pandemic games be designed in a way that prevents them from becoming outdated too quickly; this can be addressed by incorporating sufficient flexibility in game design to allow for changing guidelines or information. Although this tends to be more challenging for analog games, it is possible—the content of analog games can be updated via expansion packs, and hybrid games where physical game elements are complemented by a regularly updated mobile app can be developed.

Game Users, Design, and Use

How, where, when, and with whom a game is intended to be played can influence players' motivation and the efficiency of the learning process [105]. Thus, it is important to design pandemic games that facilitate the acquisition and transfer of the intended learning objectives under pandemic-specific learning conditions.

Consider the Target Audience and Context of Use

Overview

When designing any serious game, it is generally advised to consider the entire ecosystem of stakeholders, including not only the players but also the initiators of games (eg, governments, nongovernmental institutions, health authorities, schools, and private citizens), design agencies, and game developers. The involvement of these stakeholders in various phases of game design (ie, problem definition, product design, and tailoring) can improve a game's implementation [106]. For pandemic games, this can be challenging, especially if the game is intended to appeal to a broad variety of affected people. Therefore, it is necessary to determine exactly which stakeholders need to be targeted. The following sections focus specifically on player characteristics.

Player Demographics

According to the effectiveness studies we reviewed, certain target group characteristics—most notably, age—influence people's engagement and the perceived effectiveness of the games [87,94]. Thus, caution is required when designing multiplayer games for people of different generations (eg, family games); it is important to avoid making such games too complex for very young or inexperienced audiences or too simple to effectively motivate adults and experienced players.

A general recommendation for game design is that game instructions should be easy to understand for a targeted user group. This recommendation is especially important for pandemic-focused games to minimize as much as possible the chances of spreading misinformation or confusion. Special attention needs to be paid to the language (preferably native language or multilingual versions) and vocabulary (preferably simple and familiar expressions) in the games. Using rules or elements from popular existing games (eg, *Monopoly*, *Ludo*, *Uno*, and *Pacman*) can help users understand and adopt a game more rapidly as people can only appreciate novelty when the product is also simultaneously perceived as familiar or typical [77,107].

Player Type

The process of meaning attribution can be influenced by the players' culture, personality traits, and current mental state, as well as by other people [77]. Similarly, product emotions, which are the emotions users experience in response to (playing) the game, are influenced by their personal needs, goals, values, and abilities [77]. Thus, a detailed psychological understanding of a game's target population can increase its impact.

First, it is important to understand that different people choose to play games for different reasons. A popular typology of player personalities developed by Bartle [108] distinguishes between 4 player types that differ based on their preferred way of engaging in the virtual world: *achievers*, *explorers*, *socializers*, and *killers* (for details, refer to the study by Bartle [108]). People assume different styles of play depending on their mood or in-game goals [108], suggesting that setting appropriate goals and using game elements to influence players' moods may discourage adverse social in-game behavior. However, Bartle based his taxonomy specifically on multiuser dungeon games; thus, his taxonomy cannot be directly extrapolated to other game types. The player profiles by Bartle [108] might work for entertainment games but not for serious games. To address this issue, Siriaraya et al [28] advised that users' experiential preferences be investigated for the game world as well as for the real world.

For COVID-19 games, it is also important to consider the differences between *social* and *solitary* players, especially in the degree of autonomy, presence, and relatedness they seek to experience (for details, refer to the study by Vella et al [109]). Understanding the specific needs and sources of motivation for different players can support the preferred player interaction.

Support Player Interaction

All the analog games reviewed in this study (23/23, 100%) were multiplayer and mainly competitive, whereas only 14% (6/43) of the digital games supported a multiplayer mode, of which 83% (5/6) were co-operative. The main advantage of single-player games is that they can be played at any time independently of other people. However, most single-player games do not allow for socializing, sharing opinions, or discussing ideas. In contrast, multiplayer games allow for socializing, but the minimum number of players required can limit the number of opportunities to play the game as this may depend on other people's interest, availability, or both. Optimally, a game should be designed to support both single- and multiplayer modes, as was the case for 26% (6/23) of the analog games and 5% (2/43) of the digital games studied in this review.

During the COVID-19 pandemic, collective action and compliance with safety guidelines were paramount in reducing the spread of the virus. Co-operative games can communicate this need to the players and support social bonding and collective decision-making that can be transferred from the in-game world to real-life situations. Previous studies have suggested that participation in co-operative—as opposed to competitive—multiplayer games can support team building [110-113] and increase real-world collaboration and prosocial behaviors among players [114-117]. In contrast, the motivation to win in competitive games may leave little room for bonding and the exchange of ideas, possibly limiting the encouragement of prosocial behavior. Nevertheless, competitive games tend to be more stimulating, whereas co-operative games may support passive participation when responsibilities are not equally distributed among the players. Therefore, it is advised to design for teams or partnerships, which combines both co-operation among team members and competition against the opposing team or teams.

Balance Visual Design and the Realism of the Simulated Domain

Immersive simulations of realistic environments and experiences where acquired knowledge can be put to use without the serious consequences of a real disaster may facilitate players' transfer of new knowledge to everyday life [29]; this is particularly important during pandemics, when rapid changes in attitudes and behavior are required. Presumably for this very reason, practically all the reviewed games were either literal or metaphorical simulations of the COVID-19 pandemic. However, as such games tend to emphasize educational goals, caution is necessary to adequately balance such education with entertainment so that games remain appealing to a broader audience.

To foster players' motivation and consolidate their engagement, fun elements that are unrelated to the simulated domain (eg, avatar shape or a game within a game) can be used. For example, the authors of *Escape COVID-19* found that attractive graphics that were adapted to fit the preferences of the target population were essential in increasing players' engagement [92]. Nevertheless, the designers of *Point of Contact* [82] stressed that a game's graphics and cross-player communication need to be lightweight to minimize players' dependence on high-performance devices and high-speed networks. Similarly, it is important to avoid substantial hardware demands, which were present in 2 game prototypes that were included in this study: the *Instructional remote multi-player VR game* requires access to a VR headset, and participants need to own an Xbox 360 device for the *Physical Fitness Training Program.*

Consider Time Requirements

Most of the analog games reviewed in this study (9/15, 60%) were designed for longer durations of gameplay (up to 3 hours); we could only retrieve the predicted duration for 7% (3/43) of the digital games, but the time required to play these games was considerably shorter (up to 15 minutes). The main advantage of short game durations (a few minutes) is that they do not require high levels of commitment, so the games can be played without previous planning. However, they may fail to elicit a *flow* state, reflection, or both. In contrast, long game durations (several hours) may deter potential users, especially if the game is multiplayer and requires scheduling a time that is appropriate for all players. Moreover, players may lose interest if a game lasts too long. Therefore, it is important to carefully design pandemic-themed games for optimal duration, depending heavily on the target group, game type, and intended transfer effects.

Challenge and Progression

To avoid cognitive overload, it is generally advised that games provide a clear distinction between the *active* and *reflective* phases of gameplay. Marne et al [105] suggested that intensive action phases that engage players emotionally and shift their focus toward a game's goal can be used for practice and training, whereas less intensive phases should be provided for reflection and relief purposes. During reflective phases, games should provide feedback to players so that they can understand the consequences of their actions and keep track of their own progress. However, this information must be provided in a way that does not interfere with the player's state of flow as this could cause them to lose interest in the game.

A possible solution proposed by Marne et al [105] is that individual items of obtainable knowledge or skills are represented as collectible virtual objects (*rewards*) that can be showcased or used as an asset later in the game. In addition to *material* rewards or achieving (publicly displayed) high scores, sensory stimulation (eg, sounds or graphics indicating an achievement) can also be rewarding, as can be messages of affirmation or commendation. For example, games such as *Escape COVID-19* included a positive message at the end of each level to strengthen players' motivation to comply with guidelines [92]. In such cases, simple, commonly used terminology can help a game more effectively reach broader target audiences.

Terminology for and Testing of Serious Games

In addition to the aforementioned considerations, our investigation revealed a need to agree upon a shared terminology and standardized testing approaches to improve the discourse on serious game development. From a scientific point of view, the wide diversity of findings at present renders it practically impossible to make any definitive conclusions or generalizations. A commonly agreed-upon method for effectiveness testing could facilitate the comparison of different approaches in game design and encourage the development of more impactful games. Consequently, we propose that a shared database of knowledge be created, such as the recently developed co.LAB methodological framework, which was implemented in a collaborative web platform that allows for the co-designing, codevelopment, and coevaluation of serious games [118].

Limitations

Despite all the efforts to provide a comprehensive review of COVID-19–themed games, we acknowledge that other games that were not included in this report exist (eg, competition and game jam entries were excluded). Furthermore, information on games that were not described in scientific papers was obtained from various web-based sources, potentially limiting the study's reliability. Nevertheless, we believe that this study correctly reflects the diversity of COVID-19–themed games.

Conclusions

This study aimed to provide a structured overview of serious games developed in the context of the COVID-19 pandemic to improve people's well-being through entertainment and education. We identified 66 diverse games, most of which were digital (43/66, 65%), were developed by research institutions in 2020 (13/66, 20%), and originated in Europe and North America (38/66, 58%). An analysis of the games' characteristics was performed to identify potential pandemic-specific challenges and opportunities for improvement, and some recommendations were made based on the findings of the reviewed studies and existing game theories.

In total, 2 additional themes emerged as a result of this overview. First, better planning for effective dissemination of the games appears to be necessary if the goal of these games is to reach the broadest audience possible. Second, to increase the impact of similar future interventions, the collective effort of game developers and researchers is needed to advance the discourse on game design and testing.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of analog COVID-19–themed games (N=23).

[DOC File , 111 KB - games_v11i1e41766_app1.doc]

Multimedia Appendix 2

Summary of digital COVID-19–themed games (N=43).

[DOC File , 162 KB - games_v11i1e41766_app2.doc]

Multimedia Appendix 3

Intended transfer effects of COVID-19–themed games.
[DOC File , 90 KB - games_v11i1e41766_app3.doc]

Multimedia Appendix 4
Testing of COVID-19–themed games.
[DOC File , 145 KB - games_v11i1e41766_app4.doc]

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Abbreviations

CDC: Centers for Disease Control and Prevention
WHO: World Health Organization

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Original Paper

A Gamified Real-time Video Observed Therapies (GRVOTS) Mobile App via the Modified Nominal Group Technique: Development and Validation Study

Siti Aishah Abas[1*], MBBS, MPH; Nurhuda Ismail[1*], MD, MPH, DrPH; Yuslina Zakaria[2*], PhD; Ismassabah Ismail[3*], BIT, MCS, PhD; Nurul Hidayah Mat Zain[4*], BCS, MSCS, PhD; Siti Munira Yasin[1*], MbBChBao, MPH, DrPH; Khalid Ibrahim[1*], MBBS, MHHSM, CMIA; Asmah Razali[5*], MD, MPH; Mas Ahmad Sherzkawee Mohd Yusoff[6*], MBBS, MPH, DrPH; Norliza Ahmad[7*], BSc, MBBS, MPH; Thilaka Chinnayah[5*], MBBS, DRM, MPH

[1]Department of Public Health Medicine, Faculty of Medicine, Universiti Teknologi MARA Sungai Buloh Campus, Sungai Buloh, Malaysia
[2]Department of Pharmacology, Faculty of Pharmacy, Universiti Teknologi MARA Puncak Alam Campus, Puncak Alam, Malaysia
[3]Centre of Foundation Studies, Universiti Teknologi MARA Cawangan Selangor, Kampus Dengkil, Dengkil, Malaysia
[4]Faculty of Computer and Mathematical Science, Universiti Teknologi MARA Cawangan Melaka, Kampus Jasin, Jasin, Malaysia
[5]Tuberculosis and Leprosy Control Sector, Disease Control Division, Ministry of Health, Putrajaya, Malaysia
[6]TB/Leprosy Disease Unit, Selangor State Health Department, Shah Alam, Malaysia
[7]TB/Leprosy Disease Unit, Negeri Sembilan State Health Department, Seremban, Malaysia
[*]all authors contributed equally

Corresponding Author:
Nurhuda Ismail, MD, MPH, DrPH
Department of Public Health Medicine
Faculty of Medicine
Universiti Teknologi MARA Sungai Buloh Campus
Sungai Buloh, 47000
Malaysia
Phone: 60 361267174
Fax: 60 361267234
Email: yuda@uitm.edu.my

Abstract

Background: The success rate of tuberculosis (TB) treatment in Malaysia remains below the recommended World Health Organization target of 90% despite the implementation of directly observed therapy, short-course, a physical drug monitoring system, since 1994. With increasing numbers of patients with TB in Malaysia defaulting on treatment, exploring another method to improve TB treatment adherence is vital. The use of gamification and real-time elements via video-observed therapies in mobile apps is one such method expected to induce motivation toward TB treatment adherence.

Objective: This study aimed to document the process of designing, developing, and validating the gamification, motivation, and real-time elements in the Gamified Real-time Video Observed Therapies (GRVOTS) mobile app.

Methods: The modified nominal group technique via a panel of 11 experts was used to validate the presence of the gamification and motivation elements inside the app, which were assessed based on the percentage of agreement among the experts.

Results: The GRVOTS mobile app, which can be used by patients, supervisors, and administrators, was successfully developed. For validation purposes, the gamification and motivation features of the app were validated as they achieved a total mean percentage of agreement of 97.95% (SD 2.51%), which was significantly higher than the minimum agreement score of 70% (P<.001). Further, each component of gamification, motivation, and technology was also rated at 70% or more. Among the gamification elements, fun received the lowest scores, possibly because the nature of serious games does not prioritize the fun element and because the perception of fun varies by personality. The least popular element in motivation was relatedness, as stigma and discrimination hinder interaction features, such as leaderboards and chats, in the mobile app.

Conclusions: It has been validated that the GRVOTS mobile app contains gamification and motivation elements, which are intended to encourage medication adherence to TB treatment.

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KEYWORDS

video directly observed therapy; VDOT; mobile health; mHealth; tuberculosis; medication adherence; directly observed therapy; video-observed therapy; mobile app; mobile health app; gamification

Introduction

More than 10 million cases of tuberculosis (TB) are reported each year globally [1]. In Malaysia, from 2010 to 2015, TB cases increased from 68.4 to 79.6 cases per 100,000 people [2]. In addition, according to a model projection, the observed and projected TB incidence in Malaysia will reach 300,000 cases in 2030 [3].

In Malaysia, directly observed therapy, short-course (DOTS) is a method to ensure medication compliance by having a trained health care worker or other designated individual provide the prescribed TB drugs and watch the patient take every dose. DOTS, which was implemented in 1994, has resulted in a treatment success rate from 76% in 2013 to 81% in 2017 [2]. However, this rate has remained below the recommended World Health Organization target of 90%. In addition, there is an increase in the prevalence of TB treatment default in Malaysia, which has ranged from 4% in 2010 to 4.8% in 2015 and to 5.6% in the latest study [4]. The increasing number of TB cases indicates that there are still issues and challenges that need to be addressed at all levels.

Specifically, the problems currently facing DOTS can be categorized according to the 3 main stakeholders. For patients with TB, the compulsory need for daily DOTS monitoring results in stigma by the public and absence from home or work responsibilities [5-7]. Health workers and policy makers are hesitant to fully implement DOTS, as there are inadequate human resources, increased TB management costs, less participation from lower management, and a lack of public awareness [8,9].

To address these challenges, the World Health Organization recommends the use of digital technologies to promote TB medication adherence [10]. Video directly observed therapy (VDOT) was introduced to replace physical DOTS and has proven to significantly reduce the cost of managing TB, improve patients' access to doctors, and be less disruptive to patients' work and family life [8,11-13]. According to many studies, VDOT is a more cost-effective method that significantly increases patient treatment adherence compared to conventional DOTS [14-18].

Although data on VDOT are becoming increasingly robust, the system has yet to be rigorously evaluated within low- and middle-income countries, especially regarding its feasibility [19]. This is quite worrying, as the implementation of VDOT requires complete access to hardware and internet connectivity, which some countries cannot afford [10]. However, in Malaysia, the number of smartphone users is growing and expected to reach over 33 million by 2024, with an 87.36% smartphone penetration, which suggests that VDOT can be implemented in Malaysia [20].

Making VDOT available via mobile apps could make drug monitoring more convenient and effective [21]. However, with the large numbers of mobile health apps in existence, the problem is often about the sustainability of their use [22]. As a solution, integrating gamification elements inside mobile apps can positively impact health and well-being, improve health behaviors and patient engagement, decrease health care use, and empower patients to self-manage their disease [23,24]. In addition, the use of real-time elements such as virtual reality and augmented reality has proven to increase learning effectiveness and behavior modification, correct medication identification, correct self-administration of medication, and support patient counseling practices [25-27].

Thus, in our Gamified Real-time Video Observed Therapy (GRVOTS) mobile app, the integration of gamification and real-time elements is expected to increase patient motivation. The purpose of this study was to validate the gamification, motivation, and real-time element in GRVOTS, a mobile app for VDOT, from the perspective of the service provider (expert review).

Methods

The mobile app prototype was developed from February 2021 to May 2022. The developmental process as a whole, including content and prototype development as well as content validation (nominal group technique [NGT]), was performed using the design science research process model [28].

Development

Content development of the prototype involved a few stages of literature review, mapping, and justification of the new framework. From the literature review, we identified 3 frameworks that could be used as features of app: gamification framework, video reality and motivation framework, and technology feature framework. The gamification component, as the foundation of the proposed gamified mobile app GRVOTS, will be based on the validated framework for the gamification of diabetes self-management called The Wheel of Sukr [29]. The framework consists of 8 components: fun, esteem, growth, motivation, sustainability, socializing, self-representation, and self-management. For the video reality and motivation framework, we used the attention, relevance, confidence, and satisfaction (ARCS) model of motivational design [30]. In terms of the mapping procedure, the ARCS model of motivational design can be combined with the gamification elements to foster motivation [31]. The dynamic nature of gamification, such as self-management, self-representation, and fun, can be equal to satisfaction in the ARCS model. Further, elements of gamification, such as esteem, reward, growth, and socializing, can be equal to the components of confidence in the same model. Subsequently, these 2 frameworks can be integrated where gamification elements are added to the categories of confidence and satisfaction that are based on the ARCS model. Table 1 shows the categories and subcategories of the proposed model in matrix form.

Game dynamics can improve user desire and motivation by establishing rules that encourage users to explore and learn about the apps [32]. Figure 1 shows a screenshot of the main function of the GRVOTS mobile app and its relation to our intended gamification, motivation, and real-time elements from the framework.

The GRVOTS mobile app is designed for 3 users—patients, supervisors, and administrators—where they interact with one another via the internet. All data inputted by the patients will be automatically collected by the server and viewed by the specific supervisor (health care worker) and TB management team to help them with clinical interventions. The proposed model presented in Figure 2 is based on the development of mobile apps for smartphones only.

Table 1. Matrix of the ARCS[a] model of motivational design and The Wheel of Sukr gamification model.

Model technique	Category			
	Attention	Relevance	Confidence	Satisfaction
ARCS (motivation)	• Active participation	• Link previous experience (motive matching) • Perceive with future usefulness (motive matching)	• Self-growth • Learning requirement • Success • Opportunities • Personal responsibilities	• Reward • Immediate application
The Wheel of Sukr (gamification)	—[b]	—	• Esteem • Reward • Growth • Socializing • Sustainability	• Self-management • Self-representative • Fun

[a]ARCS: attention, relevance, confidence, and satisfaction.

[b]Not applicable.

Figure 1. The screenshot from the apps and justification of the related element. GRVOTS: Gamified Real-time Video Observed Therapies; VDOT: video directly observed therapy.

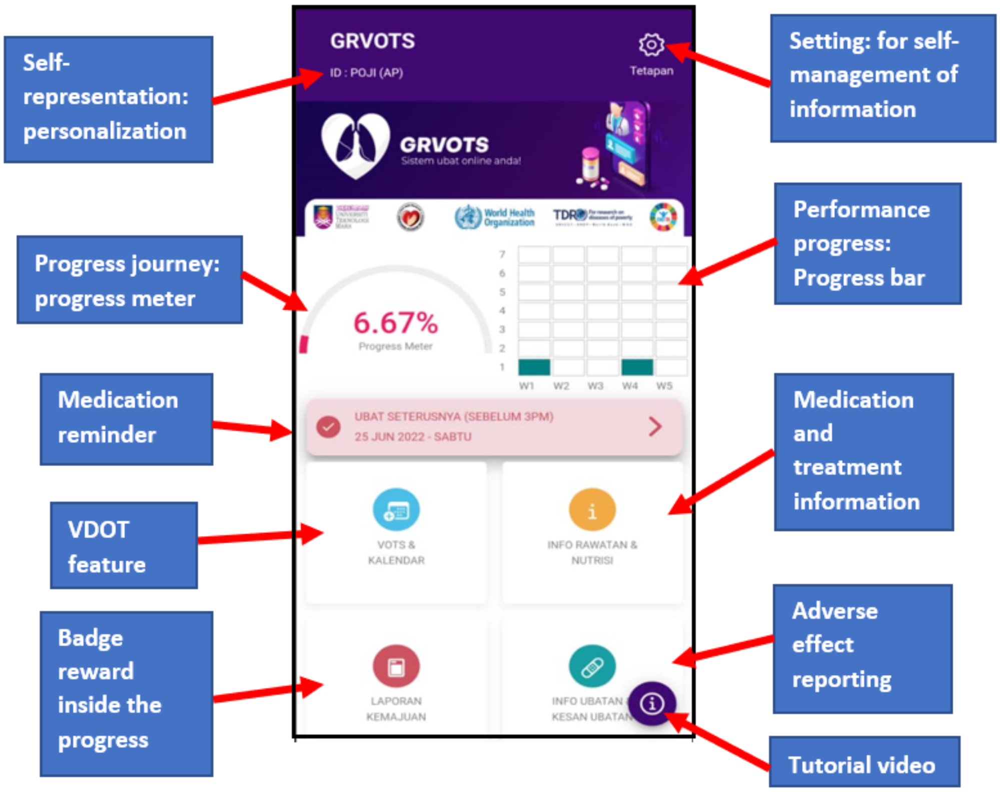
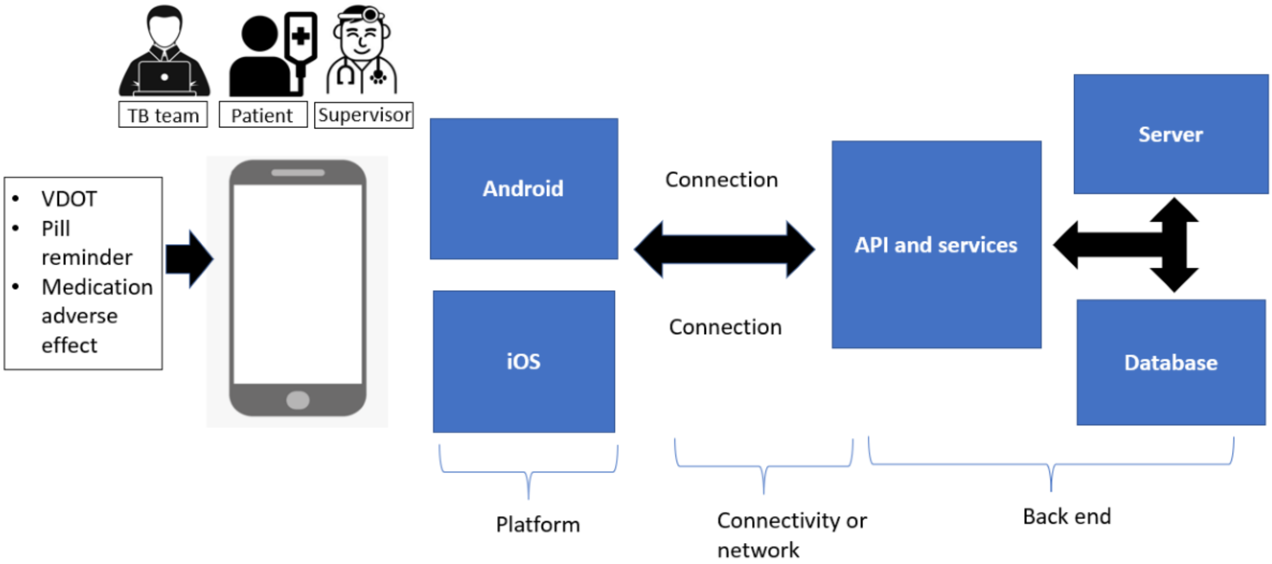


Figure 2. Systematic architecture of GRVOTS. Data from patients were collected through the apps and process with predesigned rules. API: application programming interface; GRVOTS: Gamified Real-time Video Observed Therapies; iOS: iPhone Operating System; TB: tuberculosis; VDOT: video directly observed therapy.



Content Validation via the NGT (Expert Review)

The NGT is a structured variation of a small-group discussion to reach consensus. Through the agreement of the description of the elements, the NGT was used in this research as a validation tool to evaluate the presence of the gamification and motivation components intended to be used in the app.

Sample Size

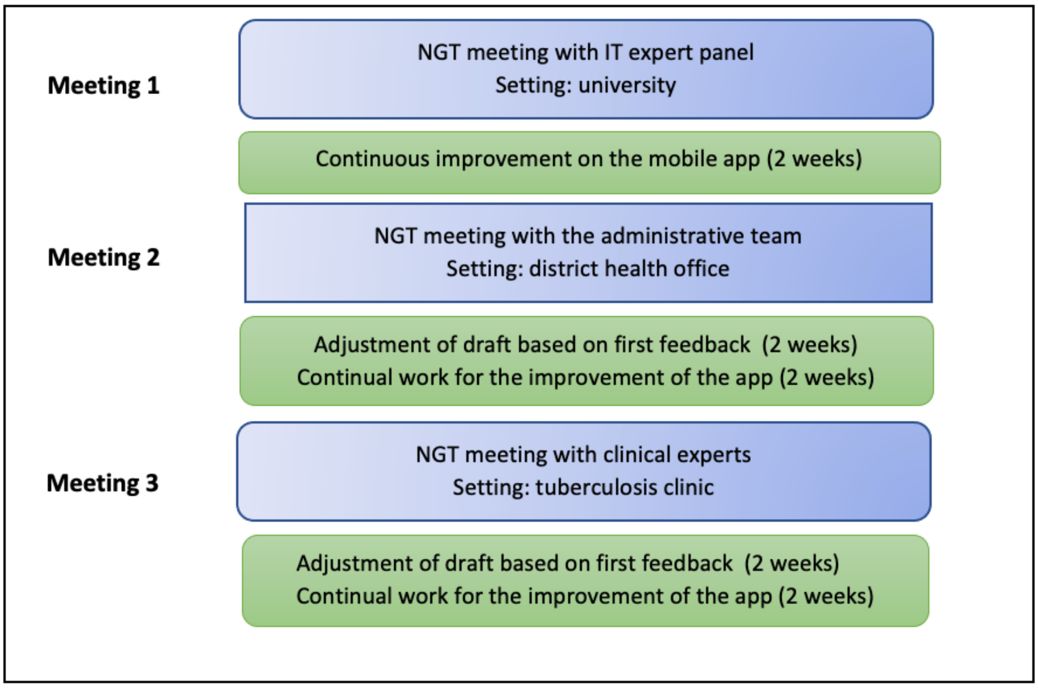
The NGT is a small-group technique suited to panel sizes of more than 10 people [33,34]. Therefore, there were 11 experts involved in this NGT session. A panel of experts was involved to validate the gamification elements in the GRVOTS app using physical meetings in 3 different settings.

Study Population Flow

This study was conducted iteratively in 3 meetings for a more comprehensive evaluation, as illustrated in Figure 3.

The criteria of the experts involved in the group were different according to each group. For the first group, IT experts were experienced and involved in mobile app development for at least 2 years and well versed in the gamification features of mobile apps. The second and third groups were composed of administrative and health care workers who were directly involved in managing patients with TB in the outpatient environment, respectively.

Figure 3. Flow of the modified nominal group technique (NGT) meetings.



Study Settings

The 3 NGT meetings were performed in 3 settings: at the university for the meeting with the IT expert panel, at the district health office for the meeting session with the administrative team, and at the TB clinic for the meeting with clinical experts.

Instrument for NGT

The instrument used in the NGT was a questionnaire, and the items were generated from a literature review based on 3 existing models as per the previous mapping. These models were developed into a panel expert checklist, and the questionnaire had 2 parts: Part A asked about the gamification-motivation–rea-time theory, The Wheel of Sukr [35], and the ARCS model, whereas Part B concerned the technology features by Anderson et al [36].

Implementation of NGT

The implementation of NGT involved experts who were selected according to the scope of the study. The workshop was conducted in a face-to-face meeting by a moderator [34]. The NGT workshop lasted approximately 2 hours. Before the workshop, the experts were given a week to use the app. Some of them experienced the task as a supervisor and some as a patient. They were required to send 3-4 VDOT videos. Table 2 shows the basic steps to carry out the NGT process, and Table 3 shows the 5 steps of data analysis for the NGT.

The data analysis process for the NGT was based on the percentage of agreement where an element is accepted when the percentage of agreement is 70% or more [37]. The 1-sample, 2-tailed *t* test was used to determine whether the mean (SD) percentage of agreement result on the gamification and motivation elements in this app was significantly higher than the percentage of agreement of 70%, with a level of significance (α error) less than .05. The software used at this stage was SPSS (version 28.0; IBM Corp) and Microsoft Excel.

Table 2. Steps of the specific guide to implement the nominal group technique session.

Step	Details
1. Introduction to problem statement and explanation	Moderator will brief the participants regarding the flow of the session.
2. Silent generation of ideas in writing	According to the checklist and GRVOTS[a] mobile app, participants were asked to answer the questionnaire using a Likert scale.
3. Round robin phase: sharing ideas	Participants were invited to share their answers in the round robin manner.
4. Discussion of ideas	Participants were asked to justify the need for the least prominent gamification and virtual reality elements in the GRVOTS mobile app prototype.
5. Voting and ranking	The voting was done by marking responses on a Likert scale from 1 (totally disagree) to 5 (totally agree). The calculation was done, and the elements were ranked accordingly.

[a]GRVOTS: Gamified Real-time Video Observed Therapies.

Table 3. The steps of data analysis for the nominal group technique (NGT) steps.

Step	Activity
1	Ensuring the number of participants (experts) involved in the study
2	The formation and calculation of score value is based on the template data analysis of the NGT
3	Convert score values into percentage form to obtain the percentage of agreement:
	where A=the total number of experts and B=Likert scale used, ie, 5 points
4	Determine the acceptance of components and elements based on the percentage of agreement
5	Determine the positions of the elements according to the percentage of agreement

Ethics Approval

Ethical approval was obtained from the Universiti Teknologi MARA Ethical Board and Medical Research and Ethics Committee, Malaysia: NMRR-21-1016-58994 (IIR).

No informed consent was taken in this study as the data were only retrieved retrospectively from the database and no identifiers were collected for this study.

Results

Mobile app development with the integration of gamification and real-time elements was performed via a literature review, and the content validation of the component was performed via the modified NGT.

Prototype

The final beta version of the mobile app used Android as the platform. The prototype was designed to be used by 3 users—patients, supervisors, and TB managers—and each user had a different role in the program. This mobile app's main function is to provide patients with a way to record daily DOTS intake via video (VDOT) as well as medication side effect reporting. After patients log in, they are directed to set up their personal profiles and learn how to use the VDOT medication reminder, which is the main activity. After each VDOT session is uploaded, it is followed by pop-up motivational quotes as well as the movement of the progress meter indicator.

The accumulated points collected from the progress meter will be translated into badges in the progress report theme. Subsequently, a daily pop-up message will also be the main reminder for the next medication, and patient will be asked if they noticed any adverse reactions to previous medication, with a selection of options concerning their symptoms. The ability to report adverse effects gives patients access to their own medication diaries, which can be reviewed during medical visits. Throughout the TB treatment journey, the progress report theme will help patients track their journey and redeem the internal and external rewards offered.

Every VDOT report and any side effects noted by patients will be verified by the supervisor as a feedback interaction. This feature enables supervisors to regularly check and understand the patients' progress as well. In addition, patients can always go to other main theme of "knowledge" to continuously learn more about TB treatment and nutrition.

The app provides different users with access to different functions and main menus. In the patients' main menu, there are 4 main themes for VDOT. Information regarding the app, progress report, and side effect reporting is shown in Figure 4. For the supervisors' main menu, there are 2 menus, one to validate the VDOT report and another to validate the side effects, as shown in Figure 5.

Figure 4. Screenshots of the GRVOTS app for patients. GRVOTS: Gamified Real-time Video-Observed Therapies.

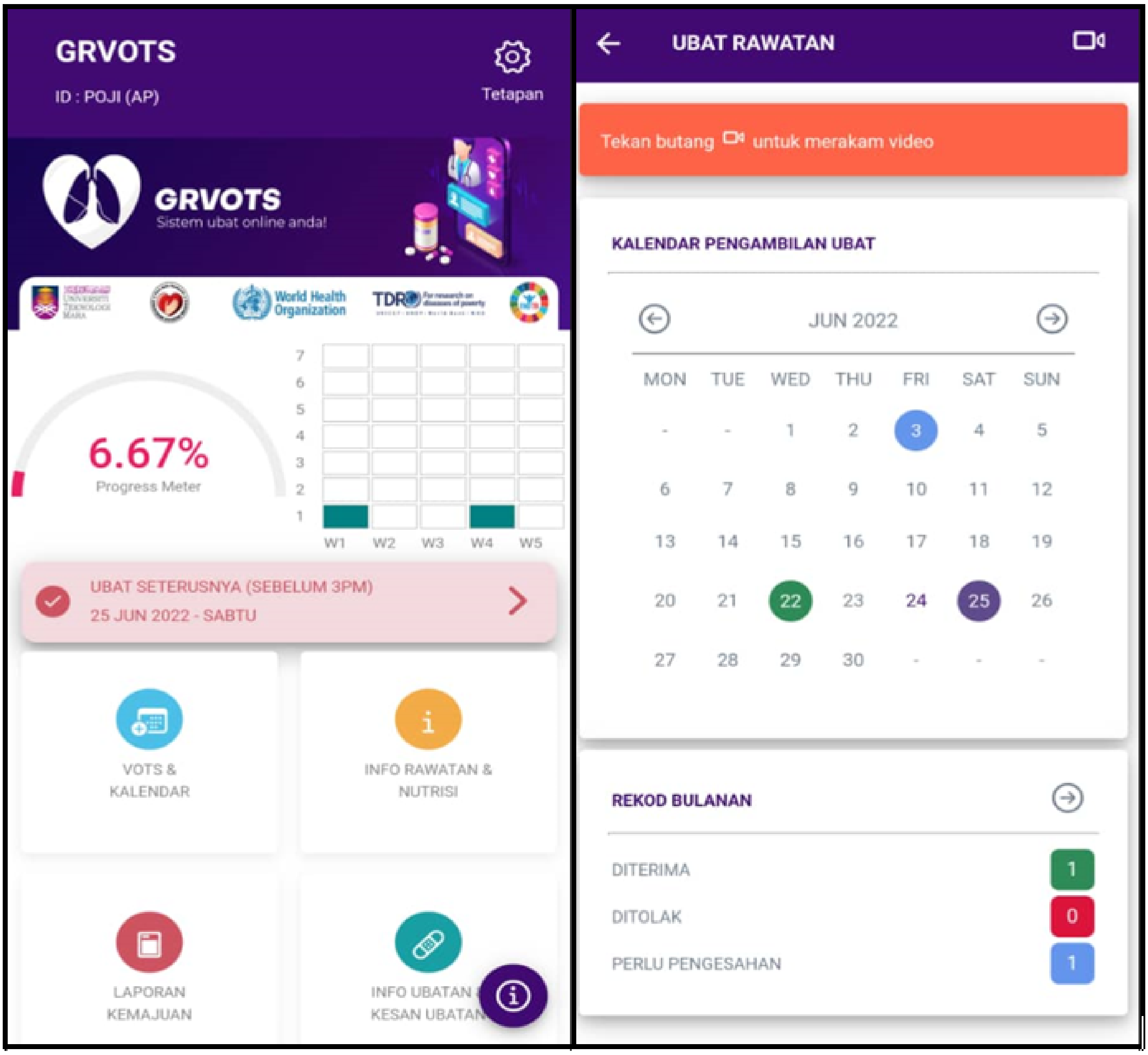
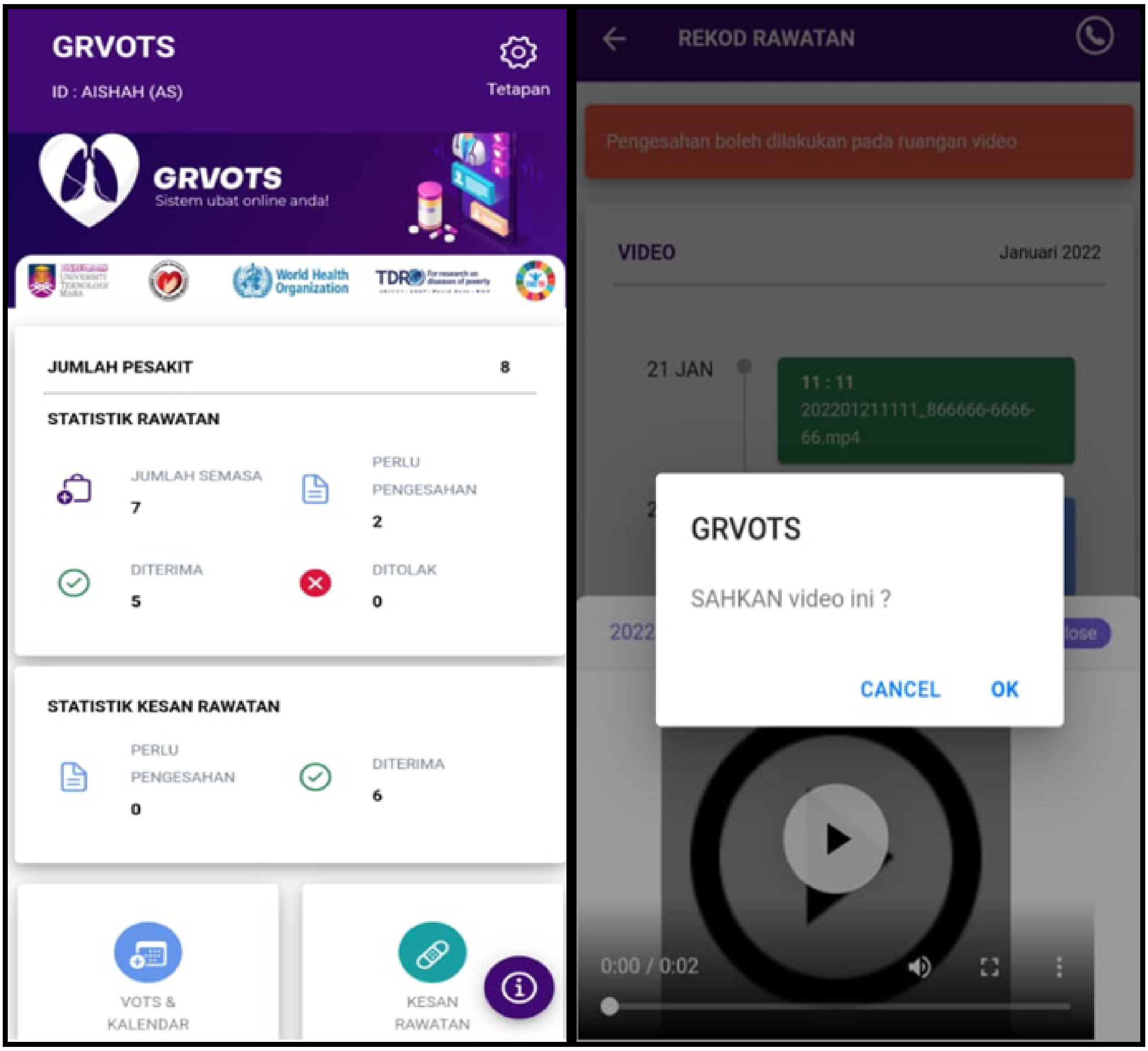


Figure 5. Screenshots of the GRVOTS app for supervisors to monitor patients. GRVOTS: Gamified Real-time Video-Observed Therapies.



NGT Output for Content Validation

A panel of 11 experts were involved in the modified NGT, including 2 gamification experts, 2 public health experts, 1 chest physician, 2 medical officers, 3 medical assistants, and 1 staff nurse. They were asked to rank the app's elements based on the expert panel checklist. Tables 4-6 show the results and rankings of gamification, motivation, and technology feature elements via the NGT.

The total percentage of agreement among experts was 97.95% (SD 2.51%), which was significantly higher than the minimum of 70%, with a difference of 27.947% (95% CI 26.74%-29.15%; *P*<.001). The *t* test confirmed the validity of all gamification and motivation components in the app.

Table 4. Results of the nominal group technique for gamification elements.

No	Main element	Explanation element	Percentage of agreement, mean (SD)	Acceptance result	Ranking
1	Self-management	• This app has a dashboard with a progress meter, medication reminders, and a VDOT[a] feature to help patients self-manage their medication. • This app has adverse effect reporting to help patients self-manage their reactions to medications.	98 (2.22)	Accepted	4
2	Self-representative (avatar)	• This app has a personalized name on the dashboard along with the roles of the user.	97 (0.00)	Accepted	6
3	Fun	• This app has a progress meter, a progress bar, motivational quotes, and badge rewards that add a fun element for the patient.	96 (0.8)	Accepted	8
4	Esteem	• This app has a progress meter, a progress bar, motivational quotes, and a feedback mechanism aimed at boosting patients' self-esteem.	99 (1.386)	Accepted	3
5	Growth	• This app has a feedback mechanism that helps patients with self-growth. • This app empowers patients' self-growth with medication information.	100 (0.00)	Accepted	1
6	Sustainability (trigger)	• This app has medication reminders aimed at the sustainability of its use.	97 (0.00)	Accepted	7
7	Motivation	• This app has a progress meter, a progress bar, and badge rewards that boosts patient motivation.	98 (2.358)	Accepted	5
8	Socializing	• This app has a feedback mechanism that enables patient-supervisor communication.	100 (0.00)	Accepted	2

[a]VDOT: video directly observed therapy.

Table 5. Results of the nominal group technique for motivation elements.

No	Main element	Explanation element	Percentage of agreement, mean (SD)	Acceptance result	Ranking
1	Attention	• This app has medication reminders, a VDOT[a] feature, and adverse effect reporting to hold patients' attention and achieve active participation. • This app has a progress meter that alerts patients regarding the status of their performance. • This app has a performance indicator (progress bar) that alerts patients about medication compliance over time.	99 (1.869)	Accepted	3
2	Relevance	• This app has a VDOT feature that links patients' current remote and previous in-person experience of taking medication.	98 (0.00)	Accepted	4
3	Confidence	• This app has motivational quotes to boost patient confidence.	100 (0.00)	Accepted	1
4	Satisfaction (achievement)	• This app has a VDOT feature, adverse effect reporting, a progress meter, a progress bar, motivational quotes, and badge rewards that help patients feel satisfied with their daily medication compliance.	99 (1.361)	Accepted	2

[a]VDOT: video directly observed therapy.

Table 6. Results of the nominal group technique for technology feature elements.

No	Main elements	Explanation element	Percentage of agreement, mean (SD)	Acceptance result	Ranking
1	Automation	• This app has automated medication reminders, pop-up notifications, and reminders to both the patient and supervisor that made it easy to use.	97 (0.635)	Accepted	5
2	Ease of use (automation)	• This app has automated pop-up notifications to remind the supervisor to approve the adverse effect reports.	100 (0.00)	Accepted	1
3	Real-time feature	• This app has a real-time stamped VDOT[a] feature.	89 (0.00)	Accepted	7
4	Self-guided video	• This app has a self-guided VDOT tutorial video that can benefit the patient. • This app has self-guided adverse effect symptom choices that can help patients identify symptoms. • This app has a self-guided feature to provide the patient with knowledge regarding nutrition and medication. • This app has a good tutorial on how to use the app.	99 (1.361)	Accepted	3
5	Aesthetic	• This app has good aesthetic features.	97 (0.00)	Accepted	6
6	Navigation	• This app has a good flow of navigation from one page to another.	100 (0.00)	Accepted	2
7	Tactile feedback	• This app has good tactile or haptic feedback.	98 (0.00)	Accepted	4

[a]VDOT: video directly observed therapy.

Discussion

This comprehensive GRVOTS mobile app was developed based on the integration of gamification and real-time motivational elements of autonomy, competence, relatedness, attention, relevance, self-control, confidence, and satisfaction. These components were successfully validated and significant.

Mobile App Developed

Our GRVOTS mobile app was able to motivate patients toward medication adherence using the ARCS model of motivation, which was translated via its gamification and motivation features. First, the interactive VDOT feature can stimulate the patient's feelings of attention and arousal. Second, by linking the previous experience of medication intake physically with the experience of using GRVOTS, the element of "relevance" can also be instilled in the patient. When patients perceive a high sense of relatedness, they are more likely to exhibit higher engagement with a program [38]. By providing goals along the journey toward medication adherence, the app can instill confidence and self-belief, especially when the patients can digitally see their previous VDOT report and a progress meter of treatment success. As they use GRVOTS to monitor their medication intake, patients experience more freedom of choice and self-control, and the results of treatment adherence will subsequently reinforce the app's value. The last element of "satisfaction" can also be realized when patients comply with the use of GRVOTS and receive rewards in the form of badges and progress meters.

Content Validation via the Modified NGT

The results of the modified NGT showed that all the components obtained from the literature and related model were validated by the experts during the NGT session, as shown in Tables 4-6. Based on the results, the elements were prioritized based on the percentage of acceptance. Considering these rankings, some of the GRVOTS functions were improved to provide a better mobile app for the next pilot study.

According to the results for the gamification elements, the growth element received the highest scores, whereas fun received the lowest scores. By definition, "fun" aspects within the gamification elements in this GRVOTS app are exemplified by a progress bar, a progress meter, inspiration quotes, and badge rewards. The fun element was voted as a less visible element in this app, perhaps due to many factors, such as the perception of fun, which varies for different people, as well as the nature of serious games, which does not prioritize the fun element. A number of studies have described that the perception of gamification features differs according to the gamer type, gender, and personality of the player. For instance, extroverts like rewards and leaderboards, which appear to be more entertaining, but introverts prefer badges and feedback [39-41].

Health apps are also considered serious games that are played for purposes other than pure entertainment [42]. In this case, having a fun component is not a priority. According to a study regarding serious games, other elements, such as explicit learning tasks, instruction, and support built into the game or added by teachers, may be more important than having fun while playing [43].

For the motivation elements of the ARCS model, the highest ranked element was confidence and the lowest was relevance. It is suggested that when patients perceive a high sense of relatedness, they are more likely to exhibit higher engagement with the program [38]. In mobile apps, relatedness is seen as a feature of leaderboards or chats that encourages engagement and collaboration to achieve a particular objective [41]. However, in this GRVOTS mobile app, the relevance element is evidenced by allowing daily communication between patients and supervisors via the VDOT and adverse event reporting components without the leaderboard or chat features. This is because most of our patients with TB refused to disclose their condition and communicate with other patients due to the stigma associated with the disease.

For the technology feature elements, the highest ranked was ease of use and the lowest was real-time features. There are 2 type of VDOT: live VDOT, also known as synchronous VDOT, in which patients and providers interact in real time [12,44]; as well as asynchronous technologies that record, upload, and digitally store videos for future review [11,19,45]. Synchronous VDOT has the advantage of human interaction but is not a feasible option, as patients and workers need to find time to meet. Asynchronous VDOT is more flexible but can be manipulated easily by sending the same recorded video. Thus, apps with real-time features ensure the originality of the video and simultaneously generate a greater degree of user engagement [25-27]. Although the real-time feature in our app provides details concerning the time and date of the video, feedback from the experts indicated that we should time stamp the videos so that they can be identified more easily later. Since users found it challenging to determine if their VDOT session was successfully uploaded or not, the addition of an upload bar was also recommended.

Strengths and Limitations

The GRVOTS mobile app can benefit users in many ways. For patients with TB, the app can help patients gain self-control, boost their self-esteem, and motivate them to take their medications. For health care workers, this app made it easier for TB system management to detect DOTS defaulters and manage them accordingly. As a portable device, mobile apps enable monitoring that can be done anywhere, saving money and time and boosting patient engagement with the DOTS program. In summary, this app can also initiate a patient self-care system and reduce dependency on health care providers such as doctors and nurses. The limitation of this study is that the mobile app prototype is only being developed for the Android platform because of time and logistics. The app does not have a virtual reality feature, and improvements are needed in the future. This study conducted the validation of the gamification and motivation elements only from the perspective of the experts and not from the perspective of patients, which may limit the review's validity; an analysis regarding its usability among patients will be conducted in the future.

Recommendation

In the future, GRVOTS should also be available on other platforms, especially the iPhone Operating System. The language options should also include English, Chinese, and Tamil, as these languages are frequently used in multiethnic communities in Malaysia. The use of various languages will expand the benefits to more users. This will enhance knowledge transfer and improve users' understanding. Next, a usability study to access the user experience will be conducted, followed by an effectiveness study via a single-arm intervention study, in which patients will use the app for DOTS during intensive phase up to 2 months monitoring, followed by an assessment at 3 time intervals to evaluate their medication adherence, motivation, and the usability of the app.

Conclusion

More comprehensive and efficient TB system management via VDOT mobile app monitoring is a way to improve patient treatment adherence. According to the literature review, gamification elements can motivate patients; thus, by integrating the uniqueness of gamification and motivation elements in an app, gamification will increase patient motivation, ensure the sustainability of use, and ultimately increase patient adherence. In addition, our GRVOTS mobile app connects up to 3 users (eg, patients, supervisors, and administrators) remotely and enable DOTS monitoring to be performed from anywhere. Based on the study findings, the GRVOTS mobile app has been validated by the expert panel as having the intended elements of gamification, real time, and motivation. Next, a usability study of the GRVOTS mobile app will be conducted to measure the user experience among patients, followed by a single-arm intervention study to assess the app's effectiveness in increasing patient motivation and medication adherence in TB treatment.

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Data Availability

All data supporting the study findings are within the manuscript. Additional details information and raw data are available from the corresponding author on reasonable request.

Authors' Contributions

SAA and NI conceived the project. SAA contributed to data collection. SAA, NI, and YZ contributed to data analysis. SAA, II, and NHMZ contributed to mapping the apps architecture. NI supervised the study. The manuscript was written mainly by SAA with the approval of all authors. All authors read and approved the final version of manuscript for publication.

Conflicts of Interest

None declared.

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Abbreviations

ARCS: attention, relevance, confidence, and satisfaction
DOTS: directly observed therapy, short-course
GRVOTS: Gamified Real-time Video Observed Therapies
NGT: nominal group technique
TB: tuberculosis
VDOT: video directly observed therapy

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Original Paper

Evaluating the Utility of a Psychoeducational Serious Game (SPARX) in Protecting Inuit Youth From Depression: Pilot Randomized Controlled Trial

Yvonne Bohr[1,2], PhD; Leah Litwin[1,2], PhD; Jeffrey Ryan Hankey[1,2], PhD; Hugh McCague[3], PhD; Chelsea Singoorie[4]; Mathijs F G Lucassen[5,6], PhD; Matthew Shepherd[6], DClinPsy; Jenna Barnhardt[1], BSc

[1]LaMarsh Centre for Child and Youth Research, York University, Toronto, ON, Canada

[2]Department of Psychology, Faculty of Health, York University, Toronto, ON, Canada

[3]Institute for Social Research, York University, Toronto, ON, Canada

[4]Nunabox, Iqaluit, NU, Canada

[5]Faculty of Wellbeing, Education and Language Studies, The Open University, Milton Keynes, United Kingdom

[6]School of Psychology, Massey University, Auckland, New Zealand

Corresponding Author:
Jeffrey Ryan Hankey, PhD
LaMarsh Centre for Child and Youth Research
York University
4700 Keele Street
Toronto, ON, M3J1P3
Canada
Phone: 1 6475616464
Email: jrhankey@yorku.ca

Abstract

Background: Inuit youth in Northern Canada show considerable resilience in the face of extreme adversities. However, they also experience significant mental health needs and some of the highest adolescent suicide rates in the world. Disproportionate rates of truancy, depression, and suicide among Inuit adolescents have captured the attention of all levels of government and the country. Inuit communities have expressed an urgent imperative to create, or adapt, and then evaluate prevention and intervention tools for mental health. These tools should build upon existing strengths, be culturally appropriate for Inuit communities, and be accessible and sustainable in Northern contexts, where mental health resources are often scarce.

Objective: This pilot study assesses the utility, for Inuit youth in Canada, of a psychoeducational e-intervention designed to teach cognitive behavioral therapy strategies and techniques. This serious game, SPARX, had previously demonstrated effectiveness in addressing depression with Māori youth in New Zealand.

Methods: The Nunavut Territorial Department of Health sponsored this study, and a team of Nunavut-based community mental health staff facilitated youth's participation in an entirely remotely administered pilot trial using a modified randomized control approach with 24 youths aged 13-18 across 11 communities in Nunavut. These youth had been identified by the community facilitators as exhibiting low mood, negative affect, depressive presentations, or significant levels of stress. Entire communities, instead of individual youth, were randomly assigned to an intervention group or a waitlist control group.

Results: Mixed models (multilevel regression) revealed that participating youth felt less hopeless (*P*=.02) and engaged in less self-blame (*P*=.03), rumination (*P*=.04), and catastrophizing (*P*=.03) following the SPARX intervention. However, participants did not show a decrease in depressive symptoms or an increase in formal resilience indicators.

Conclusions: Preliminary results suggest that SPARX may be a good first step for supporting Inuit youth with skill development to regulate their emotions, challenge maladaptive thoughts, and provide behavioral management techniques such as deep breathing. However, it will be imperative to work with youth and communities to design, develop, and test an Inuit version of the SPARX program, tailored to fit the interests of Inuit youth and Elders in Canada and to increase engagement and effectiveness of the program.

Trial Registration: ClinicalTrials.gov NCT05702086; https://www.clinicaltrials.gov/ct2/show/NCT05702086

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KEYWORDS

psychoeducation; cognitive behavioral therapy; Inuit youth; Nunavut; depression; suicide; resilience; serious game; youth; mental health; teen; adolescent; pilot study; community

Introduction

Inuit are Indigenous Peoples of the Arctic and subarctic regions of Greenland, Alaska, and Canada. In Canada, they are recognized as a distinctive group of Indigenous Canadians—alongside First Nations and Métis—primarily occupying Labrador, Northern Quebec, the Northwest Territories, and Nunavut. Pervasive youth suicide is the most urgent challenge facing Inuit in Canada today, a public health emergency of epidemic proportions [1,2]. Death by suicide in Inuit communities has spiked over the last century [3,4], currently at 9 times the national average and with male youth aged 15-24 being the most affected [5]. Under the fallout of colonialism, Inuit youth in Canada face more mental health challenges than non-Indigenous populations, due to cross-generational impacts of residential schools and multiple continuing systemic inequities [6,7]. The government era of the 1950-60s and beyond, during which the Canadian government forced Inuit into aggregated settlements, imposed a welfare state, and separated Inuit children from their families, has had lasting effects on relationships within family and community, strained kinship across generations and between genders, and left generational gaps in mental health–supporting communications between youth and their parents and Elders [3]. Further, Indigenous youth in general tend to be among those most reluctant to seek help when experiencing distress [8]. This lack of help-seeking may be due in part to a struggle to recognize symptoms of depression, which may present as anger in Inuit youth [4,9].

Those living in remote Northern communities often go without access to the mental health supports available elsewhere in Canada [10] for a number of reasons. First, few health care professionals train or practice in the Canadian North, and frontline workers often experience "burnout" due to excessive workload and personnel shortages [11]. As a result, youth in Nunavut have limited access to specialized services and are often sent out of their communities when they experience severe mental health symptoms [10,12-14]. Finally, adolescents in small, remote communities are especially prone to avoiding professional health services, as they may fear compromised confidentiality due to a lack of privacy and the stigma associated with mental illness. One study found that of all youth who committed suicide in Nunavut in the past decade, only 12% had received medication and 17% had been hospitalized in relation to their mental health, while 89% had not received any mental health support at all [14,15]. Given the reality that there are relatively few frontline mental health workers available in Nunavut communities and stigma impeding access to existing services, it is imperative to identify and develop preventive interventions for depression that are not only effective and culturally appropriate, but also easily accessible [11].

To address the dearth of available in-person mental health support options, this study aims to examine the usefulness of an e-intervention, SPARX [16,17], in Nunavut. SPARX (Smart, Positive, Active, Realistic, X-Factor thoughts) is a psychoeducational *serious game* (an e-intervention that utilizes gaming for serious purposes) [18] that teaches established cognitive behavioral therapy (CBT) strategies and techniques across 7 levels or modules (see Figure 1 for an example). The game is designed to address depressive symptoms in youth by helping them cope with negative thoughts and feelings, represented in the game as GNATs—gloomy negative automatic thoughts (Figure 2) [16]. SPARX was originally designed and developed at the University of Auckland with the specific needs of certain underserved groups of youth in mind, including Māori Rangatahi, the Indigenous young people of Aotearoa, New Zealand. SPARX's development included a Māori co-creator (MS), input from Māori CBT experts, and cultural guidance from a *kaumatua* (ie, respected Elder). Moreover, the game development company was led by a Māori woman and the voice actor (virtual therapist/instructor) was a Māori; additionally, the Māori symbolism, presented in a fantasy format, was woven throughout the intervention [17]. With these very specific cultural foundations in mind, the goal of this pilot study was to evaluate the effectiveness of the original version of SPARX in boosting resilience against depression among Inuit youth in Canada in 11 Nunavut communities. We aimed to assess whether Inuit youth who completed the SPARX program experienced increased resilience and showed a decrease in risk factors related to depression, specifically cognitive distortion, emotional dysregulation, hopelessness, rumination, self-blame, other-blame, and catastrophizing [19].

The Nunavut Territorial Department of Health sponsored this study, and a team of Nunavut-based community mental health staff facilitated youth's participation in an entirely remotely administered pilot trial. A total of 48 youths from 11 Nunavut communities completed an evaluation of the utility of SPARX in modifying dysfunctional cognitions, reducing symptoms of depression, and enhancing resilience. All youth completed conventional pre- and postintervention measures assessing their current mental health status. Measures were selected based on their use in earlier effectiveness studies [16,17]. Quantitative and qualitative data were collected and used to evaluate the program's preliminary effectiveness based on the following hypotheses:

- Youth who completed the SPARX program were expected to experience a decrease in depressive symptoms as well as risk factors related to depression, as measured by the Centre for Epidemiologic Depression Scale-Revised (CESD-R), the Hopelessness Scale for Children (HSC), and the Cognitive Emotion Regulation Questionnaire-Short (CERQ-Short; see the "Measures" section).

- Youth who completed the SPARX program were expected to experience an increase in factors related to resilience, as measured by the shortened, 12-item version of the Child and Youth Resilience Measure (CYRM-12).

Figure 1. Screenshot of a SPARX CBT module. Used with permission of the copyright owner © Auckland UniServices Limited.

Figure 2. Screenshot of approaching GNATs. Used with permission of the copyright owner © Auckland UniServices Limited.

Methods

Participants

All 25 Nunavut communities were initially recruited to participate in this study; 11 communities (Baker Lake, Cambridge Bay, Grise Fiord, Hall Beach, Igloolik, Kugaaruk, Kugluktuk, Naujaat [Repulse Bay], Taloyoak, Qikiqtarjuaq, and Resolute) completed the pilot trial. The remaining 14 communities did not complete data collection because of an inability to recruit youth, because there was no local adult facilitator able to support youth, or because facilitators had to leave the project due to extraneous circumstances. Communities were chosen based on feasibility and required both an interested community facilitator with the time to commit to SPARX and youth who were interested in the project. As many as 3-4 youths were recruited in each community with a projected participant count of 40.

Youth participants were between the ages of 13 and 18 and had been identified by the community facilitators as exhibiting low mood, negative affect, depressive presentations, or significant levels of stress. Youth had to demonstrate sufficient English language comprehension to use and understand SPARX.

Although such an approach is not reflective of Indigenized research generally, these inclusion criteria were suggested by local facilitators due to the heavy use of the English language within the SPARX game. Initially, youth were excluded if they showed limited cognitive abilities, psychotic presentation, severe depression, or elevated suicide risk, or if they were currently receiving or had previously received CBT, interpersonal therapy, or antidepressant medication within the past 3 months. However, due to safety and ethics concerns about vulnerable youth feeling left out, at the discretion of local mental health experts on the team, these exclusion criteria were relaxed. The 25 facilitators were appointed by staff at the Department of Mental Health, Government of Nunavut. In total, 24 of 48 youths who initially signed up completed the study (see the "Design" section for attrition rates at each time point).

Procedure

A preproject planning meeting was held in Toronto with managers of the Territorial Department of Health, a team of community mental health staff from Nunavut, and potential on-site facilitators on March 27, 2014. Procedural aspects of the SPARX pilot project were based on contributions and feedback from attendees of this meeting. The meeting focused on the importance of the SPARX project in Nunavut communities, how the SPARX project could achieve cultural appropriateness, and what traditional and cultural knowledges must be incorporated to gain youth trust and participation. In a collaboration among Nunavut Department of Mental Health staff, community stakeholders, and the coordinating team at York University, the design described in this work was adopted at the planning meeting.

Ethics Approval

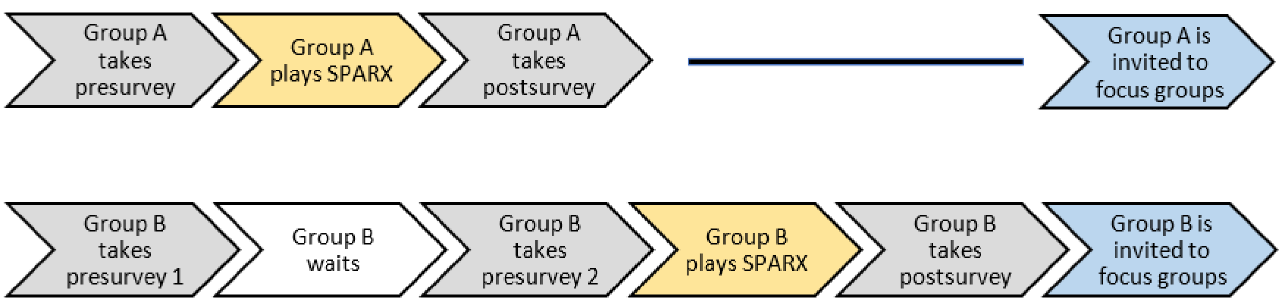
Approval for the SPARX pilot was obtained through the Human Participants Sub-Committee of the York University Office of Research Ethics (York University HPRC Certificate No. 2015-070). Approval was also obtained from the university's Advisory Group for Research Involving Indigenous Peoples. This subcommittee is guided by Chapter 9 of the Tri-Council Policy Statement "Research involving the First Nations, Inuit, and Métis Peoples of Canada," and its own Guidelines for Research Involving Indigenous Peoples. In addition, the research team received approval in the form of a research license from the Nunavut Research Institute, which represents all 25 Nunavut communities (license number 02 004 15N-M).

Design

A modified randomized control approach was adopted for this trial. Community facilitators, responsible for recruiting youth and facilitating gameplay, were trained prior to youth recruitment and played SPARX to familiarize themselves with the game. Once training was complete, community facilitators recruited youth, secured consent, and administered preintervention measures. Entire communities, instead of individual youth, were randomly assigned to an intervention group (group A) or a waitlist control group (group B), which is why a modification was made to the randomized control trial, as described in the following section.

The sequence of SPARX play differed for the youth depending on whether they were in group A or group B (Figure 3). Both groups completed the preintervention surveys at time 1, the beginning of the study. Group A youth then began to play SPARX for 7 weeks while group B waited. During their wait time of 7 weeks, group B youth were not required to participate in any SPARX activities or meet with the community facilitator, and they were provided with no additional SPARX-related information. After 7 weeks (time 2), group A youth completed postintervention surveys, while group B youth began their engagement with SPARX by first completing an additional set of preintervention surveys, immediately followed by 7 weeks of SPARX play. Once group B youth completed their SPARX gameplay (time 3), they next completed postintervention surveys. Attrition rates were 35% (7/20) for group A (the intervention group) at time 2, 32% (9/28) for group B (the waitlist control group) at time 2, and a further 47% (9/19) for group B at time 3. This was due to high community facilitator turnover, timing of holidays, loss of interest, and arising community crises that took facilitators away from supporting SPARX usage. Similar attrition rates are not uncommon in pilot studies in remote communities.

Figure 3. Sequence of SPARX play.



Youth played SPARX on the laptops in either the community facilitator's office or in an office in their school. Youth were asked to engage in SPARX play once a week; however, due to complications in some communities (eg, crises, snowstorms), some youth played more or less frequently than this. Youth engaging in SPARX were always supported and accompanied by a community facilitator, given the exploratory nature of this novel study. This assistance was provided to ensure that any support youth needed with gameplay or with their mental health difficulties was prudently available while this new intervention was being piloted. The sequence of SPARX play is detailed in the following sections.

Measures

Pre- and postintervention surveys consisted of the same set of measures at both time points. Measures were either completed online via SurveyMonkey or in printed paper format. Community facilitators were on-site with the youth while they completed the measures to provide support such as reading questions out loud to the youth, or talking through answers if any youth felt vulnerable, at risk, or triggered by the content of the questions. Measures were selected based on their relevance; use in earlier, related studies; established psychometric properties for youth; sensitivity to change over time; ease of administration; length and clarity; and constraints based on funding sources.

The goal of this pilot study was to replicate, as best as possible in this new context, the studies conducted with Māori youth [16] to assess the potential usefulness of SPARX as an intervention with Inuit youth in Canada. It was clear to the researchers that should funding subsequently be obtained for a more comprehensive study, more culturally appropriate questionnaires would then be developed, together with Inuit communities, to assess youth depression and resilience [20]. As of the time of the writing of this paper, that has indeed happened, and a study of a culturally adapted version of SPARX for Inuit youth is underway [21]. In the absence of culturally appropriate outcome measures to assess mental health factors related to suicidality in Inuit youth, and to remain as consistent as possible with existing studies of SPARX conducted in New Zealand, the following primary outcome measures were chosen to assess changes in depression, hopelessness, resilience, and cognitive emotion regulation within these communities.

The CESD-R [22] is a succinct, 20-item, self-report scale that aims to measure current depressive symptomatology. Each item is a symptom associated with depression. The CESD-R has acceptable internal consistency (Cronbach α=.85) and test-retest reliability [23]. Validity was also established based on correlations with other assessment tools [24]. A sample item includes, "In the past week, I was bothered by things that don't usually bother me." Although it has not yet been evaluated within Inuit communities, the CESD-R is the most commonly used measure of depression among Indigenous youth, and has demonstrated a good model fit, with a root-mean-square error of approximation [25] of 0.6.

The HSC [26] contains 17 true-false items, which describe negative future expectations and negative present attitudes. Scores range from 0 to 17. Internal consistency is α=.97 and test-retest reliability is r=0.52. The HSC correlated positively with depression (r=0.58) and negatively with self-esteem measures (r=–0.61) and social skills (r=0.39) [26]. A sample item includes, "I might as well give up because I can't make things better for myself." This questionnaire has good internal consistency with other Indigenous youth (α=.86) but has not been evaluated with Inuit communities [27].

The CERQ-Short [19] is an 18-item measure used with adolescents and has good psychometric properties. It is composed of 9 coping styles, which are each coded as separate subscales of emotion regulation. These include Self-blame (score 1), Acceptance (score 2), Focus on Thought/Rumination (score 3), Positive Refocusing (score 4), Refocus on Planning (score 5), Positive Reappraisal (score 6), Putting Into Perspective (score 7), and Catastrophizing (score 8). Cronbach α coefficients range from .68 to .83 for the 9 subscales. Test-retest reliability ranged [19] from r=0.48 to 0.65. A sample item includes, "I keep thinking about how terrible it is what I have experienced." The CERQ-Short has been used with selected Indigenous populations; however, no official reliability or validity values have been published and it has not been evaluated with Inuit communities.

The CYRM-12 [28] is a 12-item self-report measure that includes 3 dimensions (Individual, Relational, and Contextual) that reflect the major categories of resilience. Raters choose whether the sentences describe them and endorse either "No," "Sometimes," or "Yes." The scale was developed for use with youth between ages 13 and 22 [28]. Internal consistency had Cronbach α ranging [29] from .65 to .91. A sample item includes, "When things don't go my way, I can fix it without hurting myself or other people (for example hitting others or saying nasty things)." The CYRM-12 has frequently been used with Indigenous populations, showing good content and internal validity, but has not been evaluated with Inuit communities [28].

Data Analysis

Because of the challenges encountered with youth recruitment, and the knowledge that an ideal sample size would likely be unattainable, no formal power calculations were conducted prior to beginning this study. To analyze mental health changes in Inuit youth in Canada over time, as measured through the 4 questionnaires, paired samples *t* tests (both 1- and 2-tailed—see below) comparing pre- and postintervention outcomes and repeated measures ANOVAs were conducted via SPSS Statistics version 26 (IBM Corp). ANOVAs allowed for examining the effect of time interacting with the intervention group or the waitlist control group. Paired samples *t* tests and ANOVAs pooled group A and group B data to account for missing data across groups and fewer completed postmeasures from group B youth. As a result of pooled data, there was some loss in accuracy due to the omission of select cases that did not fit the structure required by these simpler statistical methods.

Given the structure of the study—the comparison of the intervention group (group A) and the waitlist group (group B) at all (up to 3) time points for the pre- and postmeasures (group A: premeasure at time 1, postmeasure at time 2; group B: premeasure at time 1, premeasure at time 2, and postmeasure at time 3)—mixed models (multilevel regression) using pooled data were conducted via SPSS software. Multilevel regression models were appropriate given their ability to detect individual differences across different treatment options (time points for youth in group A vs group B). Results of the multilevel regression models are considered the most accurate as they use all the nonmissing data (important with a small sample size), reflect the full design of the study, and allow for comparison between group A and group B at different time points. Multilevel regression models were fit with (1) a randomly varying intercept for each youth to account for their differing initial levels of personally identified health and (2) an intervention indicator variable (0 for not having started playing the SPARX program vs 1 for completing the treatment of playing SPARX) to account for the effect of the treatment (ie, engaging in SPARX). A time variable was not needed as there were at most 2 (group A) to 3 (group B) measurement occasions with a horizontal, time-independent trajectory after accounting for the effect of the intervention. The assumptions of the mixed models were checked (eg, normality of the residuals) and found reasonable.

Researcher Characteristics

Enduring colonial approaches to research in Canada have severely diminished Inuit sovereignty with respect to research activity in the Inuit homeland [30]. In the spirit of accountability and reconciliation, we believe it is important to acknowledge that the research team is diverse and consists of Indigenous and non-Indigenous team members. CS, our Inuit community liaison, is an Inuk and a longstanding research partner with YB and her team of researchers at York University. MS is a Māori researcher who co-developed the SPARX program with Indigenous youth in New Zealand. JB is an Indigenous status First Nations student, born and raised in Tyendinaga/Kenhteke Mohawk Territory. YB, LL, JRH, HM, and MFGL are White researchers from the South (*Qallunaat*).

Results

Overview

Table 1 provides a summary of the baseline and postintervention results for participants in groups A and B. Mean scores and the SDs for the 4 outcome measures (by subscale for the CERQ-Short) are provided below.

Table 1. Descriptive statistics by group and time point.

Outcome measure	Group A time 1 (n=20), mean (SD)	Group A time 2 (n=13), mean (SD)	Group B time 1 (n=28), mean (SD)	Group B time 2 (n=19), mean (SD)	Group B time 3 (n=10), mean (SD)
CYRM-12[a]: Resilience	44.70 (8.04)	41.07 (10.22)	43.32 (7.54)	43.62 (9.44)	45.30 (8.42)
HSC[b]: Hopelessness	4.52 (2.75)	3.79 (3.09)	5.39 (2.50)	4.73 (3.34)	3.67 (2.58)
CESD-R[c]: Depression	22.90 (8.30)	23.21 (8.86)	25.50 (8.54)	23.68 (8.58)	21.20 (7.60)
CERQ-Short[d] subscale 1: Self-blame	4.90 (2.70)	5.00 (1.84)	6.04 (2.13)	6.10 (2.13)	4.20 (1.75)
CERQ-Short subscale 2: Acceptance	6.30 (2.24)	5.64 (2.20)	7.39 (2.33)	7.26 (2.37)	7.90 (1.73)
CERQ-Short subscale 3: Focus on Thought/Rumination	5.70 (2.39)	5.07 (1.90)	7.07 (2.16)	6.68 (2.29)	6.00 (1.89)
CERQ-Short subscale 4: Positive Refocusing	5.60 (1.79)	5.21 (2.19)	5.29 (1.90)	5.58 (2.27)	6.40 (2.07)
CERQ-Short subscale 5: Refocus on Planning	7.10 (2.40)	5.86 (2.51)	6.50 (2.23)	6.58 (2.24)	6.10 (2.42)
CERQ-Short subscale 6: Positive Reappraisal	7.40 (2.35)	7.07 (2.30)	8.00 (1.61)	7.68 (1.82)	6.70 (2.47)
CERQ-Short subscale 7: Putting Into Perspective	6.40 (2.39)	5.79 (2.01)	6.43 (2.28)	6.32 (1.60)	5.50 (2.37)
CERQ-Short subscale 8: Catastrophizing	5.50 (2.70)	4.29 (1.07)	6.50 (2.46)	5.89 (2.51)	5.60 (2.41)

[a]CYRM-12: Child and Youth Resilience Measure (12-item).

[b]HSC: Hopelessness Scale for Children.

[c]CESD-R: Centre for Epidemiologic Depression Scale-Revised.

[d]CERQ-Short: Cognitive Emotion Regulation Questionnaire—Short.

Hypothesis One: Youth Who Completed the SPARX Program Were Expected to Experience a Decrease in Depressive Symptoms and Risk Factors Related to Depression, as Measured With the CESD-R, HSC, and CERQ-Short Questionnaires

Participating youth reported feeling less hopeless, and engaged in less self-blame, rumination, and catastrophizing following the SPARX intervention (Table 2). The intervention was a statistically significant predictor of the HSC score (b=–1.08; $t_{51.1}$=–2.17; P=.02<.05; 1-tailed based on the *a priori* hypothesized direction of improvement in health). The intervention decreased the HSC score: Hopelessness by 1 (1.08) unit. The intervention was a statistically significant predictor of the CERQ-Short subscale score 1 (Self-blame; b=–0.86; $t_{53.2}$=–1.95; P=.03<.05; 1-tailed). The intervention tended to decrease the CERQ-Short subscale score 1: Self-blame by close to 1 (0.86) unit. The intervention was a statistically significant predictor of the CERQ-Short subscale score 3 (Focus on Thought/Rumination; b=–0.77; $t_{53.6}$=–1.84; P=.03<.05; 1-tailed). The intervention was a statistically significant predictor of the CERQ-Short subscale score 8 (Catastrophizing; b=–0.90; $t_{52.7}$=–2.00; P=.02<.05; 1-tailed).

For scores on the CESD-R, and the CERQ-Short subscale scores 2, 4, 5, 6, and 7 (Acceptance, Positive Refocusing, Refocus of Planning, Positive Reappraisal, Putting Into Perspective), the intervention indicator variable at the α=.05 level (2-tailed, and where relevant 1-tailed) was not statistically significant.

Table 2. Overview of outcomes following the SPARX intervention (n=22).

Primary outcomes: scale or subscale score	Desirable direction of improvement	Prescore (pooled groups A and B)	Postscore (pooled groups A and B)	Pre to post *t* test (pooled groups A and B)	Repeated measures ANOVA (pooled groups A and B)	Mixed models (multilevel regression models; comparing groups A and B)
CYRM[a]: Resilience	↑	47.389	44.389	Post ↓ (*P*=.02)	Intervention ↓ (*P*=.01)	Intervention ↓ (*P*=.02)
HSC[b]: Hopelessness	↓	4.458	3.667	Post ↓[c] (*P*=.08)[d]	Intervention ↓ (*P*=.01)	Intervention ↓ (*P*=.02)[d]
CESDR[e]: Depression	↓	N/A[f]	N/A	Post ↑ (*P*=.02)	Intervention ↑ (*P*=.01)	Intervention ↑ (*P*=.08)
CERQ-Short[g] subscale 1: Self-blame	↓	5.348	4.609	Post ↓ (*P*=.01)	Intervention ↓ (*P*=.02)	Intervention ↓ (*P*=.03)[d]
CERQ-Short subscale 2: Acceptance	↑	6.238	6.476	Post ↑ (*P*=.03)	Intervention ↓ (*P*=.07)	Intervention ↓ (*P*=.07)
CERQ-Short subscale 3: Focus on Thought/Rumination	↓	6.174	5.478	Post ↓ (*P*=.04)[d]	Intervention ↓ (*P*=.05)	Intervention ↓ (*P*=.04)[d]
CERQ-Short subscale 4: Positive Refocusing	↑	5.286	5.476	Post ↑ (*P*=.03)	Intervention ↓ (*P*=.08)	Intervention ↑ (*P*=.06)
CERQ-Short subscale 5: Refocus on Planning	↑	6.905	5.9524	Post ↓ (*P*=.02)	Intervention ↓ (*P*=.02)	Intervention ↓[c] (*P*=.08, 2-tailed)[d]
CERQ-Short subscale 6: Positive Reappraisal	↑	7.714	6.905	Post ↓ (*P*=.02)	Intervention ↓ (*P*=.07)	Intervention ↓[c] (*P*=.05, 2-tailed)[d]
CERQ-Short subscale 7: Putting Into Perspective	↑	6.381	5.762	Post ↓ (*P*=.04)	Intervention ↓ (*P*=.07)	Intervention ↓ (*P*=.01)
CERQ-Short subscale 8: Catastrophizing	↓	5.435	4.7826	Post ↓ (*P*=.05)[d]	Intervention ↓ (*P*=.04)[d]	Intervention ↓ (*P*=.03)[d]

[a]CYRM-12: Child and Youth Resilience Measure (12-item).

[b]HSC: Hopelessness Scale for Children.

[c]Approaches significance.

[d]Significant results (*P*<.05; 1-tailed, unless otherwise indicated).

[e]CESD-R: Centre for Epidemiologic Depression Scale-Revised.

[f]N/A: not applicable given insufficient data.

[g]CERQ-Short: Cognitive Emotion Regulation Questionnaire-Short.

Hypothesis Two: Youth Who Completed the SPARX Program Were Expected to Experience an Increase in Factors Related to Resilience

Youth in the study did not show an increase in formal resilience indicators. The CYRM-12 intervention indicator was not statistically significant at the α=.05 level (2-tailed).

Discussion

Principal Findings

Overall, key findings suggest that youth who completed the SPARX trial learned new cognitive emotional regulation strategies to help support them in challenging maladaptive thought patterns. Youth also appeared to experience less hopelessness after engaging in SPARX. No formal indication of a decrease in depressive symptoms or an increase in resilience was noted after engaging in the SPARX program.

Youth who completed the SPARX program were expected to show a decrease in depressive symptoms, which was not evident in this pilot study. However, outcome measures suggest that, for Inuit youth in Nunavut, SPARX may be an effective program for decreasing feelings of hopelessness, as well as the cognitive emotion dysregulation signified by self-blame. Cognitive emotion regulation has consistently been linked to mental health, with those who possess more adaptive regulation strategies better able to cope with stressful or adverse life experiences [31]. Elevated self-blame, rumination, and catastrophizing are 3 factors known to be highly correlated with poor emotion regulation and mental health difficulties, such as depression and anxiety [32]. Youth who tend to ruminate on negative events, catastrophize, and self-blame are more likely to develop depressive symptoms. These youth have increased difficulty inhibiting and regulating their appraisal, which likely leads to more catastrophizing thoughts [33].

Although depressive symptoms on the whole did not decrease after youth trialed SPARX, results suggest a decrease in negative emotion regulation strategies. This is encouraging given the evidence that negative coping styles are associated with greater depressive symptoms [34]. With a reported decrease in self-blame, catastrophizing, and rumination, youth may develop enhanced coping strategies to deal with adverse life events. Hopelessness has been one of the most important mental health factors examined in attempts to understand suicidal behavior and has been linked to suicide in Indigenous populations [35,36]. It is encouraging that results show a decrease in hopelessness and an increase in cognitive emotion regulation strategies. This supports the need to further examine the effectiveness of SPARX on a larger scale as well as more longitudinally, as CBT therapies may be more effective over several months [37].

Youth who completed the SPARX program were expected to experience increased resilience after the intervention but outcome measures provided by youth did not suggest any change in the resilience measure. The small sample size may largely explain this finding. It is also possible that the resilience measure itself was not culturally relevant or appropriate. Despite the lack of significant changes recorded in the formal measures of resilience, there is reason to believe that a decrease in the hopelessness scale may promote and foster greater resilience [36]. It is possible that SPARX may prove to be an effective treatment for decreasing depressive symptoms and boosting resilience when assessed in a larger study.

Youth in Nunavut disproportionately struggle with mental health concerns in comparison to youth in other Canadian territories and provinces. Despite this disparity, Inuit youth lack access to mental health services, largely because of a shortage of staff to provide and assist with evidence-based treatments, a direct result of continued oppression and marginalization under enduring colonialism experienced by these communities [10]. Developing mental health programs that do not necessarily require staff support may be viable options in overcoming this barrier. Extant literature documents the success of computer-based CBT programs in increasing access to mental health resources for youth [38-40]. A review of over 100 studies evaluating the use of e-interventions for children and youth struggling with mental health needs showed that technology-assisted interventions are becoming an increasingly common form of service delivery in Australia, New Zealand, the United States, the United Kingdom, Canada, and the Scandinavian countries [41]. Thus, an increasing number of studies are overwhelmingly supportive of e-interventions, including serious games, as successful therapeutic tools. In addition to their clinical benefit, results suggest enhanced interest in and access to these services by youth, decreased costs compared with traditional services, and greater quality of life for those who access e-interventions [41]. Moreover, a growing field of research is specifically examining the use of these programs in remote and Indigenous communities, with promising results demonstrating the effectiveness of computer-based programs with these populations [38]. Digital interventions have demonstrated success in many remote and underserved communities, as they increase access, break down barriers, and fill key gaps in service provision [41-44].

This study aimed to establish whether SPARX would be an effective intervention for fostering resilience and decreasing the risk of depression with Inuit youth in Northern Canada. It appears as though SPARX may be a good first step for supporting youth with skill development for challenging maladaptive thoughts and providing behavioral management techniques such as deep breathing. Further larger-scale studies are required to understand whether SPARX or similar e-interventions can be effective in decreasing symptoms of depression.

Limitations

We encountered several challenges during the implementation of this pilot study: (1) complications with youth recruitment, which resulted in the adoption of less rigid exclusion criteria; (2) challenges pertaining to the staffing of facilitators; (3) unavoidable deadline extensions due to staffing challenges, technological difficulties, and barriers in communication; and (4) a poorly matched control and intervention group when it came to sample size, duration, and frequency of play for youth in each group. The numerous challenges encountered caused this study to be drawn out over 9 months instead of the proposed 4.

As is common with pilot studies, the statistical power of our analysis was limited by a small sample size. Pilot studies are not expected to provide definitive statistical results, but rather to confer suggestive results for follow-up [45], and despite the lack of power we can report some statistically significant findings at the α level of .05. In addition, the “play now play later” procedures for this study were intended to control for the effects of fluctuations in mood due to daylight hours and fluctuating temperatures in the North. This was managed by having youth in the control group exposed to SPARX 2 months after youth in the intervention group completed their use. However, a strict deadline had to be set for the end of the study, and thus many youth in the control group were given a shorter time allowance for completing the SPARX program. Differences between the 2 groups in the frequency and duration of their SPARX play undermined the advantages of having a control group. Further, as a result of this deadline, there were fewer youth who participated in the control group. Finally, for ethical reasons, no participating youth were denied access to SPARX (ie, we ensured both group A and group B participants were all eventually given access to the intervention). Without a true control group where some participants did not receive SPARX, it is impossible to rule out confounds in the results. Unmatched sample sizes across the 2 groups, and an overall smaller-than-anticipated sample size, also weakened the scientific rigor of this study.

Another limitation was that the questionnaires used in this study, which were designed and systematized based on Western, Eurocentric concepts of depression, hopelessness, and resilience, did not properly access the experiences and expressions of mental health for Inuit youth in Canada. It is also possible that challenges with English language literacy confounded findings with Inuit youth participants despite staff being available to assist. It is possible that using local dialects (Inuinnaqtun and

Inuktitut) for questionnaires would better support youth's understanding of their mental health difficulties.

Finally, inconsistent access to the internet in most communities meant it was difficult to administer surveys; this also hindered data collection, participation monitoring, and recordkeeping. The high turnover of community facilitators created confusion with frequent changes in their roles and inadequate time provided for training, knowledge mobilization, and relationship development with youth participants. The conditions under which the trial was administered understandably created ambivalence among community facilitators, who were generally in favor of an intervention that might eventually benefit their communities but also struggled with the additional workload it imposed. All of these barriers, including short staff contracts, high staff turnover, youth attrition, inordinate mental health needs, lack of phone and internet access, and communication difficulties, are closely linked to continued colonization practices. Inuit youth in Canada continue to face systemic challenges and resource disparities as a result of poor government funding and a lack of consultation with communities for needs assessment and program development.

With these barriers and limitations in mind, we are also aware that this pilot study is rooted in a positivistic Western framework and was designed, conducted, and facilitated primarily by Qallunaat (non-Inuit). However, due to limited funding, this commissioned study had to be conducted remotely and included directives from the Government of Nunavut to involve local mental health workers, most of whom are not Inuk themselves, to administer the SPARX trial. This exploratory pilot served as a feasibility study fostering enthusiasm and cohesion among participating communities and scaffolding more culturally appropriate research. In a companion study [46], participating youth and community facilitators built much of the knowledge necessary through exit focus groups to facilitate such an endeavor. Indeed, efforts are now well underway to follow-up with a more community-directed and culturally meaningful study focused on articulating Inuit knowledge and research epistemologies through holistic, relational perspectives rooted in *Piliriqatigiinniq*, the Inuit concept for working collaboratively for the common good [20]. We recognize that research in Inuit communities must be collaborative and inclusive, underscoring "the right of colonized, Indigenous peoples to construct knowledge in accordance with the self-determined definitions of what they want to know and how they want to know it" [20](p12).

Future Directions

We present here preliminary findings that suggest that serious games such as SPARX could lead to improvements in emotion regulation and, by association, depressive symptoms; however, conflicting findings suggest youth's mood did not change after SPARX engagement. It will be important to replicate this study on a larger level, including more communities. It may also be beneficial to allow for online play. This will have the added benefit of increased rigor by allowing the research team to directly monitor engagement and frequency and length of play. It will be important to add a true control condition in the next trial to ensure that SPARX's effectiveness can be more conclusively established. In addition, it will be important to gauge what mental health and mental illness mean to Inuit youth in Canada. This will help foster an understanding of more culturally appropriate questionnaires for accessing youth's experiences with SPARX. Finally, using measures that have been validated with Inuit communities in Canada may help ensure that youth can more accurately report their mental health status. With a more culturally appropriate model for understanding Inuit youth mental health symptomology, an assessment of mental health changes attributable to the SPARX program may be more accurate.

Learning from the many barriers encountered here will allow for a more culturally competent and rigorous approach to conducting future research. It will be important to examine these barriers and to address them in any future protocol (such a follow-up study is currently underway). For example, having a community facilitator working specifically on SPARX will better support youth engagement, mitigate attrition, and foster greater trust between the youth and community facilitators. SPARX in schools might synergize well with institutional curricula and help with recruitment, engagement, and the generalizability of skills. Having a researcher on-site in the communities may help with supporting the community facilitator, troubleshooting any technological difficulties, and minimizing communication barriers. These extra supports, and the concomitant potential for more rigorous research with a larger sample size and true control group, will make an effective evaluation of the SPARX program more feasible. Furthermore, it may be advisable to hire a number of youth from each community to promote SPARX, advocate for the program, and help reduce the mental health stigma their communities may be facing.

Finally, it will be imperative to work with youth and communities to design, develop, and test an Inuit version of the SPARX program, tailored to fit the interests of Inuit youth and Elders in Canada and to increase engagement and effectiveness of the program. Such an initiative is underway. Existing studies suggest that incorporating one's culture into an already compelling psychoeducational serious game has the potential to promote cultural esteem and community-based resilience, in addition to fostering individual resilience.

Acknowledgments

We wish to thank the Nunavut Territorial Department of Health for sponsoring this study. We also gratefully acknowledge youth participants and community facilitators for contributing their time, wisdom, and energy to the project.

Conflicts of Interest

The intellectual property for SPARX is held by UniServices at the University of Auckland. Any proceeds from licensing or selling SPARX outside of New Zealand will be shared in part with UniServices, MS, and MFGL (and other co-developers of SPARX who are not coauthors of this article).

Editorial Notice

This randomized study was only retrospectively registered. The authors explained that this is because it was a small, atypical pilot trial. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the risk of bias appears low and the study was considered a pilot trial. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
CONSORT extension checklist for pilot/feasibility trials.
[PDF File (Adobe PDF File), 155 KB - games_v11i1e38493_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
CERQ-Short: Cognitive Emotion Regulation Questionnaire
CESD-R: Centre for Epidemiologic Depression Scale-Revised
CYRM-12: Child and Youth Resilience Measure-Short
GNAT: gloomy negative automatic thoughts
HSC: Hopelessness Scale for Children

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Original Paper

Co-design of a Virtual Reality Cognitive Remediation Program for Depression (bWell-D) With Patient End Users and Clinicians: Qualitative Interview Study Among Patients and Clinicians

Maria Elena Hernandez Hernandez[1], PhD; Erin Michalak[1], PhD; Nusrat Choudhury[2], MEng; Mark Hewko[3], MEng; Ivan Torres[1], PhD; Mahesh Menon[1], PhD; Raymond W Lam[1], MD; Trisha Chakrabarty[1], MD

[1]University of British Columbia, Faculty of Medicine, Department of Psychiatry, Vancouver, BC, Canada

[2]National Research Council Canada, Medical Devices, Simulation and Digital Health, Montreal, QC, Canada

[3]National Research Council Canada, Medical Devices, Simulation and Digital Health, Winnipeg, MB, Canada

Corresponding Author:
Maria Elena Hernandez Hernandez, PhD
University of British Columbia
Faculty of Medicine
Department of Psychiatry
2255 Wesbrook Mall
Vancouver, BC, V6T 1Z3
Canada
Phone: 1 604 822 7314
Email: elena.hernandez@ntnu.no

Abstract

Background: Major depressive disorder (MDD) is the leading cause of global disability; however, the existing treatments do not always address cognitive dysfunction—a core feature of MDD. Immersive virtual reality (VR) has emerged as a promising modality to enhance the real-world effectiveness of cognitive remediation.

Objective: This study aimed to develop the first prototype VR cognitive remediation program for MDD ("bWell-D"). This study gathered qualitative data from end users early in the design process to enhance its efficacy and feasibility in clinical settings.

Methods: Semistructured end-user interviews were conducted remotely (n=15 patients and n=12 clinicians), assessing the participants' perceptions and goals for a VR cognitive remediation program. Video samples of bWell-D were also shared to obtain feedback regarding the program. The interviews were transcribed, coded, and analyzed via thematic analysis.

Results: End users showed an optimistic outlook toward VR as a treatment modality, and perceived it as a novel approach with the potential of having multiple applications. The participants expressed a need for an engaging VR treatment that included realistic and multisensorial settings and activities, as well as customizable features. Some skepticism regarding its effectiveness was also reported, especially when the real-world applications of the practiced skills were not made explicit, as well as some concerns regarding equipment accessibility. A home-based or hybrid (ie, home and clinic) treatment modality was preferred.

Conclusions: Patients and clinicians considered bWell-D interesting, acceptable, and potentially feasible, and provided suggestions to enhance its real-world applicability. The inclusion of end-user feedback is encouraged when developing future VR programs for clinical purposes.

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KEYWORDS

depression; cognitive remediation; cognitive dysfunction; thematic analysis; virtual reality; VR; qualitative study; user-centered design; immersive; co-design; depressive; mental health; mental illness

Introduction

The Socioeconomic Impacts of Depression

Major depressive disorder (MDD) affects approximately 5.4% of the Canadian population [1]. Most recently, the COVID-19 pandemic has increased the proportion of Canadians experiencing depression. Among people aged 25 to 44 years, the proportion of people with MDD increased from 18% in fall 2020 to 23% in spring 2021 [2]. MDD is the leading cause of disability worldwide, substantially affecting psychosocial, occupational, and academic functioning [3]. MDD costs the Canadian economy approximately >CAD $30 billion (US $22 billion) annually in reduced workplace productivity [4]. MDD also affects academic performance in young adults. University students are at higher risk of depression than general population, resulting in lower grade point averages, lower academic performance satisfaction, and higher dropout risk [5-7].

Current treatments, although effective in improving core symptoms of MDD, fall short in addressing MDD-related disability [8-10]. Symptomatic improvements are not necessarily accompanied by restoration of occupational and psychosocial functioning—patients who are diagnosed with mild or remitted depressive symptoms may still show occupational and academic disability [9,10]. Accordingly, treatment priorities have shifted to targeting functional recovery, rather than solely symptomatic remission [8,11,12]. There has been increased interest in expanding mental health services in university campuses, as well as workplace mental health programs to identify and treat employees with depression [13]. While such programs can be helpful in reducing depression symptom severity, they neither necessarily result in major improvements in workplace or academic productivity, nor in decreases in presenteeism [14-18]. Thus, depression treatment strategies specifically targeting academic and occupational recovery remains an unmet need.

Cognitive Deficits in Depression

To enhance occupational functioning in MDD, cognition is an important intermediate target [19]. Cognitive dysfunction is often found in depressive disorders such as MDD, with deficits in memory, attention, processing speed, and executive functioning detectable in acutely symptomatic and remitted patients [20,21]. Importantly, cognitive functioning has been associated with occupational functioning in acutely depressed and recovered individuals with MDD [22-24]. However, there is a lack of effective treatments for cognitive deficits in depression. Major cognitive impairments may persist in individuals who attain symptomatic response or remission with established depression treatments [20], and antidepressant medications have inconsistent and sometimes negative effects on cognitive functioning [25].

Cognitive remediation has emerged as a promising treatment strategy for addressing cognitive deficits in psychiatric disorders [26,27]. This is a treatment method based on the repeated practice of computer or paper-and-pencil exercises that target specific cognitive skills (eg, sustained attention, verbal memory, and working memory) with the purpose of enhancing patients' work and social functioning abilities [28]. Cognitive remediation has strong evidence for improving cognition and functioning in schizophrenia, as well as showing promise in bipolar disorder and attention-deficit/hyperactivity disorder [26,27,29]. However, these results are less consistent in depression—a recent meta-analysis of cognitive remediation in depressive disorders found moderate effects on attention and working memory, with no major effects on executive functioning or verbal memory [30]. It also remains unclear if the skills practiced during cognitive remediation in depression transfer out of the laboratory environment and result in substantial real-world functional improvements [31-33].

Virtual Reality for the Training of Cognitive Skills

Immersive virtual reality (VR) has attributes which could enhance the delivery of cognitive remediation and has preliminary evidence for efficacy in other neurological and psychiatric disorders [34]. The immersive and interactive nature of VR facilitates greater user engagement and enjoyment compared with computer presented tasks [35,36]. VR also allows for the practice of skills in naturalistic settings, thereby improving the likelihood of skill transfer to the real world [37-39]. Randomized controlled trials have shown that VR-delivered cognitive and vocational remediation results in substantial improvements in cognition and functioning in patients with traumatic brain injury, stroke, schizophrenia, and substance use disorders, even when compared with active control conditions such as therapist administered remediation [40-43]. Additional advantages of using VR technology—which has been growing in mainstream accessibility and decreasing in expense—include its ability to reach a broader range of individuals with minimal cost. In addition, data collected from VR programs can potentially be integrated into digital health services, allowing a highly personalized intervention.

Despite the burgeoning applications of VR technologies and growing use in psychiatric populations, a sustained course of VR cognitive remediation has not been specifically evaluated in depression. As enthusiasm for using VR in clinical settings has grown, so have the questions regarding how to best design VR clinical applications to be usable and efficacious for the target population. A working group of international experts published the first consensus guidelines for best practices in the design and testing of VR clinical applications [44]. In these guidelines, incorporation of qualitative feedback from multiple end users is identified as a critical component of VR program content development. As lack of end-user involvement in development is often at the root of digital intervention failure [45], following best practices in human-centered design is important to enhance the interventions' relevance and effectiveness. Feedback from experts and care providers can ensure that the intervention is based on solid theoretical foundations and is feasible for real-world use.

Building on the existing body of work relating to cognitive remediation in clinical populations, the National Research Council Canada and the University of British Columbia have developed the bWell Cognitive Care Platform for Depression ("bWell-D"), a prototype immersive VR cognitive remediation program for individuals with depression. Following best practices in VR clinical application design, this study collected qualitative data from clinicians and care providers regarding their perceptions and experience with VR, desired outcomes from a cognitive or functional remediation program, and perceived barriers to use of VR cognitive remediation in clinical settings. Later, participants provided their thoughts and opinions specifically regarding the bWell-D program. This information was used to guide program and protocol refinements to bWell-D to boost clinical efficacy and feasibility.

Methods

Ethics Approval

This research was reviewed and approved by the Behavioural Research Ethics Board of the University of British Columbia (Behavioural Research Ethics Board numbers H21-00028 and H20-00746). It was also approved by the Research Ethics Board of the National Research Council Canada (NRC 2020-122).

Participants

Patients

A sample of 15 patients who self-reported a diagnosis of depression were recruited to participate in this study. Recruitment was carried out on the web through the Vancouver Coastal Health Research Institute and REACH BC websites, as well as on a classified advertisements website. Interested participants were screened to ensure they met the eligibility criteria:

1. Aged 18 to 65 years

2. Self-reported diagnosis of previous or current major depressive episodes

3. Self-reported subjective cognitive or functional deficits at baseline, as indicated by a battery of self-report questionnaires. All participants were included in the analysis, regardless of their scores in the clinical measures.

4. Engaged in full-time employment (currently or in the past), with self-reported ongoing functional deficits resulting from depressive symptoms, or off work or on reduced hours with depressive symptoms reported as the primary reason.

5. Sufficient proficiency in English to complete the questionnaires and interview

Patients who were eligible and completed the entire process were compensated for their participation with CAD $20 (US $14.55).

Clinicians

A convenience sample of 12 clinicians participated, with recruitment occurring through the Vancouver Coastal Health Research Institute and REACH BC websites, as well as physical posters displayed on-site at relevant health units. Clinicians were also contacted through the researchers' professional contacts. Interested clinicians were provided a letter of invitation and confirmed their interest in participating via email. Clinicians must have been allied health professionals (eg, psychiatrists, psychologists, family physicians, occupational therapists, or nurses) with experience working with populations with depression, and experience with cognitive or functional remediation in psychiatric populations. Clinicians were not offered a monetary compensation.

Procedure

This study was conducted remotely through videoconferencing. Participants attended an approximately 1-hour Zoom interview, in which they were first explained the purposes of the study, and oral informed consent were obtained. Participants then completed a web-based Qualtrics survey asking for demographic data. In addition, patients completed a series of psychiatric and psychological questionnaires (see the *Measures* section), whereas clinicians answered questions related to their clinical practice. After completing the questionnaires, a semistructured interview was conducted, in which participants were asked regarding their perceptions and experiences with VR, their desired outcomes from a workplace cognitive or functional remediation program (bWell-D), and perceived barriers to use this type of treatment in a clinical setting. Participants were then shown previously recorded video samples of the bWell-D tasks and were asked to provide their thoughts on them, their potential relevance to daily life, and suggestions on how to improve the tasks to enhance engagement and real-world applicability (see Multimedia Appendix 1 for the interview scripts).

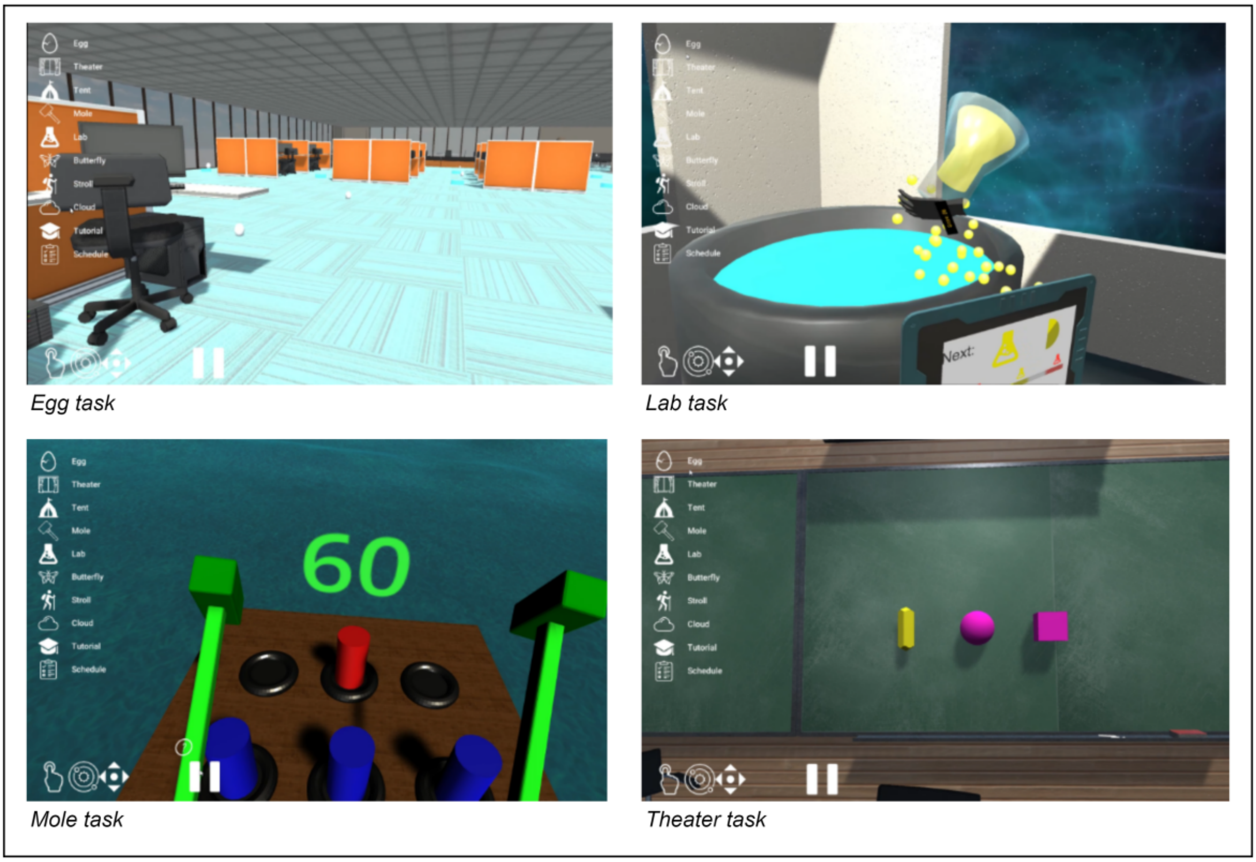
The bWell-D Program

Overview

"bWell-D" is a prototype of immersive VR cognitive remediation program for depression, developed by a collaboration between the University of British Columbia and the National Research Council Canada. The foundational platform, bWell, was developed within a network of researchers and clinicians across Canada, features configurable exercises and design as a broadly applicable toolkit targeting general aspects of cognition commonly affected across many disorders [46]. Preliminary acceptability studies in healthy individuals indicate that the platform is enjoyable, engaging, and well tolerated [35,47].

bWell-D is a customized version of bWell, targeting cognitive and real-world challenges germane to MDD depression [20,21,46]. Two bWell tasks were modified to include real-world environments, that is, the (1) office and (2) classroom. It additionally uses previously identified common components of successful cognitive remediation in psychiatric populations. These include (1) "errorless learning," wherein participants are provided support in learning all task components, with supports gradually removed as skills and confidence increase and (2) "adaptivity," in which tasks become increasingly complex to match with the participant's competence [31]. bWell-D involves 4 different tasks (Figure 1) that aim to train cognitive skills that are commonly affected in MDD. Participants can interact with the virtual environment through a headset and 2 hand controllers.

Figure 1. Screenshots of the bWell-D tasks.



Egg (Attention)

In this task, the patient is asked to look around in an office environment and look for eggs. Once locating the egg with their sight, they are required to fix their gaze on the egg until it hatches.

Lab (Multitasking)

Participants must complete 2 recipes simultaneously by pouring multicolored flasks into 2 mixing bowls. The recipes will appear in 2 tablets placed nearby, and participants will have to go back and forth between recipes.

Mole (Reaction Time and Response Inhibition)

Following similar rules to the whack-a-mole game, participants hold a hammer in each hand and hit the cylinders that pop out of a table. The cylinders are multicolored, and the colors of the hammers also change over time. Participants are asked to hit the cylinder that matches the hammer's color.

Theater (Visual Working Memory)

The participants are shown a sequence of shapes that will be hidden after a set viewing time. A pool of objects will then be presented to the participant, from which they must choose the shapes that were initially shown to them and recreate the original sequence.

The bWell-D tasks operate in three modes: (1) tutorial, (2) assessment, and (3) training. Tutorial has the aim of familiarizing the patient with the virtual environment and showing them the actions they must perform in the tasks. Assessment mode has the purpose of identifying the patients' individual needs by assessing their task performance with a fixed difficulty level. In the training mode, the level of difficulty is adaptable based on the patients' performance. Real-time feedback is provided to the patient, showing them level or score changes and successes and errors.

Measures

Along with the demographic questions included in the Qualtrics questionnaire, patients also responded to the following psychiatric and psychological measures:

Lam Employment Absence and Productivity Scale

The Lam Employment Absence Productivity Scale [48] is a work functioning and productivity scale to be used specifically with patients with depression. It is a 10-item scale, in which the first 3 questions are open-ended and ask regarding the patients' type of work, the number of working hours scheduled in the past 2 weeks, and the number of working hours missed in those 2 weeks. The following items are rated on a 5-point Likert scale ("None of the time" to "All the time"), scored as 0 to 4. Work impairment rating can range between "None to minimal" to "Very severe."

Generalized Anxiety Disorder–7 Items

The Generalized Anxiety Disorder–7 items [49] is a short measure of anxiety. Participants are asked how often they have been bothered by their anxiety symptoms during the past 2 weeks. The measure follows a 5-point Likert format, ranging from "not at all" (0) to "nearly every day" (4).

Sheehan Disability Scale

The Sheehan Disability Scale [50] is a short measure of disability and functional impairment. The first 3 questions are in a Likert scale format, inquiring regarding the severity of cognitive symptoms affecting the patients' work and social and family life from "not at all" (0) to "extremely" (10). The last 2 open-ended questions ask regarding the patients' missed days at work, and regarding the days when the patient felt underproductive.

Perceived Deficits Questionnaire–Depression

The Perceived Deficits Questionnaire–Depression [51] is a 20-item questionnaire that assesses subjective cognitive dysfunction in people with depression in the past 7 days. It follows a 5-point Likert scale, with response options ranging from "Never" (0) to "Almost always" (4).

Beck Depression Inventory

The Beck Depression Inventory [52] is a 21-question, self-report Likert scale that measures the severity of depression symptoms. Responses range from 0 to 4, in which a higher number indicates a more pronounced symptom severity.

Cognitive Failures Questionnaire

The Cognitive Failures Questionnaire [53] is a measure of self-reported failures in perception, memory, and motor function over the past 6 months. It is a Likert scale consisting of 25 items ranging from "Never" (0) to "Very often" (4).

Qualitative Data Analysis

Interviews were recorded and transcribed verbatim. The transcriptions were made with Otter.ai, a web-based service that uses artificial intelligence to transcribe audio recordings. The transcriptions were reviewed and corrected by hand after being processed by Otter.ai. The initial 5 interviews (3 clinician interviews and 2 patient interviews) were coded by the first author to identify an emerging thematic framework [54]. Coding was conducted separately for the clinician and patient groups. However, members of the research team (EM, TC, and MEHH) discussed and identified emerging patterns in the data and determined that the coding framework between the 2 groups was similar; therefore, it was decided to analyze the 2 groups together. Subsequent transcripts were coanalyzed and discussed based on the initial thematic framework. Thus, the data analysis began with the delivery of the first interview and proceeded concurrently and iteratively. The NVivo (QSR International) software was used to aid with the coding and thematic analysis process.

Results

Participant Characteristics

Patients

Participants were aged between 21 and 63 years, with a median age of 31 (mean 34.2, SD 11.5) years. Most participants self-identified as women (n=10), with 3 as men and 2 as nonbinary. The most common diagnosis was MDD (n=8), and 1 patient was diagnosed with dysthymia, 1 with bipolar disorder, 4 of them reported being diagnosed with depression but did not remember the specific diagnosis, and 1 did not have a formal depression diagnosis, but manifested having all the clinical symptoms for it (this was later confirmed at the screening stage). Patients with a formal diagnosis reported being diagnosed between 3 and 16 years ago. At the time of the interview, none of the patient participants were undertaking any psychological treatment, however, 4 of them were taking medication to treat their depression symptoms.

Patients' clinical scores are provided in Table 1. Overall, participants surpassed the threshold for a clinical diagnosis in all measures. All participants reported having their work or academic performance affected by their depression symptoms, and all of them have had to take some time off work or school, ranging from a few sporadic days, to several years. Participants stated working only approximately 80% of their scheduled work hours, some of them having to quit work completely because of the severity of their depression symptoms. Furthermore, 9 patients were either currently employed or studying, while 6 of them were unemployed and identified depression as one of the main causes for their unemployment. From the participants who were employed at the time of the interview, 4 had administrative jobs, 3 had professional jobs, and 2 worked in sales.

Table 1. Patients' clinical measures.

Measures	Values, n	Values, median (range)	Severity[a]
LEAPS[b,c]	9	15 (4-29)	Moderate
GAD-7[d]	15	19 (9-27)	Severe
SDS[e]	15	22 (6-30)	Markedly impaired
PDQ-D[f]	15	46 (7-69)	Risk range
BDP[g]	15	25 (8-47)	Moderate depression
CFQ[h]	15	62 (15-79)	Above average cognitive complaints

[a]On the basis of median scores.

[b]The LEAPS is only for participants who are currently engaged in paid employment, hence the reduced sample who responded to this specific measure.

[c]LEAPS: Lam Employment Absence and Productivity Scale.

[d]GAD-7: Generalized Anxiety Disorder–7 items.

[e]SDS: Sheehan Disability Scale.

[f]PDQ-D: Perceived Deficits Questionnaire–Depression.

[g]BDP: Beck Depression Inventory.

[h]CFQ: Cognitive Failures Questionnaire.

According to the open-ended questions in the Lam Employment Absence Productivity Scale, employed participants had between 50 and 80 scheduled work hours in the previous 2 weeks, and although most of them worked their full shifts, 2 participants only worked between 15 and 20 hours. Four participants were currently working reduced hours, and they have been in this work modality between 2 months and 1 year. The responses to the open-ended questions of the Sheehan Disability Scale indicated that employed participants had lost between 1 and 20 days of work in the past month because of their depression symptoms. Even when attending work or school, participants reported that depression affected their performance in the last month, ranging from 30% of the days to 50% of the days. One participant reported feeling these effects daily.

Clinicians

Participants self-identified as 5 women and 7 men. There were 7 psychiatrists, 2 occupational therapists, 1 psychologist, 1 clinical counselor, and 1 neuropsychologist. They had varied years of experience as mental health practitioners, ranging from 2 to 50 years, with a median of 17.5 years. Five clinicians reported having <5 years of experience in clinical practice, while 6 of them reported having >20. One clinician reported having between 5 and 10 years of experience.

Most of the clinicians worked in an outpatient setting (n=10), either at hospital clinics or private practice. Only 1 clinician worked at an inpatient psychiatric hospital, and another one worked at a community health center. In total, 7 clinicians provided a consultation and assessment and short-term follow-up model of care, 3 of them offered long-term follow-up, and 2 of them did single consultation and assessment with no follow-up. Furthermore, 4 clinicians offered primarily pharmacological and medication treatment modality, 3 of them offered primarily psychotherapy, 3 of them a combination of medication and psychotherapy, and 2 focused primarily in functional rehabilitation. Clinicians who provided psychotherapy offered behavioral treatments, such as cognitive behavioral therapy, dialectical behavior therapy, and acceptance and commitment therapy.

A total of 7 clinicians estimated <50% of their patients had a depressive disorder, while the remaining 5 estimated that more of the 50% of their patients had depression. Five clinicians had experience with cognitive or functional remediation, and they had between 0.5 and 5 years of experience with this type of treatment. Most clinicians (n=9) had been working remotely because the start of the COVID-19 pandemic, mostly relying on videocalls, phone calls, and (less commonly) computer tasks with their patients.

Thematic Analysis

Overview

Participants held mostly positive opinions regarding bWell-D, considering it an entertaining and safe treatment modality. Five themes were identified during the thematic analysis, specifically participants' previous knowledge regarding VR technology, its potential for clinical uses, a desire for realistic settings and situations, the entertaining features of VR, and the need for an inclusive treatment. A description of each theme and representative quotes are presented below.

Familiarity and Optimism: Openness to Trying VR for Mental Health Symptoms

Both patients and clinicians had at least some degree of familiarity with VR. Patients were familiar with VR mostly from videogames and movies, while clinicians were also aware of its use for clinical purposes, especially for anxiety-related conditions, psychosis, and brain injury. When participants did not have direct experience with VR, they mentioned hearing good things regarding it. Participants with little or no exposure to the technology spoke of their curiosity regarding trying it.

> *I mean, I'm curious to see if it could, in any way, help my own mental health issues. And, I don't know, it's something I haven't tried yet. And I'm open to trying things that might improve my wellness.* [Patient 003; woman; 43 years]

> *I don't really know too much about it. But I'm very open to learning more. I guess, like I don't know enough to say whether I see potential or not, so I'm eager to learn more.* [Clinician 005; woman; occupational therapist]

Participants with a higher exposure to VR, and the ones who enjoyed videogames, were the ones who showed higher enthusiasm regarding this technology.

VR as a Potential but Underexplored Treatment Option for Cognitive and Functional Deficits in Depression

Although both patients and clinicians often considered mood symptoms as the most salient symptom in depression, they acknowledged that cognitive symptoms are also affected. They described cognitive issues as particularly harmful for work life, because they have a direct effect on job performance, which can in turn exacerbate feelings of shame and stigma:

> *It was just a really hard time. I just, I couldn't concentrate, well, I still have a hard time concentrating. Just my, my work ethics went down. I don't know, everything became really hard. I missed a few days here and there, like I felt, but at the same time, like even though I was told by the doctors like, 'No, you need to take time off,' I kept going because I didn't want to be judged behind my back. But if anything that made it worse [...] But I know that my, my work has gone down, like, and I have a really hard time concentrating.* [Patient 001; woman; 21 years]

Several patients considered that training their cognitive skills through VR can help them not only for work purposes but also with their day-to-day life:

> *I go into a room to get band aids, I forget what I'm in there for, literally my house is not that big. And I go back in the living room wondering what the hell I was looking for. So it, I feel like it would help with work and with my personal life, which is just a double bonus.* [Patient 003; woman; 43 years]

They were confident that their cognitive abilities can be re-established after experiencing depression. When asked regarding the potential applications of VR for depression, 2 clinicians and half of the patient sample struggled to see how this technology could be used for this condition:

> *I'm aware of the promise of virtual reality treatments for anxiety disorders and things like that. I would be, I don't see the application to depression or bipolar disorder. So you know, in that end, those are the two disorders I treat the most. So therefore, I'm not particularly looking at this. And I'm surprised to hear about a virtual reality treatment for depression* [Clinician 009; man; psychiatrist]

Participants considered VR a safe alternative to conventional psychiatric treatments, and most patients were willing to try it because of its perceived lack of serious side effects. Participants believed that more effective treatments for mood disorders are needed, and therefore, VR can be a promising alternative.

> *I don't always enjoy the medication approach, like the side effects can be quite frustrating at times. So I think something without, like, a less medicalized approach could be really helpful. And you could avoid some of the negative side effects.* [Patient 014; woman; 21 years]

> *I think we need all the treatments we can get for mood disorders. So I'm curious.* [Clinician 009; man; psychiatrist]

Participants believed that VR is a novel approach to treat depression, and because it is becoming increasingly popular for clinical purposes, they would like to explore this treatment modality further:

> *I think will become more common in the future. So I think it might be like a good way to look into it and learn about it before it like the, as is, you know, gaining more popularity.* [Clinician 005; woman; occupational therapist]

A few participants, however, considered this "newness" a limitation to start using VR, because it is not standard practice in most health care institutions:

> *I practice in a large university hospital type setting. The university hospital always is incredibly bureaucratic, and never wants anything that's innovative or different. They only want things that are standard. So anytime you try to introduce something new, it's very challenging. So I would say that it would be unlikely that even if this treatment were approved tomorrow by Health Canada or the FDA, I would say it's very unlikely that our system would use it for anytime in the next few years.* [Clinician 009; man; psychiatrist]

Despite the general enthusiasm regarding using VR and cognitive remediation, both patients and clinicians had some further reservations, and mentioned needing more evidence before undertaking a treatment of this nature. Most clinicians mentioned that, although this type of treatment has shown promising results in some conditions, they would like to have more evidence for its specific use in depression. They would like to obtain this information from methodologically sound research studies:

> *If there is going to be evidence for that, for the type of patients that I've seen, and the patients are willing to participate? So yeah, for sure [...] It's not part of the kind of the regular practice, or part of the standard guidelines. But once the evidence is there, for sure.* [Clinician 012; man; psychiatrist]

Furthermore, approximately half of the patient sample mentioned that the VR format might not have any particular advantages over other modalities of cognitive remediation delivery:

> *I think the only like, pushback that might be received is like, what is the difference between doing this and playing like, a task related like, video game, I guess? Like, I think that there's an, there's maybe an opportunity for, like, people who are depressed to be like, "Well, if I if I'm basically just going to a lab to play a game, what's the difference between me doing that, and me just like downloading a game on my phone where you're being asked to, like, do memory parts?"* [Patient 008; woman; 30 years]

Desire for Ecologic Validity

Several patients mentioned that they would like to understand exactly how the tasks practiced in bWell-D work, so they do not feel like they are "just playing a game." They also mentioned needing an explanation regarding how to extrapolate the trained skills to their real-life world:

> *My honest opinion on the games, they all seem like kid games. They all seem very simple and straightforward, but simple animation. And I find like, I might think it's just a silly game, but I think once I start actually playing them, I would realize how it's helping.* [Patient 007; woman; 28 years]

> *I think I would need the therapist to, like, fully explain what this was training and helping with, because, like, the one thing that triggered me when I was in a depressive state was that, like, I knew I was smart, but then like, when I was in a depression, I wasn't functioning, that, like, as normal, and then I would feel really, really dumb. And like, seeing this kind of activity makes me feel like, you know, it gives a reaction like, I'm not a child, like, why am I putting shapes together?* [Patient 10; woman; 27 years]

Most participants mentioned that VR offers the possibility of immersing themselves in settings and situations that resemble real life in a highly accurate manner:

> *It's very interesting in the way that all new technology is very interesting. And it's remarkable, you know, the sense of presence when you're in the VR environment. It, you know, unless you've experienced it, it's hard to imagine, you know, it's very much like being in the real world.* [Clinician 011; man; psychiatrist]

Most patients mentioned they would like the virtual environments to look like their own work or school setting, as well as including objects (eg, office supplies or school furniture) and situations (eg, conversations with colleagues, following instructions given by their boss or teacher) that emulate real life (eg, interactions with humans and distractions). They believed that these naturalistic aspects can enhance skill extrapolation:

> *I think that it would also require some effort relevant to their daily activities, or have some translational component.* [Clinician 004; man; psychiatrist]

> *I think if I work in an office, it would, it would be better because I'd be able to take what I'm doing within that virtual reality, and apply it more to the environment that I'm hoping to improve my concentration in. But because it doesn't look like where I work it's difficult to connect the two.* [Patient 007; woman; 27 years]

Participants considered VR as "the second-best thing to real life," because it allows an immersion in highly realistic environments. Participants desired to obtain this realism through several ways, (1) by having virtual settings that emulated patients' own real-life environments, (2) by including distractors in the VR world that would occur in real life, and (to a lesser extent) (3) by having realistic-looking graphics. Patients and clinicians also stated that VR environments allow for the practice of skills and exercises in a more controlled and less intimidating setting:

> *If I were able, was able to get better at that, and because it's a low stress environment in the game, maybe having it, having that experience in a low stress situation would help me in my more stressful situations.* [Patient 014; woman; 21 years]

> *It's like the traditional thing when you, when you're nervous about speaking in front of a crowd is that, you like, you practice your speech in the mirror. It could be something similar to that but in a VR setting, with there being more of a...I don't quite know how to articulate it, exactly.* [Patient 005; nonbinary; 25 years]

A few patient participants mentioned that VR can allow them to focus on only training their skills without getting sidetracked. However, they emphasized the need for improving their cognitive symptoms overall, rather than just improving their performance in the virtual tasks:

> *I'm skeptical because of the literature that's behind this, because there's a lot of evidence saying that you only get better at the game instead of the skill itself, or the cognitive aspect that you're focusing on itself.* [Patient 001; woman; 21 years]

Three clinicians mentioned the importance of ensuring that the skills practiced in programs like bWell-D are actually training what they intend to train, and that the tasks are representative of the actual cognitive processes that patients must perform at their work or day-to-day life:

> *If there's evidence that depressed people have trouble on that sort of task, it makes sense. If you're pulling it out of thin air, because they have trouble on an attempt and inhibition task that's not like that one, then you better rethink how close that task mimics the process you're interested in.* [Clinician 011; man; psychiatrist]

Approximately a quarter of the participants were concerned regarding the long-term effectiveness of the treatment. To address this, a patient suggested having a lengthier VR cognitive remediation treatment, whereas a clinician suggested adding booster sessions. Several participants expressed a desire to obtain treatment progress data through a reliable instrument. Although a few of participants mentioned wanting improved graphics in bWell-D (more realistic looking), others mentioned that this is not too important if the content of the tasks is well designed, and the objects are clear to see. Most participants mentioned that any possible glitches and malfunctions should be minimal or nonexistent for the treatment to be effective and enjoyable.

A Fun and Engaging Treatment: The Advantages of a Digital Environment

Most participants mentioned that the gamified experience of VR adds fun, engaging, and immersive elements to the treatment. A need for multisensory stimuli (ie, tasks that incorporated auditory and visual components) was mentioned by most of the participants and was considered key for the immersion and involvement in the virtual tasks. Participants also stressed the importance of having a difficulty progression in the tasks, to enhance the challenging aspect of the treatment (without it turning so difficult that it becomes discouraging). A clinician mentioned how this difficulty progression can provide a sense of accomplishment for patients:

> *It definitely gives you kind of that drive, while at the same time being complicated and interesting enough to keep your attention wanting to keep going [...] – I found that one was always a really fun task, a difficult task. Not difficult, but it required enough energy without being overwhelming.* [Patient 015; woman; 33 years]

Most clinicians and patients stressed the importance of having a simple, user-friendly VR interface that included some training period and clear instructions to practice the tasks. A few clinicians considered important to assess patients' satisfaction with the program session to session.

Several participants, especially clinicians, found the versatility of VR to be beneficial for the treatment. They noted that the flexibility provided by VR allows a wide variety of virtual settings, going beyond what is achievable in real life:

> *I think you can help us create a very realistic environment to do some therapeutic work in and potentially make some progress that we haven't been able to outside.* [Clinician 007; woman; psychologist]

A few participants considered a treatment, such as bWell-D less emotionally draining treatment modality than medications or talking therapy:

> *When I was watching it, it occurred to me it's kind of nice to have these videos not relating to real life experiences, and things that are supposed to be kind of fun, because it doesn't feel like you're doing work, even though you are. And that is, at least for me, isn't as emotionally or cognitively draining.* [Patient 015; woman; 33 years]

Seven participants (both patients and clinicians) mentioned that the game-like setting of VR also allows for progress tracking (eg, score and level changes and improvements), either from the beginning to the end of a session, or from session to session.

One Size Does Not Fit All: The Need for Inclusivity and Customizability

Most patients and clinicians mentioned that they would like to have some agency in the manner the VR treatment is conducted. One of the most recurring comments among patients and clinicians was a preference for the patient to have the treatment individually at home, either partially or completely. Participants believe this modality provides a sense of comfort and control:

> *It seems like a nice way to do it yourself. Like, in your own time in, in quiet, in a quiet environment and not have to go anywhere.* [Patient 002; woman; 36 years]

> *I think it would be helpful for people who can't get there, like remotely. Like, there are days when I can't like, get out of bed or like, get overwhelmed by taking the bus, and like, that might be super helpful to be able to join in like that.* [Patient 10; woman; 27 years]

However, a few patients and clinicians believed a treatment of this nature would be better performed at a clinic. In particular, patients with limited space, or with suboptimal conditions to carry out the treatment at home, would like to have the option to do it at a clinic if necessary:

> *If I had to use it at my own home, that would be almost impossible with three kids and, I think, life.* [Patient 012; womana; 42 years]

Participants mentioned wanting a person involved in the treatment even if they choose to do it remotely. Several patients stated that the involved person should be a well-trained facilitator who they trusted. Most of the patients and clinicians mentioned they would like to engage in a VR treatment when mood symptoms and other potential comorbidities are under control, and therefore had enough motivation to undertake the treatment:

> *It depends on the severity, so I think it could be quite hard for some individuals to sustain, you know, attention or memory, if they're having more severe symptoms. But I think as a symptom, sort of subside or set, you know, it's more mild to moderate, we might be able to focus a bit more and pay attention to it a bit better.* [Clinician 007; woman; psychologist]

> *I think like when you are depressed, like, it'd be really hard [...] if there's any sort of resistance in that process. I think like, a really anxious person or really depressed person would be like, 'Nope, I can't deal with it. It's not working. I'm done with it. Not going to use it today' sort of mentality.* [Patient 008; woman; 30 years]

In fact, several patients and a few clinicians mentioned the usefulness of including an activity in bWell-D that specifically targeted mood. After looking at the task video samples, 4 patients also mentioned that some tasks could be more useful than others (eg, patient not currently struggling with memory issues or wanting to focus more on multitasking). Therefore, they would like to tailor the treatment according to their own cognitive struggles and needs. A clinician also commented that, although the office or school-like VR settings could be useful to emulate naturalistic settings, these settings can trigger emotional responses from some people:

> *For people who are not working, many people with depression are on short or long term disability from work, I was just wondering if seeing the office environment might trigger something.* [Clinician 010; woman; psychologist]

Despite the overall positive perceptions regarding bWell-D, approximately half of the clinician sample and one patient stated they would like to do a VR treatment in parallel with other conventional depression treatments (eg, medications or psychotherapy):

> *You target that symptom, but then you work with the clinician long term to, to use this as sort of one of the other interventions that you're using, and I would see this not being a single intervention being used. I see this being used in combination.* [Patient 001; woman, 21 years]

Another of the most mentioned topics among patients and clinicians was how age could be an important factor when undertaking a VR cognitive remediation treatment. In particular, participants believed that the more technologically savvy individuals (often the younger generations) would like the treatment better. In turn, participants believed that older patients might need more coaching and adjustment time to become used to bWell-D. Several participants also believed that people prone to sensorial issues might dislike a VR treatment, because it can make them feel physically ill:

> *The other problem with all of this is that people go into their depression with some of them, depression of course worsens all of this, it can worsen this, but some people have pre-existing audio processing difficulties or visual processing difficulties either genetically or by head injury or a stroke or medical injuries, etc..* [Clinician 002; man; psychiatrist]

Participants also mentioned that the treatment should be accommodating to people from different backgrounds and with different needs, such as people with color blindness or visual impairments, people whose English is their second language, and people with limited mobility. One of the most common concerns was the actual access to the bWell-D program and the necessary equipment (eg, headset, controllers, or computer). Most participants acknowledged that these technological devices, although they are becoming cheaper with time, may still be inaccessible for people with more limited economical resources:

> *They [VR sets] cost a little bit of money, and most people with mental illness don't have any money. So yeah, just having access to it, having access to a headset* [Patient 004; man; 49 years]

> *The job that I work, I don't have coverage yet, and when I do get coverage, I don't know how much it is. And maybe, I'm not sure if the city offers it, like if it's readily available. So I guess cost and availability would be the biggest challenges for that.* [Patient 007; woman; 28 years]

However, a clinician mentioned that, if the treatment shows to be effective for patients, then every effort should be made to open access to it.

Changes Made to bWell-D After Qualitative Feedback

Following the guidelines proposed by Birckhead et al [44], the changes suggested by end users to improve the bWell-D program were discussed among the research team, translated into representative software functionalities during team brainstorming sessions, and were given priority for implementation based on (1) how frequently these changes were suggested by end users and (2) whether these changes were feasible for development in a VR environment. The main areas of improvement suggested by both clinicians and patients were based on the thematic analysis, and mainly centered in (1) taking greater advantage of the potential of VR to create more multisensorial tasks; (2) the inclusion of more ecologically valid VR elements (to reflect more realistic VR environments), as well as having bridging exercises to relate the skills trained in bWell-D to real-world situations; and (3) providing sufficient challenge for fun and engaging tasks. In addition, end users suggested having a user-friendly interface and tutorials to have an opportunity to practice the tasks, which they considered especially important for an at-home treatment. Moreover, participants recommended to include an additional VR activity that specifically targets their mood. Participants believed that these modifications could make bWell-D more interesting, engaging and useful to improve cognitive deficits. The implemented functionalities are described in Multimedia Appendix 2, while Multimedia Appendix 3 provides a more in-depth description of these changes, and Multimedia Appendix 4 shows some visual examples.

Although efforts were made to cover as many of the suggested changes as possible to bWell-D, there were some areas that the research team determined to address with alternative strategies. In particular, one of the suggestions made by several participants was the addition of more VR environments that better emulated patients' real-life settings, such as their own workplace or school. However, the research team concluded that the addition of these VR environments would be too demanding in terms of resources required for software development. Instead, it was decided that such need would be addressed trough bridging exercises, which are clinician-led discussions that help cognitive remediation participants to apply what is trained in the tasks to everyday life [55].

As part of the iterative process in the design of bWell-D, the changes made to bWell-D were later shown to a subset of 4 patient participants, once more as prerecorded video samples. After looking at the updated version of the program, participants were provided with additional information regarding bWell-D and were asked regarding their general opinions regarding the implemented changes (see Multimedia Appendix 5 for the reinterview script). All the participants reacted positively to the changes, and considered them an improvement to the initial version of the program.

Discussion

Principal Findings

The main aim of this study was to explore the opinions of patients and clinicians regarding the use of VR for the treatment of depression-related cognitive disfunction. bWell-D, a VR treatment specifically designed for treating cognitive symptoms of depression, was used as the main VR treatment example for the participants. The results indicate that VR interventions for treating depression and its cognitive symptoms are generally accepted by both patients and clinicians. In the particular case of bWell-D, they considered it an innovative and fun alternative for the treatment of mental health issues. Some suggestions were made for the improvement of bWell-D, such as including multisensorial tasks, cues, and distractors, a progression in the difficulty of the tasks, realistic virtual settings and activities, having a user-friendly interface, including tutorials and an opportunity to practice the tasks before initiating the treatment, and adding a task or VR activity that targets patients' emotional state.

Although the general perceptions regarding VR for clinical purposes and bWell-D were mostly positive, participants also expressed some reservations. In particular, clinicians needed more evidence before implementing a treatment of this nature in their own clinical practice. Although there is a growing body of evidence supporting cognitive remediation [56] and VR in health care settings [57], structural obstacles within health institutions, as well as health professionals' own personal preferences (ie, an inclination for more traditional therapeutic approaches), can prevent them from being open to use strategies or technologies that deviate from their usual practice. This phenomenon has been previously described as resistance to change [58], and it is one of the main reasons why novel approaches in the treatment of several conditions remain underused [59].

Similarly, patients mentioned wanting a thorough explanation regarding how the skills trained in programs such as bWell-D can extrapolate to the real world. To this end, psychoeducation has been identified as a key component in the treatment of depression [60], which could address the utility of training cognitive skills as a means to achieve recovery. This psychoeducation component has been found useful by patients in previous studies, such as the study by Lindner et al [61]. It is worth mentioning that 3 of the younger participants considered the VR tasks too infantile or simple to relieve cognitive symptoms of depression, which could be an indication of a generational preference regarding the type of tasks offered through bWell-D. As a result, the inclusion of realistic paraphernalia in the VR environments, as well as the increasing difficulty of the tasks, can potentially address these concerns.

Patients also commented regarding the need of a customizable VR treatment in which they could decide over how, when, and where the treatment was conducted. There was a strong preference for doing the treatment individually at home, because this was considered the most convenient modality for patients. Although considering patients' opinions within any psychiatric or psychological intervention is essential, clinicians should be mindful regarding not losing key components of the intervention when accommodating patients' preferences. By doing so, clinicians might be drifting away from best practice, preventing patients of receiving the best treatment available [62].

There was an overall positive perception toward VR interventions for depression and other mental health conditions, and toward bWell-D itself. Participants indicated that they would use this type of treatment if available, and this acceptance was mainly motivated by the fact that a VR intervention was perceived as a treatment with no adverse long-lasting consequences or side effects. Participants believed that, in the worst-case scenario, the treatment may not improve their cognitive skills but would not worsen them, which was an advantage when compared with other more conventional treatments, such as medication. This relative safety provided by VR treatments can be highly beneficial by end users, given that, besides the economical investment, there are little to no risks associated with this treatment. However, the accessibility concerns manifested by end users should be a consideration for implementation and future directions in the bWell-D development process, given that currently there are no clear plans regarding how this treatment will be made available for clinicians and patients.

This study shares some specific findings with previous literature. In the study by Kramer et al [63], clinicians also indicated a need for more empirical evidence to support the use of VR as an assessment or therapeutic tool, and they also expressed a concern regarding how the use of VR faces challenges regarding its adoption and assimilation. In the study by Thompson et al [64], participants were also worried regarding technological difficulties, mentioning how they might not have access to the necessary equipment to undertake the treatment, and how including a VR intervention in their routine might interfere with patients' schedules. The lack of perceived adverse effects was also highlighted in the study by Nason et al [65], in which patients experienced only minimal motion sickness. As in our own study, Krebs et al [66] found that relatable humanoid avatars are important in virtual environments, given that they promote the suspension of disbelief, which is the key difference between a gamified intervention and a more traditional one. The results of our research join the large body of studies in which VR interventions for mental health issues are perceived positively by end users [67-69]. However, to the best of our knowledge, this is the first study that analyses qualitatively the use of cognitive remediation for cognitive symptoms of depression.

Limitations and Strengths

This research had some limitations. Further insights might have been obtained from participants if they have had hands-on experience with bWell-D, instead of watching prerecorded samples. While it was initially intended that participants would trial bWell-D before completing the qualitative interview, COVID-19 pandemic restrictions prohibited on-site testing during the data collection period, necessitating the change to the virtual format used here. Related to these COVID-19 pandemic restrictions, patient participants were recruited through various web-based sources and self-reported their depression symptoms. Future studies might benefit from in-person assessments in which a health care professional administers the clinical questionnaires. In addition, most of the clinician sample did not have practical experience with cognitive remediation, clinicians with direct experience could have clearer expectations of a VR cognitive remediation treatment and may have therefore provided more extensive feedback. The sample included both people who were still working or in school but had depression-related impairments, as well as people who were off work—these 2 groups might conceivably have different concerns and needs from cognitive remediation. Finally, the clinician sample was formed mostly by psychiatrists working in outpatient settings—a more diverse clinician sample might have provided broader perspectives regarding the use of cognitive remediation and VR for depression. In terms of strengths, this is, to our knowledge, the first study that focused on obtaining end-user feedback regarding a VR intervention for cognitive symptoms of depression with a qualitative approach. We were able to obtain rich and extensive feedback from a varied sample that included patients from a wide range of ages, backgrounds, and genders, which offers an inclusive and comprehensive perspective toward the use of VR and cognitive remediation. Finally, reinterviewing the participants reaffirmed the relevance of the changes made to the program and enhanced the user-centered design, which will continue to be central in the iterative process of bWell-D development until its application in clinical populations.

Conclusions

Virtual interventions for the improvement of cognitive symptoms in depression are generally acceptable and potentially feasible for patients and clinicians. Although VR and its use for the treatment of health-related conditions is relatively new, participants were familiar with it and open to try it, given its perceived safety. They were curious regarding a treatment of this nature and saw potential in its implementation. Participants considered it to be important to have realistic virtual settings, tasks, and cues to enhance the extrapolability of the skills trained in the VR program. The virtual format of this intervention was perceived as an advantage, and participants believed it offered a versatile and fun alternative to conventional depression treatments. Patients' own needs and preferences should be considered when implementing a VR treatment for psychiatric conditions, and all efforts should be made to make it more accessible and convenient for end users.

Conflicts of Interest

IT has received research funding from the Michael Smith Health Research and BC Schizophrenia Society Foundation and Canadian Institutes of Health Research, and has served as consultant for Lundbeck Canada, Sumitomo Dainippon, Boehringer Ingelheim, and Community Living British Columbia. RWL has received honoraria for ad hoc speaking or advising and consulting, or received research funds, from Abbvie, Asia-Pacific Economic Cooperation, Bausch, BC Leading Edge Foundation, Brain Canada, Canadian Institutes of Health Research, Canadian Network for Mood and Anxiety Treatments, CAN-BIND Solutions, Carnot, Grand Challenges Canada, Healthy Minds Canada, Janssen, Lundbeck, Lundbeck Institute, Medscape, Michael Smith Foundation for Health Research, MITACS, Neurotorium, Ontario Brain Institute, Otsuka, Pfizer and Viatris, Shanghai Mental Health Center, Sunnybrook Health Sciences Center, Unity Health, Vancouver Coastal Health Research Institute, and the Vancouver General Hospital-University of British Columbia Hospital Foundation. TC has received grant funding from the Michael Smith Foundation for Health Research, and the National Research Council Canada.

Multimedia Appendix 1
Interview scripts.
[PDF File (Adobe PDF File), 229 KB - games_v11i1e43904_app1.pdf]

Multimedia Appendix 2
Modifications made to bWell-D tasks after end-user feedback - Overview.
[PDF File (Adobe PDF File), 124 KB - games_v11i1e43904_app2.pdf]

Multimedia Appendix 3
Changes made to bWell-D - Description.
[PDF File (Adobe PDF File), 102 KB - games_v11i1e43904_app3.pdf]

Multimedia Appendix 4
Examples of modifications made to bWell-D after end-user feedback - Screenshots.
[PDF File (Adobe PDF File), 46552 KB - games_v11i1e43904_app4.pdf]

Multimedia Appendix 5
Re-interview script.
[PDF File (Adobe PDF File), 162 KB - games_v11i1e43904_app5.pdf]

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Abbreviations

MDD: major depressive disorder
VR: virtual reality

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Original Paper

Effectiveness of a Personalized, Chess-Based Training Serious Video Game in the Treatment of Adolescents and Young Adults With Attention-Deficit/Hyperactivity Disorder: Randomized Controlled Trial

María Rodrigo-Yanguas[1,2*], PhD; Marina Martín-Moratinos[1,2*], MSc; Carlos González-Tardón[3], PhD; Fernando Sanchez-Sanchez[4], MSc; Ana Royuela[5,6], PhD; Marcos Bella-Fernández[1,7,8], MSc; Hilario Blasco-Fontecilla[1,2,9,10], MD, PhD

[1]Servicio de Psiquiatría, Hospital Universitario Puerta de Hierro Majadahonda, Majadahonda, Spain
[2]Facultad de Medicina, Universidad Autónoma de Madrid, Madrid, Spain
[3]Universidad de Diseño y Tecnología, Madrid, Spain
[4]R&D Department, Hogrefe TEA Ediciones, Madrid, Spain
[5]Biostatistics Unit, Hospital Universitario Puerta de Hierro Majadahonda, Madrid, Spain
[6]Consorcio de Investigación Biomédica en Red: Epidemiología y Salud Pública, Madrid, Spain
[7]Facultad de Psicología, Universidad Autónoma de Madrid, Madrid, Spain
[8]Departamento de Psicología, Universidad Pontificia de Comillas, Madrid, Spain
[9]Consorcio de Investigación Biomédica en Red: Salud Mental, Madrid, Spain
[10]Ita Mental Health, Madrid, Spain
[*]these authors contributed equally

Corresponding Author:
Hilario Blasco-Fontecilla, MD, PhD
Servicio de Psiquiatría, Hospital Universitario Puerta de Hierro Majadahonda
C/ Manuel de Falla s/n
Majadahonda, 28222
Spain
Phone: 34 911911690
Email: hmblasco@yahoo.es

Abstract

Background: Compared with traditional approaches, gaming strategies are promising interventions for the treatment of attention-deficit/hyperactivity disorder (ADHD). We developed a serious game, The Secret Trail of Moon (TSTM), for ADHD treatment.

Objective: The main objective of this clinical trial was to demonstrate the effectiveness of an add-on, either TSTM or Therapeutic Chess (TC), in previously optimally drug-titrated, clinically stable patients with ADHD.

Methods: This study is a prospective, unicentric, randomized clinical trial in clinically stable patients with ADHD, aged 12 to 22 years. The TSTM (n=35) and TC groups (n=34) performed 12 weekly sessions of their respective treatments. The control group (CG) patients (n=35) were called by phone every week, but they received no cognitive intervention. The primary end point was the change from baseline to end point in the parent “Behavior Rating Inventory of Executive Function-2” (BRIEF-2; patients’ parents) in the per-protocol population (31 serious videogame: 24 TC and 34 CG).

Results: Our study failed to probe clear-cut improvements in the global score of the BRIEF-2. However, the TC group showed improvements in measures of emotional control, emotional regulation, and inattention. The TSTM group showed improvements in measures of emotional regulation, inattention, and school context.

Conclusions: TSTM and TC did not improve executive function symptoms, but they improved ADHD symptomatology related to emotional regulation. Further studies with bigger samples are required to confirm these preliminary findings.

Trial Registration: ClinicalTrials.gov NCT04355065; https://clinicaltrials.gov/ct2/show/NCT04355065

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KEYWORDS

attention-deficit hyperactivity disorder; ADHD; serious video games; cognitive training; chess; video game; teen; young adult; game; intervention; treatment; emotional; control; regulation; attention; school; function; symptom

Introduction

Attention-deficit/hyperactivity disorder (ADHD) is the most frequent neurobehavioral disorder, with a worldwide prevalence of 4% to 8% [1,2] and a relative risk of 3:1 against males [3]. ADHD is multicausal; about 70% is due to genetic factors, and the other 30% is due to environmental factors [4]. It is characterized by the presence of 3 core symptoms: inattention, hyperactivity, and impulsivity. These symptoms must be present in 2 or more contexts and interfere with daily functioning [5,6]. Furthermore, patients with ADHD experience a main deficit in prefrontal and anterior areas [7,8], the inferior parietal lobe, supramarginal gyrus, basal ganglia, and premotor area. Deficiencies in both executive functions [9-13] and emotional intelligence [4,14] are critically involved with ADHD.

Reference guides recommend multimodal treatment for ADHD: pharmacological intervention and behavioral therapy—behavioral training (BT) for parents and organizational training for adolescents and adults or a combination [4,15,16]. Unfortunately, multimodal treatment is not always sufficient for the treatment of ADHD symptoms [17,18]. The literature on the efficacy of cognitive behavioral therapy in ADHD is still equivocal, although some trials focused on organizational training in adolescents and adults showed promising results [19-21]. Cognitive behavioral therapy is not recommended in children younger than 10 years. Accordingly, novel strategies are warranted [22-24]. For instance, BTs are the most recommended psychological treatments for ADHD [25]. BTs are aimed at stimulating executive functions, among others [26]. Unfortunately, BTs are financially expensive and may be monotonous for adolescent patients [27]. To address these handicaps, some therapists have begun to use gaming strategies, such as (1) traditional board games like chess [28-30] and Go [31], (2) 2D video games [32-36], and (3) virtual reality serious video games [37-39]. Indeed, in a recent clinical trial including 857 children with ADHD, the patients randomized to Akili Interactive—the first videogame that can be prescribed to patients with ADHD—improved more than those who were randomized to the digital control intervention group [40]. Compared with traditional therapies, gaming strategies have several advantages, such as increased engagement, lower costs [28,41-44], and improved performance [45].

In this context, we developed The Secret Trail of Moon (TSTM), a virtual reality chess-based serious video game aimed at improving attention, impulse control, visuospatial capacity, planning, self-regulation, working memory, reasoning, and cognitive flexibility. TSTM is innovative, motivating, and customizable; it is fun, easy to understand and play, displays enjoyable graphics, and has adequate duration for most participants [39].

This study is aimed at comparing the effectiveness of 2 cognitive gaming strategies in previously optimally drug-titrated, clinically stable patients with ADHD: (1) electronic Therapeutic Chess (TC); and (2) TSTM. Recently, we published the protocol study of our add-on clinical trial [46]. Basically, the TC group received chess lessons and had to solve both traditional chess exercises (related to the video tutorial for each week) and TC exercises. These exercises use the pieces and board but can be done without knowing how to play chess [46]. The control group (CG) received no specific cognitive intervention. We hypothesized that patients randomized to either TSTM or TC, compared to the CG group, would improve in executive functions and ADHD core symptoms.

Methods

Study Design

The study protocol (registered on the ClinicalTrials website: NCT04355065) is published elsewhere [46], but it is basically a prospective, unicentric, randomized, non-equality trial in 105 patients with ADHD. All participants were clinically stable before baseline. Subjects were randomized into 3 groups: TC group (electronic cognitive training with TC), TSTM group (cognitive training using TSTM), and CG (patients were called by phone every week, but they received no cognitive intervention). The allocation ratio was equal in all 3 groups (n=35 per branch).

Ethics Approval

The study was approved by the Ethics Committee of the Puerta de Hierro University Hospital in Majadahonda on December 2, 2019 (PI 187/19).

Study Population

The clinical trial included children, adolescents, and young adults between the ages of 12 and 22 years (mean age 14.38, SD 2.26 years). The minimum participation age was 12 because virtual reality is discouraged for children younger than 12 years. The maximum age was 22 because brain maturation continues until that age, approximately [47,48]. Furthermore, adolescent patients admitted in Child and Adolescent Psychiatry units are progressively referred to be followed up in Adult Psychiatry services, which means that patients up to the age of 20 (and occasionally 22) years are already followed up in Child and Adolescent Psychiatry units [46]. Inclusion criteria were as follows: adolescents or young adults between the ages of 12 and 22 years with a diagnosis of ADHD and clinically stable on any medication related to ADHD, meaning that participants had a consistent drug prescription and were not allowed to change it during their participation; however, during the trial, 5 participants changed their medication, another 5 participants increased their medication dosages, another 5 participants decreased their medication dosages, and medication was removed for another participant. Exclusion criteria were the following: comorbidities with autism or intellectual disability, epilepsy, or another severe clinical condition; plans to begin another clinical treatment or moving out during the following 3 months; and risk of suicide [46]. A total of 105 patients (35 per group) were recruited for the clinical trial, of which 47 (45.2%) had an inattentive ADHD subtype and 57 (54.8%) had a mixed ADHD subtype.

The participants were recruited between December 18, 2019, and November 16, 2020. The last evaluation was performed on February 6, 2021.

Randomization and Masking

To warrant clinical trial randomization, AR generated a sequence of random numbers through Epidat 4.2 software (Dirección Xeral de Saúde Pública, Xunta de Galicia). The 105 patients were randomly assigned to the 3 groups by HBF following the randomized sequence. Each randomization number was introduced inside a closed, opaque envelope. When a patient came to the hospital to participate in the trial, the inclusion and exclusion criteria were applied to them (one participant was excluded then); the patients and their parents received and signed informed consents, and after the first assessment (D0), each participant received and opened the envelope corresponding to their inclusion number, and the group assigned to that number.

Study Interventions

Visits

The number of visits depended on the group. The TSTM group made 15 in-person visits over 3 months: pre-inclusion visit, inclusion visit (D0), 12 cognitive treatment visits (1 per week) with TSTM, and one final visit (D90).

The TC and CG groups made 3 in-person visits over 3 months: pre-inclusion visit, inclusion visit (D0), and postassessment visit (D90). A total of 12 remote (web- or phone-based) visits were also made during the 3 months.

Interventions

A more detailed description of the intervention groups can be found elsewhere [46]. Basically, the interventions were different for each group, as follows:

- Cognitive intervention with TSTM (TSTM group): TSTM was constructed for 5 different cognitive training mechanisms: smasher, enigma, teka-teki, kuburi, and chess. Each session was divided into 3 blocks (2 blocks for training into 2 different game mechanics and a chess training block). Sessions were personalized in the sense that difficulty levels were adjusted, taking into account individual performance.
- Cognitive intervention with TC (TC group): in the initial visit, each patient received a flash drive containing the 12 training sessions in TC. Every session was divided into 3 parts: video tutorials, traditional chess exercises, and TC exercises.
- Control group intervention (CG group): each patient received 12 phone communications (1 per week). In these communications, they were asked about medication usage, mood, and school performance, among other issues.

Study Outcomes

Primary Outcome

The primary end point was the change from baseline to the end of treatment in the "Behavior Rating Inventory of Executive Function-2" (BRIEF-2) questionnaire filled out by the patients' parents [49,50]. This scale consists of 63 items and 4 main indicators: emotional regulation, cognitive regulation, behavioral regulation, and executive function global index. The design of TSTM is based on cognitive training and task and aimed at improving executive functions [39]. Additionally, TC has shown a certain effect on executive functions [28].

Secondary and Safety Outcomes

Secondary measures were the ATENTO questionnaire [51], with versions for patients and for parents; the emotional intelligence inventory by the BarOn model of Emotional Quotient Inventory (BarOn EQ-i: Youth Version), with a version for younger people [52]; the ADHD rating scale V (ADHD-V); the quantitative scale by Swanson, Nolan, and Pelham (SNAP-IV) [53]; the Conners' Parent Rating Scale (CPRS-HI) [54]; and the Conners' Continuous Performance Test 3 (CPT-3) for computers [55]. In addition, the TSTM group filled out the Udvalg für Kliniske Undersolgester (UKU) questionnaire [56,57].

Statistics

Sample-Size Calculation

Sample sizes were calculated for 80% of statistical power, assuming 2-tailed Student *t* tests for comparison between groups, with a 1:1:1 proportion, assuming a 20% loss. In each group, 35 patients were included (a total of 105 patients).

Analyses

Analyses were performed for two types of populations: analyses for treatment intention (ATI) and analysis per protocol (PP). In ATI, data were analyzed according to the assigned treatment for each patient. In PP, data were analyzed according to the treatment that each patient completed.

A descriptive analysis was performed for qualitative variables using absolute and relative frequencies. For quantitative variables, the median and the quartiles 1 and 3 were used as descriptive statistics.

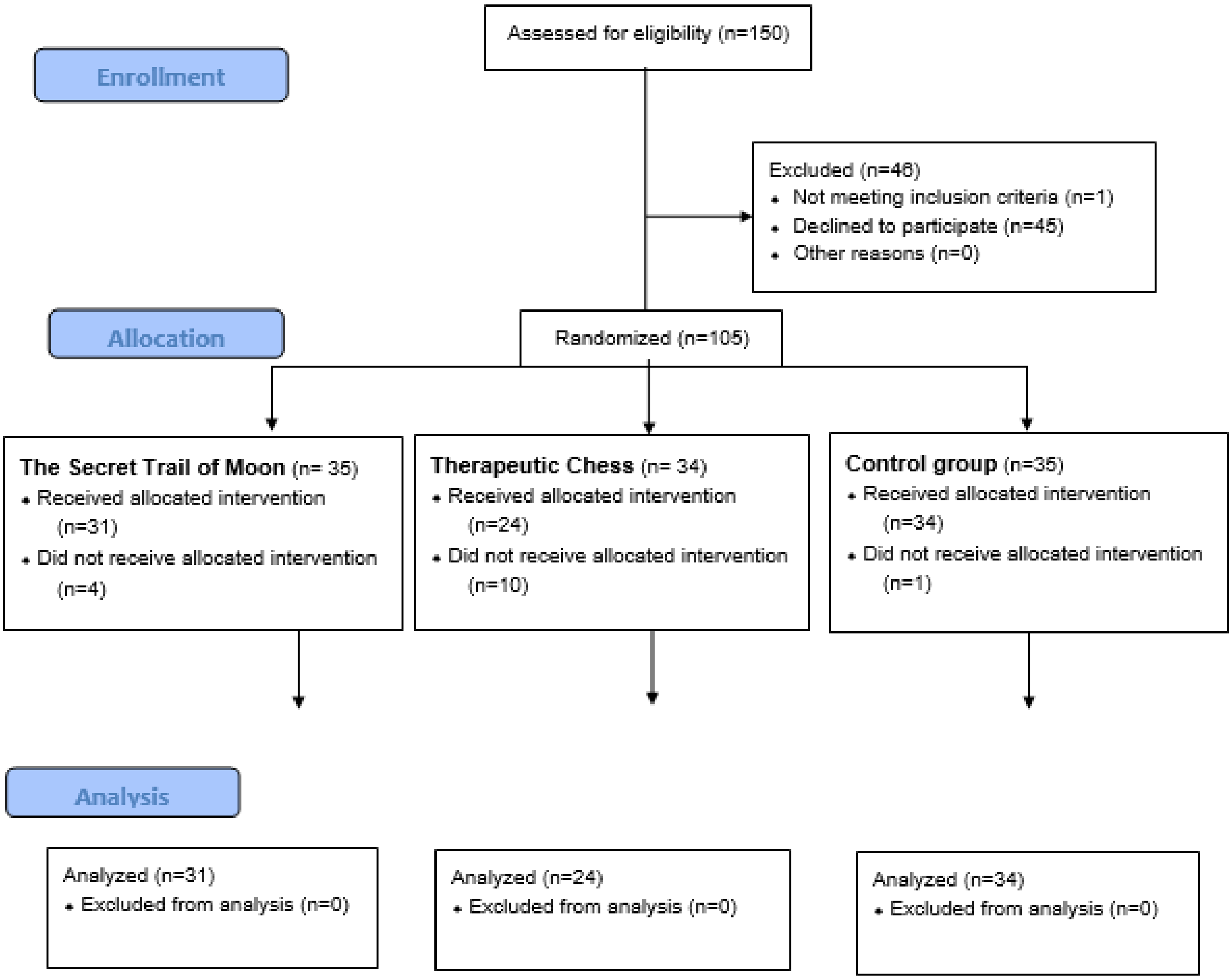
To compare the groups TSTM versus CG and TC versus CG, 2 series of analyses were performed in parallel. To compare the basal and final differences, the Kruskal-Wallis test was performed, as the normality assumption for ANOVAs and *t* tests was generally violated. The signification level was fixed at P=.10 mainly due to the pandemic situation and the early stage of this trial [58]. Subsequently, for those variables reaching statistical significance in Kruskal-Wallis tests, pairwise Mann-Whitney tests were performed to compare pairs of experimental groups. The effect sizes were estimated through ε^2 for Kruskal-Wallis tests and η^2 for Mann-Whitney tests [59]. The statistical package SPSS 26 (IBM Corp) was used to perform the tests. Ultimately, the study was powered to detect an effect of Cohen $d \geq 0.52$ in two-way comparisons.

Results

Patient Inclusion and Randomization

A total of 105 patients agreed to participate in the trial and signed a reported consent form. Ultimately, 1 patient was excluded for having a previously unreported history of epilepsy. The other 104 patients were randomized to one of 3 groups: TSTM (n=35), TC (n=34), and CG (n=35). Figure 1 shows a flow diagram describing in detail the number of participants in each trial stage.

Figure 1. CONSORT Flow Diagram for the number of participants in each stage of the trial.



Baseline Characteristics

In the PP population at D90, participants were male in 71.9% (64/89) of the cases (TSTM group: 27/31, 87.1%; TC group: 19/24, 79.2%; and CG: 18/34, 53.1%). The mean ages for the groups were 14.7 (SD 2.4) for TSTM, 13.8 (SD 1.9) for TC, and 14.8 (SD 2.4) for CG. Table 1 and Table 2 show all the sociodemographic and baseline variables.

Table 1. Sociodemographic and baseline variables for analysis for treatment intention (ATI). Italicized *P* values are significant.

Characteristics	ATI					
	TSTM[a] (n=35)	TC[b] (n=34)	CG[c] (n=35)	Chi-square (df)	Kruskal-Wallis (df)	*P* value
Gender (female), n (%)	8 (22.86)	9 (26.47)	16 (45.71)	4.866 (2)	N/A[d]	*.09*
Age (years), mean (SD)	14.7 (2.4)	13.8 (1.9)	14.6 (2.4)	N/A	3.171 (2)	.20
Birthplace (Spain), n (%)	34 (97.14)	29 (85.29)	34 (97.14)	5.188 (2)	N/A	*.08*
Adoption, n (%)				1.992 (4)	N/A	.74
Adopted	2 (5.71)	2 (5.88)	2 (5.71)			
Shelter home	0 (0)	0 (0)	1 (2.86)			
ADHD[e] diagnosed, n (%)				1.771 (2)	N/A	.41
Inattentive	19 (54.29)	14 (41.18)	14 (40)			
Combined	16 (45.71)	20 (58.82)	21 (60)			
Medication, n (%)				17.016 (12)	N/A	.15
Elvanse	24 (68.57)	24 (70.59)	26 (74.29)			
Medikinet	7 (20)	2 (5.88)	3 (8.57)			
Equasym	3 (8.57)	1 (2.94)	2 (5.71)			
Rubricon	1 (2.86)	2 (5.88)	2 (5.71)			
Stratera	0 (0)	3 (8.82)	0 (0)			
Intuniv	0 (0)	1 (2.94)	0 (0)			
Concerta	0 (0)	0 (0)	2 (5.71)			

[a]TSTM: The Secret Trail of Moon.
[b]TC: Therapeutic Chess.
[c]CG: control group.
[d]N/A: not applicable.
[e]ADHD: attention-deficit/hyperactivity disorder.

Table 2. Sociodemographic and baseline variables for analysis per protocol (PP). Italicized *P* values are significant.

Characteristics	PP					
	TSTM[a] (n=31)	TC[b] (n=24)	CG[c] (n=34)	Chi-square (df)	Kruskal-Wallis (df)	*P* value
Gender(female), n (%)	4 (12.9)	5 (20.8)	16 (47.1)	10.222 (2)	N/A[d]	*.006*
Age (years), mean (SD)	14.3 (2.246)	13.81 (1.939)	14.83 (2.479)	N/A	2.310 (2)	.31
Birthplace (Spain), n (%)	30 (96.8)	21 (87.5)	33 (97.1)	2.938 (2)	N/A	.23
Adoption, n (%)				2.316 (4)	N/A	.68
Adopted	1 (3.2)	2 (8.3)	2 (5.9)			
Shelter home	0 (0)	0 (0)	1 (2.9)			
ADHD[e] diagnosed, n (%)				1.800 (2)	N/A	.41
Inattentive	17 (54.8)	11 (45.8)	13 (38.2)			
Combined	14 (45.2)	13 (54.2)	21 (61.8)			
Medication, n (%)				16.8 (10)	N/A	.08
Elvanse	21 (67.74)	15 (62.5)	26 (76.47)			
Medikinet	6 (19.35)	2 (8.33)	3 (8.82)			
Equasym	3 (9.68)	1 (4.17)	2 (5.88)			
Rubricon	0 (0)	2 (8.33)	2 (5.88)			
Stratera	0 (0)	3 (12.5)	0 (0)			
Concerta	0 (0)	0 (0)	2 (5.88)			

[a]TSTM: The Secret Trail of Moon.
[b]TC: Therapeutic Chess.
[c]CG: control group.
[d]N/A: not applicable.
[e]ADHD: attention-deficit/hyperactivity disorder.

The BRIEF-2 questionnaire shows that the TSTM group performed better than the TC and CG groups in "working memory," "planification and organization," and "cognitive regulation" scales, the groups being approximately equal in the rest of the BRIEF-2 scales (Tables S1 and S2 in Multimedia Appendix 1 present descriptive baseline characteristics).

For both primary and secondary outcomes, we calculated individual pre-post differences and used these differences as the dependent variables in our tests.

Primary Outcomes

The goal of this study was ultimately to compare the changes between D0 and D90 in every group as well as the differences among groups. The main measurement for testing the differences were the BRIEF-2 scores, according to the indications already presented elsewhere [46]. The groups were compared through Kruskal-Wallis tests.

ATI showed improvements for the TC group compared to the CG group in "emotional control" and "emotional regulation" ($P<.10$) scores. PP also showed a significant difference in "emotional control" between the TC and CG groups ($P<.10$). None of the rest of the comparisons reached a statistical significance. All tests and significance levels are shown in Tables 3 and Table 4.

Table 3. Kruskal-Wallis tests for primary outcomes (Behavior Rating Inventory of Executive Function-2 [BRIEF-2] scales).

Characteristics	ATI[a] (n=100)			PP[b] (n=89)		
	Kruskal-Wallis	ε^2	*P* value	Kruskal-Wallis	ε^2	*P* value
Inhibition	0.693	0.007	.71	1.039	0.012	.60
Self-supervision	0.255	0.003	.88	0.201	0.002	.90
Flexibility	1.425	0.014	.49	1.891	0.021	.39
Emotional control	4.388	0.044	.11	4.417	0.050	.11
Initiative	0.114	0.001	.95	0.053	0.001	.97
Working memory	0.610	0.006	.74	0.025	<0.001	.99
Planning and organization	0.617	0.006	.73	0.233	0.003	.89
Task supervision	3.055	0.031	.22	2.953	0.034	.23
Material organization	0.301	0.003	.86	0.026	<0.001	.99

[a]ATI: analyses for treatment intention.
[b]PP: per protocol.

Table 4. Kruskal-Wallis tests for BRIEF-2 Indexes.

Characteristics	ATI[a] (n=100)			PP[b] (n=89)		
	Kruskal-Wallis	ε^2	*P* value	Kruskal-Wallis	ε^2	*P* value
Behavioral regulation	0.496	0.005	.78	1.286	0.015	.53
Emotional regulation	3.090	0.031	.21	2.920	0.033	.23
Cognitive regulation	1.808	0.018	.41	0.718	0.008	.70
Global executive function	1.435	0.014	.49	0.926	0.011	.63

[a]ATI: analyses for treatment intention.
[b]PP: per protocol.

Secondary Outcomes

Analyses for secondary outcomes were performed in the PP population. Table 5 shows all the tests and significance levels for the secondary outcomes. Table 5 highlights those variables that reached significance in Kruskal-Wallis tests and the pairwise comparisons between the three trial groups.

Table 5. Kruskal-Wallis tests for secondary outcomes (only for PP). The italicized *P* values are significant.

Characteristics	Kruskal-Wallis	ε^2	*P* value
SNAP-IV[a]: inattention	2.859	0.032	.24
SNAP-IV: hyperactivity	0.231	0.003	.89
SNAP-IV: total	1.218	0.014	.54
ATENTO (self-report): inattention	2.262	0.026	.32
ATENTO (self-report): hyperactivity	1.300	0.015	.52
ATENTO (self-report): attentional control	1.785	0.020	.41
ATENTO (self-report): behavioral regulation	0.975	0.011	.61
ATENTO (self-report): emotional regulation	3.507	0.040	.17
ATENTO (self-report): working memory	0.439	0.005	.80
ATENTO (self-report): flexibility	2.137	0.024	.34
ATENTO (self-report): planning and organization	2.776	0.032	.25
ATENTO (self-report): time orientation	7.170	0.081	*.03*
ATENTO (self-report): behavioral problems	1.942	0.022	.38
ATENTO (self-report): sleeping problems	0.741	0.008	.69
ATENTO (self-report): family context	0.750	0.009	.69
ATENTO (self-report): school context	5.283	0.060	*.07*
ATENTO (self-report): social context	0.431	0.005	.81
ATENTO (family): inattention	0.219	0.002	.90
ATENTO (family): hyperactivity	0.272	0.003	.87
ATENTO (family): attentional control	1.236	0.014	.54
ATENTO (family): behavioral regulation	0.380	0.004	.83
ATENTO (family): emotional regulation	0.799	0.009	.67
ATENTO (family): working memory	1.337	0.015	.51
ATENTO (family): flexibility	2.902	0.033	.23
ATENTO (family): planning and organization	2.563	0.029	.28
ATENTO (family): time orientation	3.521	0.040	.17
ATENTO (family): behavioral problems	3.097	0.035	.21
ATENTO (family): sleeping problems	1.146	0.013	.56
ATENTO (family): family context	2.640	0.030	.27
ATENTO (family): social context	2.230	0.025	.33
EQ-i:YV[b]: positive impression	5.826	0.066	*.05*
EQ-i:YV: mood	2.307	0.026	.32
EQ-i:YV: total emotional intelligence	3.827	0.043	.15
EQ-i:YV: intrapersonal	0.696	0.008	.71
EQ-i:YV: interpersonal	5.002	0.057	*.08*
EQ-i:YV: adaptability	1.909	0.022	.39
EQ-i:YV: stress management	2.772	0.032	.25
CPT-3[c] response style	2.905	0.033	.23
CPT-3 detectability	5.483	0.062	*.06*
CPT-3 omissions	2.552	0.029	.28
CPT-3 commissions	2.369	0.027	.31

Characteristics	Kruskal-Wallis	ε^2	*P* value
CPT-3 perseverations	5.207	0.059	*.07*
CPT-3 reaction times (hits)	4.139	0.047	.13
CPT-3 reaction time variability (hits)	6.465	0.073	*.04*
CPT-3 variability	3.340	0.038	.19
CPT-3 block change	7.605	0.086	*.02*
CPT-3 inter stimulus change	9.007	0.102	*.01*
CPRS[d]	0.884	0.010	.64

[a]SNAP: Swanson, Nolan, and Pelham.
[b]EQ-i:YV Emotional Quotient Inventory: Youth Version.
[c]CPT-3: Continuous Performance Test 3.
[d]CPRS: Conners' Parents Rating Scale.

Table 6. Pairwise Mann-Whitney tests for those variables that reached significance in Tables 3 to 5. The italicized *P* values are significant.

Characteristics	TSTM[a] vs TC[b]				TSTM vs CG[c]				TC vs CG			
	Mann-Whitney test	η^2	*P* value	Direction of difference	Mann-Whitney test	η^2	*P* value	Direction of difference	Mann-Whitney test	η^2	*P* value	Direction of difference
ATENTO (self-report): time orientation	219	0.068	*.01*	TC>TSTM	519	<0.001	.94	—[d]	273	0.058	*.02*	TC>CG
ATENTO (self-report): school context	315	0.007	.43	—	357.5	0.055	*.03*	TSTM>CG	328.5	0.023	.16	—
EQ-i:YV[e]: positive impression	261	0.034	*.08*	TC>TSTM	351	0.060	*.02*	CG>TSTM	402	0.001	.78	—
EQ-i:YV: interpersonal	340	0.001	.73	—	397.5	0.032	*.09*	CG>TSTM	286.5	0.048	.04	—
Conners' CPT-3[f] detectability	219	0.068	*.01*	TC>TSTM	428.5	0.018	.20	—	356.5	0.011	.33	—
Conners' CPT-3 perseverations	234	0.056	*.03*	TC>TSTM	427.5	0.019	.19	—	348.5	0.015	.25	—
Conners' CPT-3 reaction time variability (hits)	224	0.063	*.02*	TC>TSTM	402.5	0.029	.11	—	335	0.019	.19	—
Conners' CPT-3 block change	290	0.017	.22	—	370.5	0.047	*.04*	CG>TSTM	265.5	0.064	.02	CG>TC
Conners' CPT-3 inter stimulus change	215.5	0.071	*.01*	TC>TSTM	334	0.071	*.01*	CG>TSTM	359	0.010	.35	—

[a]TSTM: The Secret Trail of Moon.
[b]TC: Therapeutic Chess.
[c]CG: control group.
[d]Not applicable.
[e]EQ-i:YV Emotional Quotient Inventory: Youth Version.
[f]CPT-3: Continuous Performance Test 3.

According to the protocol study of our add-on clinical trial [46], scores on ADHD-5, CPRS, SNAP-IV, ATENTO, BarOn EQ-i:YV, and CPT-3 tests are considered secondary end point analyses. The groups were compared by means of Kruskal-Wallis tests and, subsequently, Mann-Whitney tests. Neither SNAP-IV nor CPRS-HI scores showed significant differences between CG and any of the other groups. ATENTO (parents' reports) showed no significant differences between the CG and the other groups.

ATENTO (self-report) scores showed a significant difference between the TSTM and CG groups in "school context" (P<.10). Additionally, the TC group showed a statistically significant difference with the CG in "time orientation" measures. None of the other comparisons reached statistical significance.

BarOn EQ-i:YV scores showed statistically significant differences between the TSTM and CG groups in "positive impression" on the interpersonal scales (P<.10). None of the remaining comparisons reached statistical significance.

CPT-3 scores showed differential improvements in "block change" and "inter stimulus change" in the TSTM group compared with the control group and differences in improvements in "block change" between the TC and control groups (P<.10). None of the other comparisons reached statistical significance.

Discussion

Principal Findings

This prospective, unicentric, randomized study in clinically drug-stable children with ADHD did not confirm our hypothesis that using an augmentation strategy (either TSTM or TC) may improve executive functions as measured by the BRIEF-2 total scores. An exception was the improvement in emotional control and regulation as measured by the BRIEF-2 in the TC group. Furthermore, significant pre-post symptom reductions were found for several scales measuring secondary end points, and they differ depending on the type of intervention (as explained in the following sections).

TSTM

We found no improvements in executive functioning after using TSTM. This finding is consistent with literature using other serious video games such as ACTIVATE [60] or Plan-It Commander [61]. However, this last video game demonstrated improvements in working memory and planification skills, which have not been observed in our study. In addition, a recent review found that some video games may be beneficial for executive function training in patients with ADHD [62].

However, we found that the TSTM group showed better posttreatment scores in core ADHD symptoms, in particular inattentive symptoms, compared to the CG, mainly in self-reported tests. Moreover, parents reported improvements in social and school skills, consistent with results coming from studies using other serious video games like Plan-It Commander [61] and ThinkRx [63].

But the most relevant finding is that the TSTM group, compared to the CG, showed some improvement in some emotional domains. Both self-reports and parent reports provided better scores on scales related to emotional intelligence, emotional regulation, and performance in school context compared to the CG, which is in keeping with some other literature [64-67]. Better than a purely cognitive tool, the TSTM video game may serve as a way to train and improve self-regulation and social skills through facing challenging problems and competitions with a social component.

TC

As was the case with TSTM, we did not find any improvement in the TC group when compared with the CG, with the remarkable exception of emotional control and regulation. This negative finding is in contradiction with several studies reporting improvements in executive functioning using a therapy based on board games (eg, chess and Go) [31]. Demily et al [68] reported that patients with schizophrenia who played chess for just 10 sessions improved executive functioning (z=–3.41). Finally, a recent systematic review and meta-analysis suggested that some of these board games may improve self-efficacy, attitudes, social functioning, and executive functions [69]. Our negative findings might be explained either by differences in the studied populations (the studies were devoted to patients with diagnoses apart from ADHD) or that TC was implemented electronically.

However, core ADHD symptoms benefited from TC. In particular, inattentive symptoms improved most in the TC group when compared with the CG. This result is consistent with that obtained in a pilot study using chess in children with ADHD [28]. Furthermore, as was the case with TSTM, the greatest improvements obtained by TC training were in the emotional and interpersonal spheres. Significantly better improvements were shown in emotional intelligence, emotional regulation and control, as well as interpersonal scales, as measured by the BRIEF-2 and BarOn EQ-i:YV scores. Our findings are in keeping with previous studies reporting that chess training has shown good results in emotional intelligence development [30,70].

Strengths and Limitations

The main strength of this study is the use of 2 gaming strategies for treating ADHD, following an add-on strategy with clinically stable patients; one of them was disruptive—the use of a serious video game (TSTM)—and the other (TC) was more traditional, thus allowing for testing the effectiveness of each tool in executive functions and ADHD core symptoms. In contrast, the main limitation was the irruption of the COVID-19 pandemic, which impacted the clinical trial, as some patients randomized to the TSTM group had more difficulty completing the cognitive training sessions. Another limitation was the use of just one TSTM session per week in the TSTM group, which may have limited the effectiveness of this cognitive training. Accordingly, we plan to include a 2-3 session-per-week strategy in the next clinical trial using TSTM, scheduled to begin in April 2023. Furthermore, the evaluation was not blind and was based on clinical judgment and either self-report or parental reports. However, previous work states that teachers, rather than parents, tend to be the most reliable external observers of ADHD symptoms in children [71]. Furthermore, we used the CPT-3 to have an objective measure of our results. Another limitation was the difference between the ATI and the PP populations. Samples sizes for the groups were not very different, but a potential survival bias may have conditioned our results. It is possible that adherence to treatment was conditioned by the differential attractiveness of the video game and TC, that is, children who like video games or chess were more likely to complete the trial, and that could bias the results for the PP population. Indeed, in the PP analyses, fewer patients finished the TC intervention in the TC group. It is possible that only those patients with ADHD who were motivated or who liked chess finished the treatment, thus biasing our results in the TC arm. Another difference is the alternate location of the TSTM treatment, administered in our hospital, compared to the TC treatment, self-administered at the patients' homes. Moreover, a possible limitation is the use of drug-stable samples; perhaps the effects of playing serious video games or TC may be more prominent in patients without a stable pharmacological treatment. Furthermore, to have clinical samples as representative and general as possible, we recruited participants in a wide age range, but our samples were not large enough to allow for analyses across developmental stages; future research should study in depth the differential effects across ages. Finally, the lack of a long-term follow-up approach kept us from studying the maintenance of any beneficial effect over time.

Conclusions

Neither TSTM nor TC produced a significant improvement in the executive functioning of patients with ADHD who were clinically stable on ADHD drugs. However, both TSTM and TC produced a significant improvement in some ADHD symptoms, particularly in emotional regulation areas. Further studies are warranted to extend these preliminary but motivating findings.

Acknowledgments

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Authors' Contributions

MRY and MMM conceptualized the study and were in charge of the software, investigation, data curation, writing the original draft, and funding acquisition. MMM also reviewed and edited the manuscript. CGT contributed to the conceptualization and the software.

FSS provided resources. AR conducted the methodology, formal analysis, and data curation. MBF contributed to the formal analysis as well as writing, reviewing, and editing the manuscript. HBF conceptualized the study; provided resources; contributed to the writing, reviewing, and editing the manuscript; supervised the study; and was also in charge of funding acquisition.

Conflicts of Interest

In the last 24 months, HBF has received lecture fees from Shire. He is the principal investigator (PI) of an iPFIS (Contratos Predoctorales de Formación e Investigación en Salud) research contract (Instituto de Salud Carlos III; IFI16/00039) and the co-PI of a MINECO research grant (RTI2018-101857-B-I00); he is the recipient of (1) a grant from the Fundación para la Innovación y la Prospectiva en Salud en España and (2) an intensification grant from Puerta de Hierro Health Research Institute-Segovia de Arana; involved in 2 clinical trials (Mensia Koala, NEWROFEED Study; ESKETSUI2002); and the cofounder and CEO of Haglaia Solutions. He is also an employee and member of the advisory board of Ita Salud Mental (Korian). MMM is the recipient of a grant from the Centro para el Desarrollo Tecnológico y la Innovación, funded by the European Fund for Regional Development (IDI-20180701; file 00107278). The remaining authors do not have any conflicts of interest.

Editorial notice: This randomized study was only retrospectively registered, as the authors thought it to be registered, but after starting the trial realized that it had not been registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low and the study was considered formative, guiding the development of the application. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
Descriptive baseline characteristics.
[DOCX File , 23 KB - games_v11i1e39874_app1.docx]

Multimedia Appendix 2
CONSORT e-Health checklist.
[PDF File (Adobe PDF File), 75 KB - games_v11i1e39874_app2.pdf]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ATI: analyses for treatment intention
BRIEF-2: Behavior Rating Inventory of Executive Function-2
CG: control group
CPRS: Conners' Parent Rating Scale
CPT-3: Continuous Performance Test 3
EQ-i: YV Emotional Quotient Inventory: Youth Version
PP: per protocol
TC: Therapeutic Chess
TSTM: The Secret Trail of Moon
UKU: Udvalg für Kliniske Undersolgester

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Original Paper

Serious Game for the Screening of Central Auditory Processing Disorder in School-Age Children: Development and Validation Study

Ana-Marta Gabaldón-Pérez[1], MSc; María Dolón-Poza[1], MSc; Martina Eckert[2], PhD; Nuria Máximo-Bocanegra[3], PhD; María-Luisa Martín-Ruiz[1], PhD; Iván Pau De La Cruz[1], PhD

[1]Grupo de Investigación Innovación Tecnológica para las Personas (InnoTep), Departamento de Ingeniería Telemática y Electrónica, ETSIS de Telecomunicación, Campus Sur, Universidad Politécnica de Madrid, Madrid, Spain

[2]Centro de Investigación en Tecnologías Software y Sistemas Multimedia para la Sostenibilidad (CITSEM), Universidad Politécnica de Madrid, Madrid, Spain

[3]Department of Physiotherapy, Occupational Therapy, Rehabilitation, and Physical Medicine, Faculty of Health Sciences, Universidad Rey Juan Carlos, Madrid, Spain

Corresponding Author:
María-Luisa Martín-Ruiz, PhD
Grupo de Investigación Innovación Tecnológica para las Personas (InnoTep)
Departamento de Ingeniería Telemática y Electrónica
ETSIS de Telecomunicación, Campus Sur, Universidad Politécnica de Madrid
Calle Nikola Tesla
Madrid, 28031
Spain
Phone: 34 910673316
Email: marialuisa.martinr@upm.es

Abstract

Background: Currently, many central auditory processing disorder screening tests are available for children, and serious games (SGs) are frequently used as a tool for the diagnosis of different neural deficits and disorders in health care. However, it has not been possible to find a proposal that unifies both ideas. In addition, the validation and improvement of SGs, in general, does not take into account the player-game interaction, thus omitting valuable information about the playability and usability of the game.

Objective: This study presented Amalia's Planet, a game conceived for use in school environments, which allows a first assessment of a child through their performance of the proposed tasks related to different aspects of auditory performance. In addition, the game defines a series of events in relation to the execution of the tasks, which were evaluated for the subsequent optimization of its performance and the improvement of its usability.

Methods: Using screening tools based on the use of SG technologies, a total of 87 school-age children were evaluated to test the various hypotheses proposed in this study. By grouping users according to whether they had personal history of hearing pathologies, the discriminant power, playability, and usability of the final solution were examined using traditional statistical techniques and process mining (PM) algorithms.

Results: With a confidence level of 80% for test 2 (P=.19), there was no statistical evidence to reject the null hypothesis that a player's performance is affected by whether the player had a previous auditory pathology. Furthermore, the tool allowed the screening of 2 players initially categorized as *healthy* because of their low level of performance in the tests and the similarity of their behavior with that of the group of children with a previous pathology. With regard to the validation of the proposed solution, the use of PM techniques made it possible to detect the existence of events that lasted too long, which can lead to player frustration, and to discover small structural flaws in the game.

Conclusions: SGs seem to be an appropriate tool for the screening of children at risk of central auditory processing disorder. Moreover, the set of PM techniques provides a reliable source of information regarding the playability and usability of the solution to the development team, allowing its continuous optimization.

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KEYWORDS

serious games; central auditory processing disorder; process mining; screening; school environment; children

Introduction

Goal of This Study

Owing to their high degree of neuroplasticity, children and young people can be highly influenced by the stimuli they receive from the environment around them. Given the nature of central auditory processing disorder (CAPD), it is believed that the inclusion of auditory stimulation may lead to functional changes in the individual's central auditory nervous system [1]. More specifically, "children come to experience greater and more complex demands on central auditory processing as they face more academically, intellectually and linguistically demanding challenges" [2].

Before the therapeutic treatment of CAPD, it is necessary to carry out a diagnostic or screening process so that the presence of the pathology can be detected, thus facilitating a prognosis and the suppression or reduction of the limitations that it may cause in the patient. Among the diagnostic and rehabilitation tools for different pathologies are the well-known serious games (SGs). According to Piaget [3], "games form a part of the child's intelligence, because they represent the functional or reproductive assimilation of the reality." However, despite the existence of numerous screening tests for CAPD [4] and the more than palpable efficacy of SGs in multiple settings [5], it has not been possible to find a project in which these 2 techniques are unified to support the screening of individuals who may have the disorder in question.

In the field of SGs, there is a wide variety of methodologies that guide the development and validation of such tools according to their purpose [6-8]. Despite this, most game evaluation and optimization processes focus on game performance, omitting a complete analysis of the player-game interaction, which includes other relevant aspects such as playability, usability, and game understanding. At this point, it is important to highlight the fact that the term *usability* refers to "the extent to which a system (product or service) can be used to achieve the goals with effectiveness, efficiency, and satisfaction in a specified use context" [9].

Process mining (PM) techniques can be used to deepen our knowledge about this player-game interaction. PM allows for the discovery of patterns and tendencies, even without previous models, enabling and improving the comprehension of real processes by recording events. "Process Mining aims to discover, monitor, and improve real processes by extracting knowledge from event logs readily available in today's information systems" [10].

In view of this, the main objective of this research was to develop and validate a screening tool for CAPD based on the SGs technology, supporting the diagnosis of the disorder in school-age children. Amalia's Planet was conceived as a game for use in school environments, which allows a first assessment of a child through their achievement of the different proposed tasks related to auditory discrimination, lateralization and localization of sounds, and different aspects of auditory performance. In addition, the game defines a series of events in relation to the execution of the tasks, which were evaluated using PM techniques for the subsequent optimization of its performance and improvement of its usability [11].

It is important to note that throughout this paper, SG is defined according to the study by Tarja et al [12], which stated that an SG is "any game whose main purpose goes beyond the mere entertainment."

Background

The American Speech-Language-Hearing Association uses the term CAPD to refer to deficits in the neural processing of auditory information in the central auditory nervous system not due to higher-order language or cognition, as demonstrated by poor performance in one or more of the skills used to preserve, refine, analyze, modify, organize, and interpret information from the auditory periphery [13].

As indicated in the technical reports published by the Working Group on Auditory Processing Disorders, the process of training the abilities affected by CAPD should be implemented as early as possible, taking advantage of the plasticity and cortical reorganization characteristics of the human brain [13,14]. This principle of action could have a much more positive impact on children because the maturation of the cerebral cortex and creation of neural interconnections occur during childhood. Therefore, from the perspective of the consequent therapeutic process, diagnostic testing or screening for CAPD in school-age children is highly desirable. Undiagnosed children often present with learning disabilities, occasionally mistaken for other pathologies simply because auditory processing problems were not considered.

Currently, there are different tools that allow the observation and subsequent screening and diagnosis of CAPD in individuals. Focusing on children, the Hearing in Noise Test for Children [15] lists a total of 130 sentences to determine the quality of information received by an individual in a noise context. Similarly, the Pediatric Speech Intelligibility test proposes a context of overlapping sounds, with relevant and distracting information being uttered in the same or opposite ears [16,17]. The Test Everyday Attention for Children [18] focuses on the assessment of different aspects of an individual that determine their attention levels [19]. Despite their proven efficacy, all these tests tend to be time-consuming and depend on a high degree of specialization on the part of professionals, which restricts their accessibility for the general child population.

Through the use of SGs, a greater number of children can simultaneously take different screening tests, requiring only the company of their relatives or educators and being able to carry out the activity in a familiar environment. Added to these facilities is the fact that because evaluation is performed using a game, the child is stimulated during the process. Finally, another notable advantage of the use of these technologies is that they allow for their evaluation and consequent evolution, making it possible to add different criteria or informative factors in the future as well as to optimize the existing ones. Despite these advantages and the existence of some games focused on the therapeutic process of CAPD, it has not been possible to find a game with these characteristics for the screening of children with CAPD [20-23].

The self-evaluation feature and potential evolution of the games are made possible by the validation process carried out after the use of the games by the end users. During this process, the characteristics of the tool, such as its playability, usability, and discriminating power, must be evaluated. Owing to the lack of publications related to the generation of CAPD-screening SGs for children, different methodologies proposed for the development and validation of this type of technology in the health field have been reviewed. However, most of them base the validation of the tool on performance indicators without assessing aspects of the individual or the tool that may alter the value of these parameters. In the first place, Verschueren et al [24] generated a framework for the conception of SGs for health. This framework was created to ensure that the final product is relevant, theoretically driven, and evidence based through 5 stages. More centered on auditory impairments, Cano et al [25] carried out an exhaustive study of different methodologies for the conception of SGs. According to the authors, all methodologies lacked a register of the player's learning in a quantitative manner. After learning about the successes and failures of these methodologies, they created the *metodología para la concepción de juegos serios para niños con discapacidad auditiva* (MECONESIS) methodology. MECONESIS is a methodology consisting of 4 stages, namely analysis, preproduction, production, postproduction, and is based on 6 models, namely the analysis, user, pedagogical objective, task, scenario, and validation models.

Among the methodologies that take into account the player-game interaction, the one proposed by Serrano et al [26] in 2014 stands out. The authors proposed a "framework to improve evaluation in educational games." On the basis of learning analytics and game analytics techniques, the authors suggest a Learning Analytic Model and Learning Analytic System, in which the authors point to some events carried out by players on a graphical interface, the evolution of game stages, and even some logic events. Despite all these sources of information, no tool or model capable of analyzing the collected information was provided.

PM, as a set of techniques designed to extract information from existing data in activity log files, draws on the so-called *event logs* or *game events* from different systems, allows them to be cleaned, establishes contextual relationships, and presents them graphically to facilitate decision-making [27]. This tool provides great advantages to those who use it, among which 3 are worth highlighting in this study [9,28]:

1. PM is based on real events; therefore, the information collected and analyzed is a reflection of reality. It is obvious that, in general, when extracting information for reaching a series of conclusions, the aim is to gather information that is as representative of reality as possible. However, traditional statistical techniques, for example, try to extract such information from a sample of a specific population (sampling techniques). That is, a sampling behavior is generalized to the entire population. In addition, statistics have techniques for the elimination of so-called missing values and outliers so that their presence does not affect the final conclusions that can be reached. For its part, PM works with all the information collected in the *event logs*, thanks to its high degree of automation. Thus, behaviors are neither generalized nor modified. Atypical behaviors are taken into account and compared with standard or normal behaviors.
2. It includes a set of defined algorithms, which allow complex events to be analyzed and conclusions to be drawn to improve the system. That is, PM provides the capability to analyze and optimize the system. Every system, tool, and environment in its first phase of development and throughout its use must be evaluated and updated for its correct functioning. The aim is not only to optimize the system in terms of performance but also to adapt the system to the end user so that it provides the desired usability.
3. It presents the analyzed information in a visual manner, making it easily understandable by any user, to facilitate the decision-making process.

All these advantages make PM the ideal tool for the future optimization and improvement of the SG proposed in this study.

Methods

Overview

Amalia's Planet was conceived as an SG for use in the school environment, which allows a first detection of children at risk of CAPD through their completion of the different tasks proposed. Therefore, through the game and the proposed activities, schools will be able to perform screening in cases in which there is no suspicion of CAPD or in which such suspicion is not entirely clear. In addition, the game defines a series of events in relation to the execution of the tasks, which were evaluated using PM techniques for the subsequent optimization of its performance and improvement of its usability.

From the aforementioned statement, 2 conclusions regarding the approach to the solution are evident. First, a multidisciplinary team must be assembled to cover the wide variety of fields of expertise required for the correct deployment of the solution. In this regard, the team was composed of 3 engineers; 1 PM expert; 1 occupational therapist; 2 audiologists; and 1 ear, nose, and throat specialist. Second, the development of the solution must be approached from 2 points of view: in terms of the health field, there is a need to develop a screening tool with discriminant power for children at risk of CAPD and, in terms of new technologies and data analysis, there is a need to develop of a game that provides relevant information related to different aspects of playability and usability to allow for its evaluation and subsequent optimization.

Nonetheless, although the existence of the aforementioned 2 approaches (health and technological or analytical) is clear, it should not be forgotten that the proposed solution is one and has to cover all the requirements that have been imposed in each of the 2 approaches. This is why, later in this paper, both approaches are mentioned simultaneously.

Ethics Approval

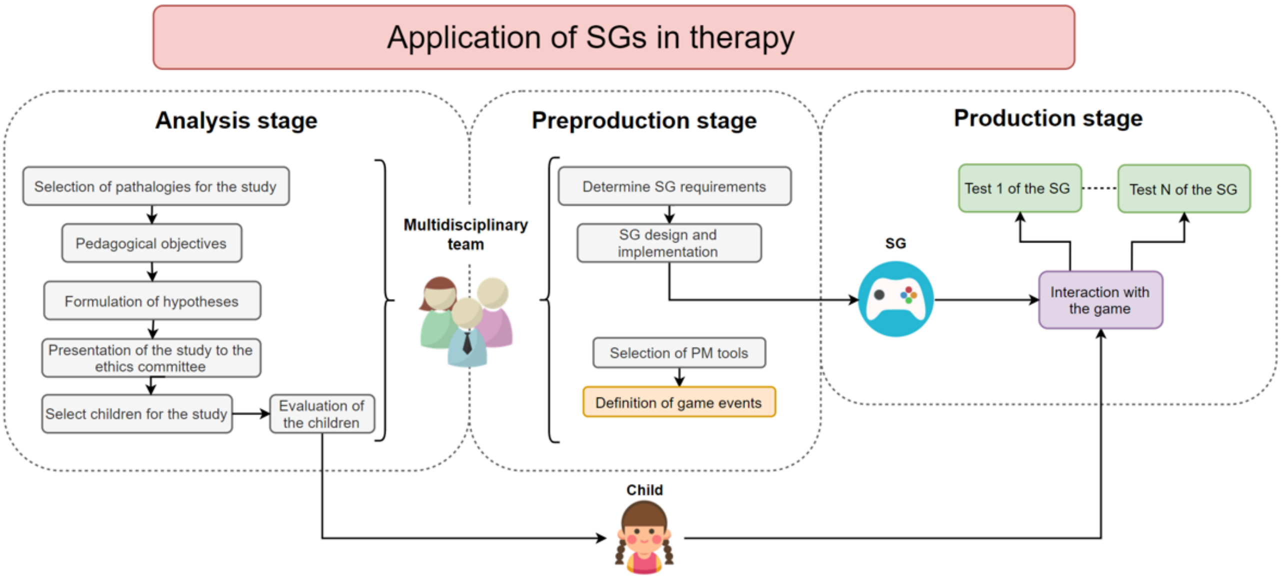
This study was approved by the Ethics Committee of the Rey Juan Carlos University (reference 1203201805218). The trial was conducted in accordance with the Declaration of Helsinki, as amended in October 2013 by the 64th World Medical Association General Assembly [29].

Amalia's Planet for Screening Children at Risk of CAPD

As there is no unified screening method for CAPD, current standard screening methods for CAPD include observing the listening process, recording the patient's behavior, and performing a series of tests that examine the patient's auditory function performance [30]. In general, individuals with CAPD have difficulty discriminating sounds, impaired ability to determine the stimulated ear and location of the sound source, and problems processing nonverbal acoustic signals and recognizing the order or pattern of presentation of certain stimuli [31]. These and other conditions experienced by affected individuals should serve as indicators for the tool so that it can detect the presence of the pathology.

In addition, the proposed solution is oriented toward its use among school-age children. As children are the end users for whom the solution is developed, it should take into account not only the characteristics of the disorder to be studied but also the characteristics of the age range of the users. In other words, the game should present an attractive and a motivating environment for children, making them increase their commitment when interacting with the tool. Figure 1 presents an outline of the process of developing the game as a screening tool.

Figure 1. Phase 1: deployment of a screening tool for school-aged children from a health care perspective. PM: process mining; SG: serious game.

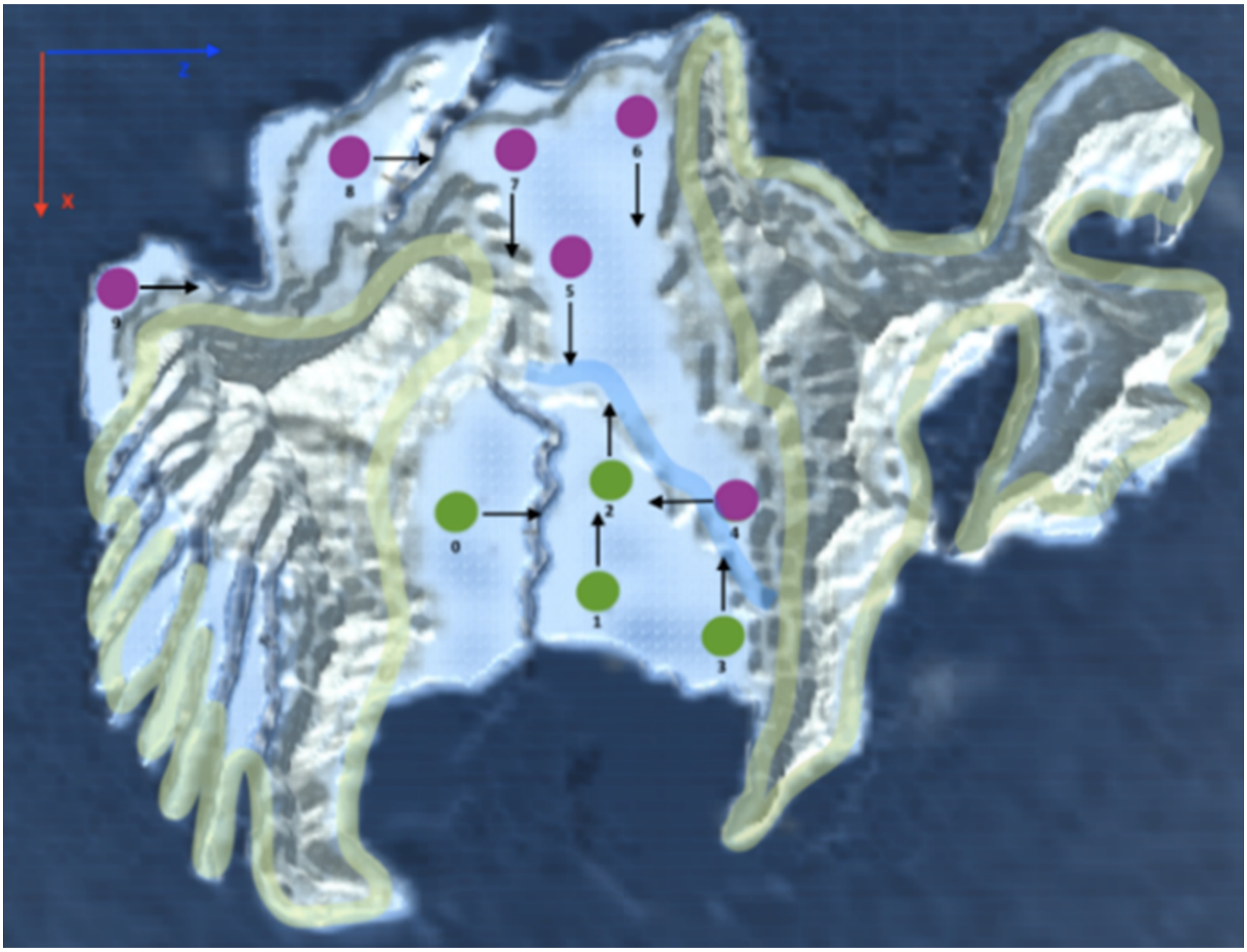


Amalia's Planet is set, as the name suggests, on a planet consisting of multiple modules ("habitats" or "islands") of different types. Each "habitat" is home to a different type of animal and incorporates multiple mini-games, all created with a simple cartoon design, making them easily accessible to primary-school children. The animals chosen are those that normally form herds or flocks, and they emit different sounds that are collectively handled as "noise." This makes it possible to establish noisy backgrounds that produce sound and visual distractions for the child and thus forces them to train listening skills where they have difficulties.

Located in Antarctica, the habitat presented in this paper focuses on the assessment of certain skills affected by various CAPD-related pathologies. More specifically, the skills assessed in the first module are auditory discrimination, sound localization, auditory memory, and auditory separation in noise. For this, the habitat has a series of mini-games, which sequentially assess the mentioned skills. Each of these mini-games provides a series of stimuli and rewards throughout the game so that the player's motivation is maintained.

As the first mini-game in the Antarctic habitat, the child has to find a stray baby penguin of a herd in a wide area guided only by the sound generated by the animal (auditory localization). The original positions assigned to both the penguin and player are randomly chosen by the game each time the game starts (Figure 2). As a measure of the individual's performance in this test, the time taken to find the little penguin is collected. Once the child finds the little penguin, this achievement is celebrated by the herd through an applause given to the player.

Figure 2. Semirandom distribution of start points and locations of the group of penguins. The yellow lines mark the unreachable areas. The blue line is a slope in the terrain. The green and violet dots are the possible positions of the player and the flock.



Once the player passes the first test, the second mini-game starts automatically (Figure 3). This is an auditory memory game. Playing with the head penguin, the child must be able to memorize the sequences of sounds produced by the penguin. Each of the sequences emitted by the head penguin can comprise a series of sounds that the player would have to remember: clapping the wings, twinkling an eye, rattling the beak, and stomping a foot. For the player to become familiar with the aforementioned sounds, the penguin first exposes them together with an animated movement (visual aid). Once the child is deemed to have the necessary information to play the game independently, the penguin hides within its huddle (disappearance of the visual aid) and proceeds to emit sequences of sounds in a given order. The player must remember both the sounds heard and the order in which they were produced to reproduce them once the penguin finishes emitting the sounds.

With regard to the length of the sequences, they become more complex as the child passes the tests. The number of sounds to be distinguished and the length of the sequence emitted by the animal gradually increase in 3 different levels of difficulty, each of which consists of 3 sublevels (Figure 4). In addition, each sublevel provides the individual with 3 opportunities to pass, and if all 3 opportunities are exhausted without success, the sublevel and its corresponding level shall be considered as not passed. If the player manages to pass any of the levels, applause starts to ring out, and the penguin congratulates the player so that they feel motivated and satisfied with the task performed. If the player does not manage to complete any of the tasks correctly, the penguin encourages them to continue playing (thereby trying to avoid frustration and abandonment) and repeats the sequence of sounds that the child has to recreate.

In addition, the game allows the configuration of this auditory memory test for the evaluation of auditory discrimination skills and sound separation in noise. If desired, the penguin colony hiding the main penguin will emit noise to distract the player, demanding higher auditory abilities. This background sound is adjustable for each player and can vary between 0 dB and 30 dB.

Figure 3. Sequence exposure in the second mini-game.

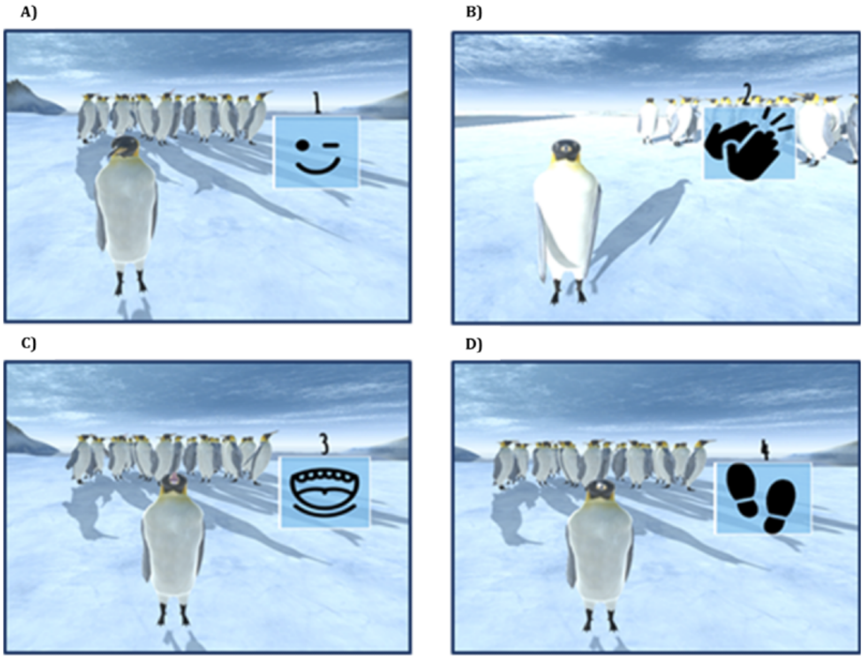
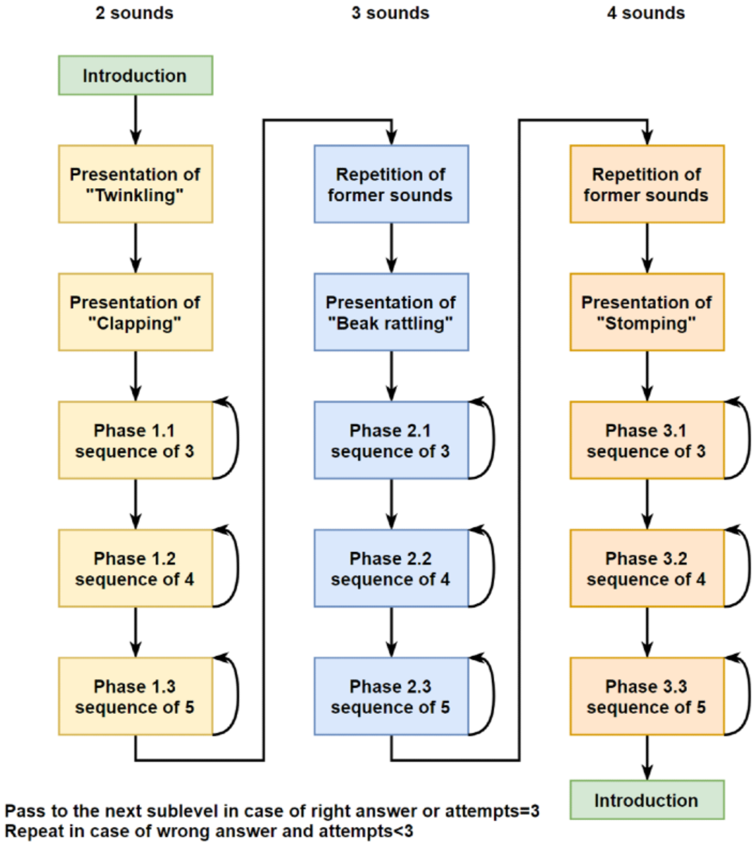


Figure 4. Structure of levels and sublevels to pass in the second mini-game.



Amalia's Planet as Its Self-evaluator

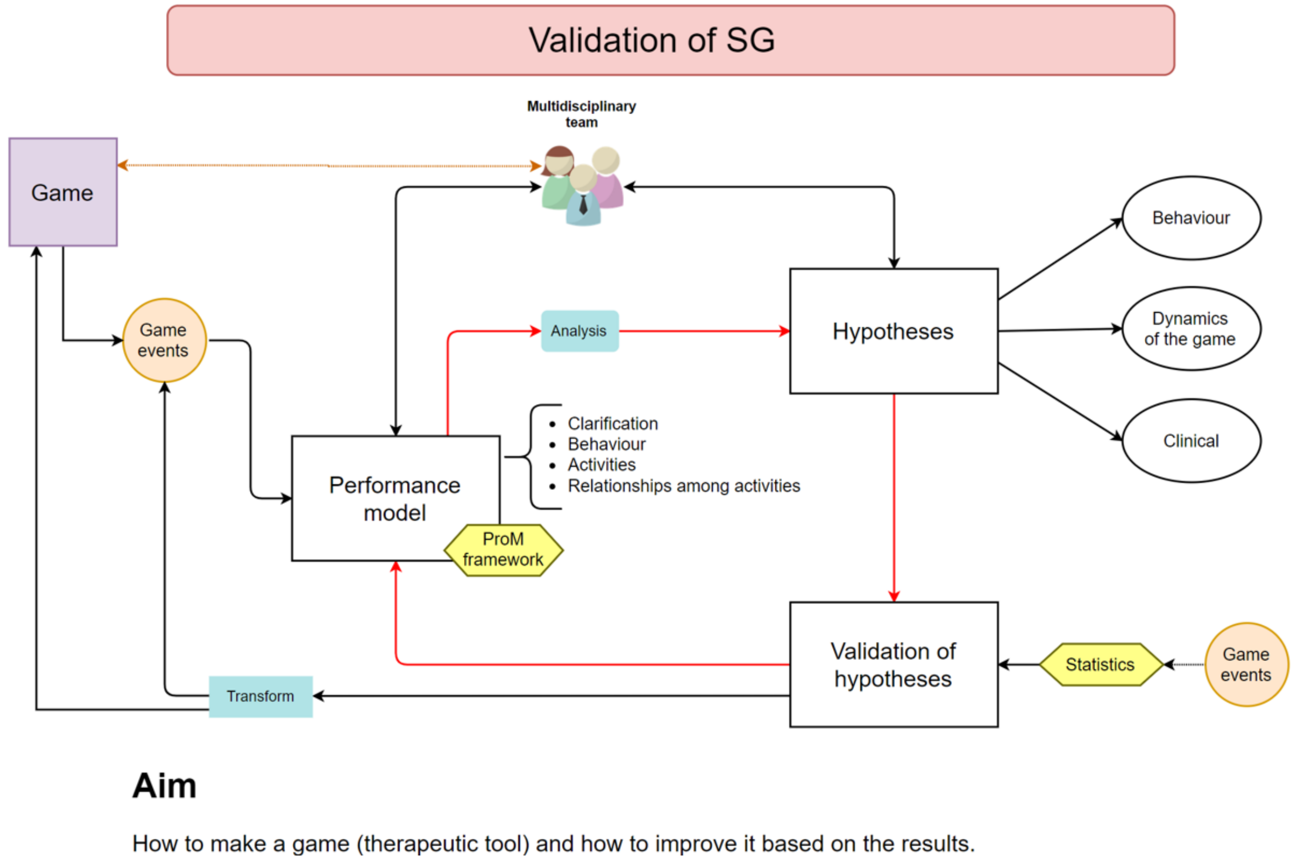
The postproduction stage "corresponds to the evaluation of the serious game, where an evaluation model is proposed, taking into account 2 roles of evaluators, the end user and the expert" [25]. It is at this stage that the previously mentioned PM techniques were introduced as a novel tool for the validation of the proposed solution. However, as reflected in Figure 1, it was at the preproduction stage that the *event logs* that would be analyzed later have to be determined.

Because information was collected in the system logs, it allowed the definition of events by the team, which provided flexibility when addressing problems. Looking at the structure of the game (Figure 4) and with the idea of knowing the behavior of the players throughout the game, the team defined the events according to the result that the player had obtained in each sublevel. At this point, 3 possible outcomes were defined:

1. Passing the sublevel: the player reproduces all the sounds of the sequence in the correct order.
2. Omitting the sublevel: the player does not reproduce all the sounds in the sequence. This result was considered a failure.
3. Failing the sublevel: the player either does not reproduce all the sounds of the sequence correctly or does not reproduce the sounds in the correct order.

Thus, the traces of the event logs consisted of events that report the path followed by each player throughout their progress in the game. This definition of events allowed us to know the basic behaviors of the players, such as the number of attempts a player needed to pass a level and the nature of the level (omission or failure). In addition, it allowed us to recognize patterns of interest that could occur, such as more frequent cycles, traces, or paths among players that are not easily perceived using conventional statistical tools. Figure 5 schematically shows the tool validation process proposed by the development team.

Figure 5. Phase 2: Proposed Amalia's Planet validation process. SG: serious game.



The information provided by PM about the system's functioning, performance, and use as a tool for achieving specific objectives can serve as a source of input for various purposes, which highlights PM's capacity in this regard. Not only can conclusions be drawn about the achievement of the objectives by users, but hypotheses that could not be validated or were poorly formulated at the outset can also be modified because of the new information obtained. In fact, new hypotheses can be put forward on the basis of behaviors collected in the *event logs*, which had previously not been taken into account because of a lack of knowledge.

As shown in Figure 5, the validation process of the hypotheses raised affects previous steps, such as the definition of the game events or the very conception and design of the game. This iterative and dynamic process is what allows the solution to be fine-tuned. The ultimate goal of this loop process is that, based on the information self-generated by the game, the system itself is nourished, updated, and adapted to the demands and characteristics of the player, as well as to the process of analysis of this information presented to the team of experts.

Experiment and Hypothesis

Amalia's Planet was tested twice in a school in the Community of Madrid, Spain.

Information was collected through interviews with parents about their children's medical history related to previous hearing pathologies, such as previous hearing infections (otitis, drains, and secretions) and ear surgeries, and whether their children had a diagnosis of attention-deficit/hyperactivity disorder (ADHD) or learning difficulties [32,33]. Hereafter, this group of conditions will be referred to as previous hearing pathologies.

To evaluate the achievement of the discriminating objective of the game (screening tool), the interdisciplinary team proposed the following hypotheses:

1. There is a difference in gameplay performance between children with previous hearing pathologies and children without previous hearing pathologies.

2. "Healthy" players learn faster. Children who have not had any of the aforementioned conditions are expected to improve their gameplay performance faster than children with a diagnosed pathology.
3. Children learn while they play. Regardless of whether children have had a hearing condition, it is interesting to know whether the game improves their trained skills.

To test the formulated hypotheses, a statistical study of the difference in means between the 2 groups of children (with and without previous hearing difficulties) was conducted. In addition, different scatter plots were studied with respect to measures of central tendency with the aim of finding atypical behaviors that reveal the presence of individuals at risk. These hypotheses are assessed later in this paper.

Results

Sample Summary

The sample size was determined in such a way that, according to the central limit theorem, the statistical distribution of each of the populations considered for the study (children with previous hearing pathologies, children without previous hearing pathologies, distribution of children by sex, etc) was correctly reflected in the collected data [34]. Thus, theoretically, a sample size of 50 children was determined for each sample group (n>30), with a total sample of 100 children in the study. Nevertheless, owing to the limited availability of users of interest for the study and some problems in data collection using the tool (3 players were excluded), the final size of the sample used for this study was 87 children.

The sample consisted of children of both sexes (50 female and 37 male children) aged between 5 and 14 (mean 8.87, SD 1.74; median 9) years. Most of the players (76/87, 87%) were aged between 7 and 11 years, of whom 55% (42/76) were female and 45% (34/76) were male, maintaining approximately the initial distribution of the sample.

Regarding the pathology line, without taking into account sex or age, 45% (39/87) of the players had or used to have at least 1 pathology among those contemplated in the study, resulting in 55% (48/87) of "healthy" participants. The sex ratio was as follows: 57% (50/87) female and 43% (37/87) male. Health information obtained through the parent questionnaire revealed the following classification by previously identified pathology: (1) 55% (48/87) of the sample had a history of otitis, of whom 33% (16/48) had major complications, although only 28% (24/87) had undergone a surgery for drainage; (2) 3% (3/87) were diagnosed with ADHD; and (3) a similar percentage 3% (3/87) had learning disorders.

The sample included children with a history of hearing pathologies and children without a history of hearing pathologies. Hence, focusing on the players with some previous pathology (39/87, 45%), there were 49% (19/39) of players with just 1 pathology, 31% (12/39) of players with 2 different pathologies, and 21% (8/39) of players with up to 3 types of pathologies. Overall, 92% (36/39) of the players with at least 1 pathology had or used to have otitis.

Among the 19 children with just 1 affliction, 84% (n=16) had otitis (a percentage close to the prevalence of otitis in the total population of 87 children, which is estimated at 80% [35]), and 11% (n=2) had ADHD, making it the second most frequent pathology appearing individually. Generally, suppurations and learning disorders appeared to be accompanied by at least 1 other type of pathology in all cases. The most common combination of afflictions was made up of otitis and suppurations, which was present in 11 children (55% of the players with at least 2 pathologies). In terms of sex, the percentage of female players with some kind of affliction was close to the percentage of male players with some kind of affliction: of the 50 female players, 22 (44%) had a pathology, and of the 37 male players, 17 (46%) had a pathology.

Overview of the Obtained Health Results

Results Obtained in Test 1

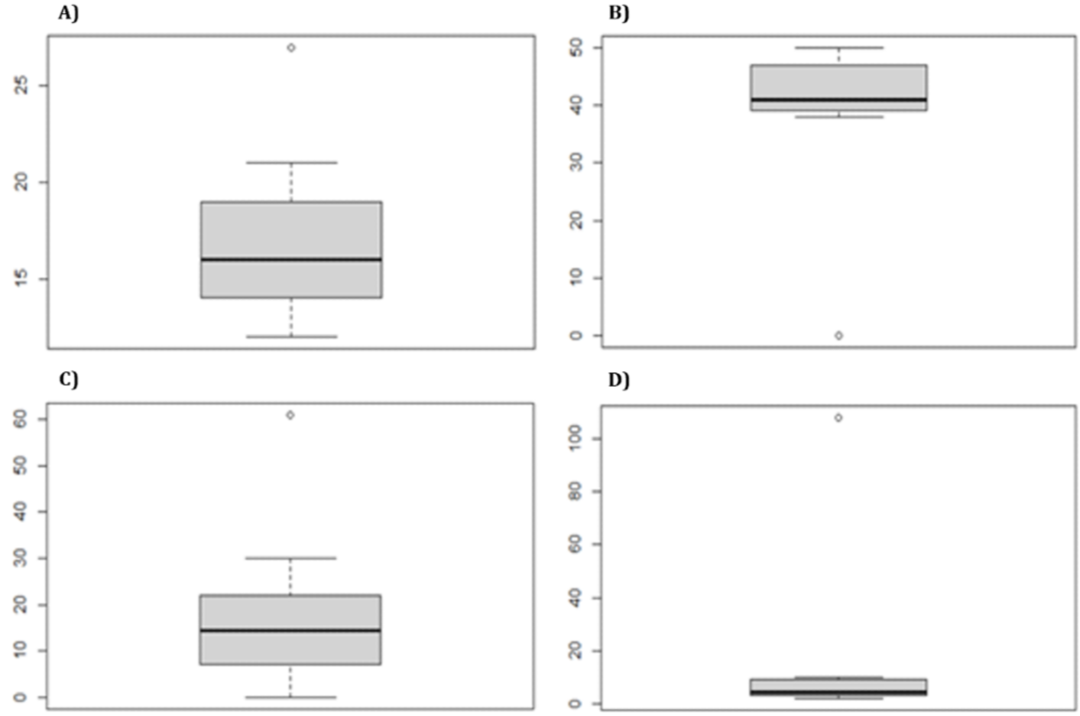
For this first test, a sample of 59 children was available. Among the 59 children, 29 (49%) had previous hearing pathologies, with a total of 14 (48%) male and 15 (52%) female children. On the other hand, a total of 51% (30/59) children were part of the group of children who were not diagnosed with hearing pathologies, with a total of 50% (15/30) male and 50% (15/30) female children.

The percentage of players with afflictions who managed to finish the game successfully was lower than the percentage of "healthy" players (11/29, 38% of players with some affliction against 16/30, 53% of "healthy" players). To determine whether this difference in the level of playing between the different groups was statistically significant, a chi-square test was performed, obtaining a *P* value of .24. Therefore, whether the child had or used to have a hearing pathology did not seem to affect their ability to successfully complete the game. However, it was interesting for the team to answer the following question: is it possible that some of the children initially classified as "healthy" players may in fact have one of the pathologies considered in the study or a different one and have not been diagnosed? Taking the following variables as references, throughout the collection of the information, it was observed that there were certain players initially cataloged as "healthy" whose level of gaming stood out compared with the level of playing of their peers:

- TOTAL_ATTEMPTS: the number of attempts the player has made throughout their game
- TOTAL_ACCURACIES: the number of successes the player has produced throughout the game
- FAILURE_TOTAL: the total number of failures the player has faced during the game
- TOTAL_SUBS: the number of sounds omitted by the player throughout the game

Figures 6A to 6D show (from left to right) the existence of players initially classified as "healthy" who, compared with their group, showed atypical behaviors in their results, particularly, the players who did not manage to pass the game, presenting a large number of errors or omissions throughout their game (ID 30 and ID 74).

Figure 6. Test 1: (A) total number of attempts for healthy players who did not complete the game, (B) total accuracies for healthy players who did not complete the game, (C) total number of failures for healthy players who did not complete the game, and (D) total number of omissions for healthy players who did not complete the game.



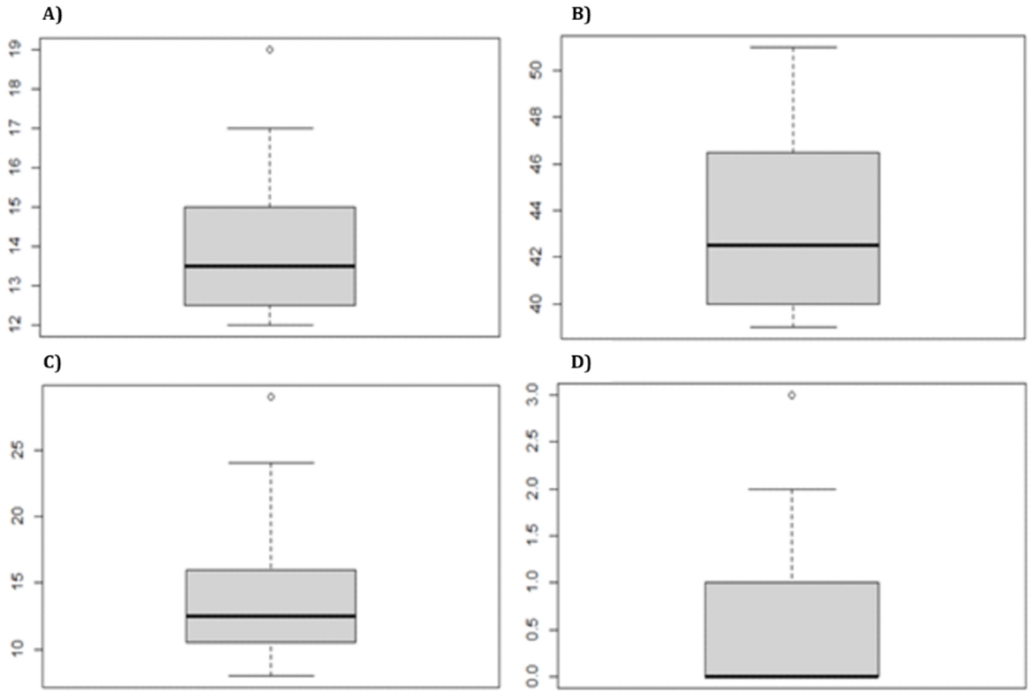
Results Obtained in Test 2

For the second test, a sample of 70 children was available. Among the 70 children, 28 (40%) had previous hearing pathologies, with a total of 13 (46%) male and 15 (54%) female children. On the other hand, a total of 60% (42/70) children were part of the group of children who were not diagnosed with hearing pathologies, with a total of 45% (19/42) male and 55% (21/42) female children.

In this second test, most players managed to pass all the levels of the game. There was a clear difference between the percentage of children with previous pathologies who managed to finish the game completely and the percentage of children without previous pathologies who managed to finish the game completely (26/42, 62% of the players without pathology against 12/28, 40% of the players with some type of diagnosed pathology). To determine whether this difference was statistically significant, a chi-square test was performed, obtaining a *P* value of .19. Therefore, at a confidence level of 80%, there was no statistical evidence to reject the hypothesis that having the afflictions in question affects the ability to complete the game successfully.

To determine whether the players who stood out in test 1 maintained the trend in the second test, the variables mentioned earlier were analyzed again to study their distribution in the sample. Figure 7 shows that these players maintained the same tendencies along the second trial.

Figure 7. Test 2: (A) total number of attempts for healthy players who did not complete the game, (B) total accuracies for "healthy" players who did not complete the game, (C) total number of failures for healthy players who did not complete the game, and (D) total number of omissions for healthy players who did not complete the game.



Overview of the Obtained Game Validation Results

As noted earlier, the achievement of the test objectives should not be the only measure of the test's fitness for purpose, but aspects such as the time required to pass each of the tasks and the different event traces constituted by each player can be sources of information to be considered. To this end, the team used the ProM (Prom Software Inc) software, which is an extensible framework that supports a wide variety of PM techniques in the form of plug-ins [27]. By evaluating the different event logs defined in the previous stages, the abovementioned features can be evaluated and, if necessary, modified further by adapting the tool to its final objective.

Figure 8 depicts the duration of each of the events that were defined in the initial stage. Based on the understanding that the duration of an event is the time that elapses from the time when the "faster" player initializes it until the time when the "slower" player finishes it, this graph can reveal the existence of events that pose a greater challenge to the individual. To avoid the feeling of frustration that the player may experience, and the consequent decrease in performance, this particular feature of PM techniques allows the team to modify such game events.

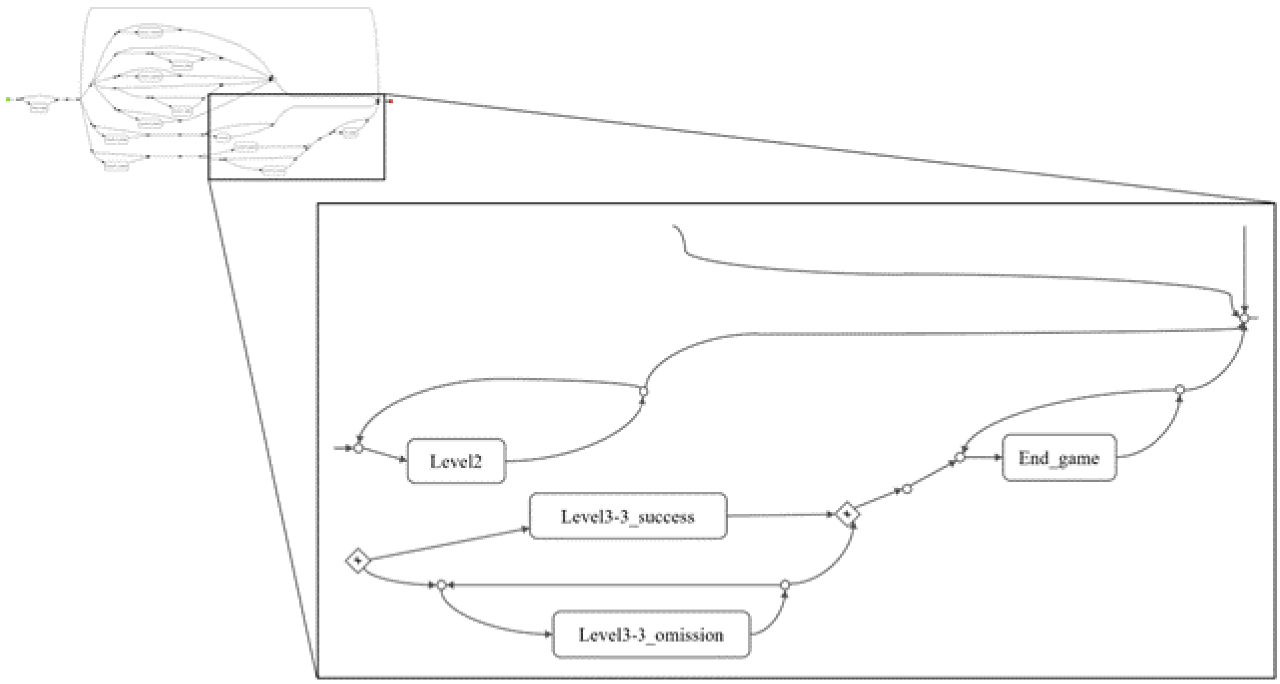
Figure 8. Duration of events.

Furthermore, the study of event traces and the frequency with which they appear in the collected sample serves as a mirror of the correct functioning of the game (Figure 9). Thus, it is possible to detect structural faults in the tool, such as jumps between levels that are not consecutive, backtracking that is not allowed, and advancing to a new level without having completed the previous one. All these constituent faults can be corrected by the technical part of the development team, ensuring the correct functioning of the tool in future tests.

Finally, another graph of interest that can be obtained using the ProM software is the so-called Business Process Model Notation [27]. This graph provides information about the route that different players followed to pass the game, identifying the main events that each player went through. Furthermore, loops and cycles can be detected using this graph; thus, the team can deduce the possible learning resources of the players (Figure 10).

Figure 9. Obtained traces and their frequency.

Figure 10. Business Process Model Notation with inductive visual miner.



Discussion

Principal Findings

SGs are increasingly being used as support tools for the development and improvement of skills in individuals of different age ranges in areas such as education and health. In addition, it is nowadays demonstrated that an early diagnosis of CAPD in an individual is a desirable characteristic from the point of view of the consequent therapeutic process [36]. In other words, school-age children who are screened for CAPD may benefit greatly from the treatment of CAPD symptoms. Despite this, it is currently not possible to find a tool that brings together these 2 ideologies to minimize, or even eliminate, the afflictions that this disorder causes in those who have it.

On the basis of the conception and development of an SG, Amalia's Planet, and its use in a real school environment, the research team was able to contrast the different hypotheses put forward in previous sections regarding the suitability of the use of SGs as screening tools for CAPD. More specifically, this study showed that once the users become familiar with the game and its rules, users who were affected by auditory pathologies related to the disorder in question perform less well on the tasks they are given. More specifically, at a confidence level of 80%, there was no statistical evidence to reject the hypothesis that there is a difference in gameplay performance between children with hearing pathologies and children without hearing pathologies. That is, the fact that the player had any of the pathologies considered in this study directly affects their performance in the game. Moreover, the abovementioned statement only supports the hypothesis that "healthy" children learn faster than children with a diagnosis. Finally, an improvement in the performance of the players could be observed when comparing their performance in test 1 with that in test 2.

One of the main results obtained in this study is that using the proposed solution, the team was able to detect the presence of 2 users who were initially assigned to the group of "healthy" individuals owing to the lack of diagnosis but who presented a gameplay performance more similar to that of the group of at-risk individuals. Such an outcome allows family members, educators, and health professionals to pay more acute attention to these users. Such children can then be examined to determine whether their performance was altered by the presence of an auditory processing pathology or by other external factors.

At this point, it is worth highlighting the fact that if, using traditional statistical techniques on extreme values, both users were eliminated from the sample, and the data were reanalyzed, the results obtained would have been even more discriminant. For both tests 1 and 2, with statistical confidence levels of 85% and 95%, respectively, there would have been no statistical evidence to reject the hypothesis about the difference in performance between "healthy" players and those who had been diagnosed.

In turn, the use of PM techniques as a tool for evaluating the suitability of the solution to the problem posed allowed the team to develop different methods for improving the game. In particular, by studying the duration of the game events, the team detected some phases of the game that can generate frustration in the players, thus reducing their level of attention and, consequently, their performance. In addition, different learning resources used by the players were detected. By studying cycles and loops along the player's traces, learning resources based on failure and omission that were used by the player to subsequently complete the levels could be detected. Finally, the team was able to detect jumps between nonconsecutive levels of the game. All these features to be improved in the tool could be addressed in future versions, thanks to the validation of the proposed solution through PM techniques.

Limitations of the Study and Future Works

After testing the developed tool, the team was able to detect a series of aspects to improve in the application. First, at the time of data analysis, a lack of information was detected from a total of 3 users. This lack of information due to an error in the deployment of the solution led to the exclusion of these players from the final analysis. Moreover, in the first game in which the child has to find the baby penguin, a bug was detected. Here, some players had to cross a bridge to reach their goal. However, some of them fell from the bridge into the water and required the help of adults to continue, adding time to their markers and lowering their score. Moreover, thanks to the use of PM tools, events in which the dynamic followed in the game was not established could be detected a priori. Thus, in Figure 10, a jump from the initial event to the final event without going through any intermediate states can be detected. In addition, in other cases, player games were detected in which the game "jumps" from one level to another, ignoring intermediate sublevels.

Finally, events that were "excessively" long compared with others were detected. These events will have to be reviewed, as they can suppose a defective performance on the part of the tool or a high level of complexity for the players involved.

In addition to the revision and correction of the mentioned errors, the team of authors is currently developing new "habitats" for the Amalia's Planet ecosystem, which covers new aspects related to CAPD screening and were not included in this first version.

Conclusions

CAPD is a disorder that is difficult to detect during childhood, and its early detection is a challenge to be solved in the near future using quick and easy-to-apply screening tools. To our knowledge, this is the first study that unifies the ideology of a screening test for CAPD in school-age children and the use of SGs to support the diagnosis and consequent treatment of CAPD. Despite the need for further testing of the usability of the tool and the improvement of certain functional aspects of the tool, the development team was able to obtain results with statistical evidence that support the use of Amalia's Planet as a screening tool for children at risk for CAPD. Amalia's Planet can be expanded to include games that assess other forms of afflictions experienced by children with the disorder under study.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
CAPD: central auditory processing disorder
MECONESIS: metodología para la concepción de juegos serios para niños con discapacidad auditiva
PM: process mining
SG: serious game

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Original Paper

Serious Games Based on Cognitive Bias Modification and Learned Helplessness Paradigms for the Treatment of Depression: Design and Acceptability Study

Arka Ghosh[1], PhD; Jagriti Agnihotri[1], BTech; Sradha Bhalotia[1], MTech; Bharat Kumar Sati[1], BTech; Latika Agarwal[1], BTech; Akash A[1], MTech; Swastika Tandon[1], MBA; Komal Meena[1], BTech; Shreyash Raj[1], BS; Yatin Azad[1], BTech; Silky Gupta[2], MS; Nitin Gupta[1,2,3], PhD

[1]Department of Biological Sciences and Bioengineering, Indian Institute of Technology Kanpur, Kanpur, India
[2]Department of Cognitive Science, Indian Institute of Technology Kanpur, Kanpur, India
[3]Mehta Family Center for Engineering in Medicine, Indian Institute of Technology Kanpur, Kanpur, India

Corresponding Author:
Nitin Gupta, PhD
Department of Biological Sciences and Bioengineering
Indian Institute of Technology Kanpur
Kalyanpur
Kanpur, 208016
India
Phone: 91 5122594384
Email: guptan@iitk.ac.in

Abstract

Background: Depression is a debilitating mental health disorder, with a large treatment gap. Recent years have seen a surge in digital interventions to bridge this treatment gap. Most of these interventions are based on computerized cognitive behavioral therapy. Despite the efficacy of computerized cognitive behavioral therapy–based interventions, their uptake is low and dropout rates are high. Cognitive bias modification (CBM) paradigms provide a complementary approach to digital interventions for depression. However, interventions based on CBM paradigms have been reported to be repetitive and boring.

Objective: In this paper, we described the conceptualization, design, and acceptability of serious games based on CBM paradigms and the learned helplessness paradigm.

Methods: We searched the literature for CBM paradigms that were shown to be effective in reducing depressive symptoms. For each of the CBM paradigms, we ideated how to create a game so that the gameplay was engaging while the active therapeutic component remained unchanged.

Results: We developed 5 serious games based on the CBM paradigms and the learned helplessness paradigm. The games include various core elements of gamification, such as goals, challenges, feedback, rewards, progress, and fun. Overall, the games received positive acceptability ratings from 15 users.

Conclusions: These games may help improve the effectiveness and engagement levels of computerized interventions for depression.

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KEYWORDS

serious games; cognitive bias modification; learned helplessness; depression; digital intervention; mobile phone

Introduction

Background

Depressive disorders are a leading cause of disability worldwide, affecting >264 million people [1]. Antidepressant medications and cognitive behavioral therapy (CBT) are currently the most effective treatment modalities for depression [2-4], but there is a large treatment gap owing to the lack of accessibility, high cost of therapy, and social stigma associated with the visits to a psychiatric clinic [5-7]. In the past 2 decades, digital interventions have been gaining traction. The most widely studied digital intervention for depression is computerized CBT (cCBT). Although cCBT is an effective form of treatment [8-10], a recent meta-analysis has demonstrated that guided cCBT is less acceptable than being on a waiting list [11]. There is a need for other digital treatment modalities.

The cognitive theory of depression posits that information processing—attention, interpretation, and memory—is negatively biased in depression [12,13]. This biased information processing has been implicated in the onset and maintenance of depression [14]. Experimental studies have corroborated the cognitive model by providing empirical support for self-referential information processing, attention bias, interpretation bias, and memory bias [15-19]. Psychological training paradigms, known as cognitive bias modification (CBM) paradigms, have been used to modify these cognitive biases in subthreshold, clinical, and remitted populations [20-28], albeit with mixed results. Despite the mixed results and small effect sizes [29,30], this field promises novel treatment approaches and warrants further research.

The previously mentioned evaluations of CBM paradigms have been mostly performed in laboratory settings; these paradigms have received much less attention than cCBT as a potential treatment approach for depression outside the laboratory [31-33]. CBM paradigms tend to have low user engagement owing to the repetitiveness of the paradigms [34-37] and a lack of credibility in some cases [34,38]. In a digital intervention, in which the user needs to engage with a paradigm without any external supervision, the paradigm's ability to engage becomes the determining factor for the success of the intervention.

One way to make the CBM paradigms more engaging to users is by developing serious games based on the paradigms [39]. A game serves as an interactive medium that provides game designers with considerable control in creating engaging experiences and can reduce the attrition rate in digital interventions [40]. Serious games have been evaluated for multiple conditions, including posttraumatic stress disorder [41,42], autism spectrum disorder [43-45], attention-deficit/hyperactivity disorder [46], cognitive functioning [47,48], alcohol use disorder [49,50], trait anxiety [51,52], etc. The results of a meta-analysis that evaluated the effectiveness of serious games demonstrated a moderate effect size of serious games for reducing psychiatric disorder–related symptoms compared with no intervention controls [53]. In a review of 4 studies that evaluated CBM interventions based on serious games, only 2 studies reported their gamified interventions to be effective [54].

Serious games have been developed for various aspects of depression. Bespoke serious games have been created to diagnose depression [55,56], treat depression [57-63], and describe the experience of depression either metaphorically [64] or literally [65]. Off-the-shelf commercial games have also been used to target depression [66]. There are multiple serious games based on different therapeutic techniques—CBT [67-69], solution-focused therapy [70], and interpersonal therapy [68]—that do not target depression specifically but can be useful. There is only 1 serious game based on a CBM paradigm targeting depression, but it was found to be ineffective [62]. Serious game–based interventions have been shown to be acceptable to the users overall [57,60,67-69]. A recent review, however, suggests that the effectiveness and acceptability data are not convincing enough yet to warrant clinical adoption [71].

Objective

In this study, we selected specific CBM paradigms that had received empirical support for targeting cognitive biases underlying depression and appeared suitable for conversion to games. Then, we described the design and development of these games in detail. Furthermore, we developed 1 serious game based on the learned helplessness theory.

Methods

Embedding Training Paradigms Into Serious Games

We searched the literature for known CBM paradigms and selected those that have shown promise in reducing depressive symptoms and were amenable to conversion to games. Our team discussed multiple game ideas for each paradigm. While thinking of the ideas, the primary aim was to make the gameplay engaging while keeping the active therapeutic component unchanged. After multiple sessions on ideations, the team selected the most promising game idea for each paradigm. Once the team agreed on a game idea, minimally viable prototypes were created and tested within the team. These minimally viable prototypes were improved upon to create the final versions by using the feedback obtained from informal tests performed in a larger group of approximately 10 friends and colleagues.

Software Development

We used Angular 8 (Google LLC) and JavaScript (ECMAScript 2018) for creating the front end of the games and Django-rest-framework 3.9.2 (Encode OSS Ltd) and Django 2.2 (Django Software Foundation) for creating the backend of the games. Two games required the detection of the swipe gesture on the screen, for which we used a readily available library, *hammer.js*. For 1 game that required the simulation of gravity and collision in the game environment, we used the *phaser.js* framework. The games were optimized for smartphone screens and were also compatible with tablets, laptops, and desktop devices. We created the graphical elements required for the game using Adobe Illustrator (Adobe Inc). Musical elements required for some of the games were collected from open web resources. The *negative attention bias training game* required the combination of 20 rhymes (Rock a bye baby, Wheels on the bus, etc) and famous compositions (Ode to joy, Für Elise, etc). The musical notations for these rhymes and compositions were collected from various YouTube channels. A few of them were readily available in the scientific pitch notation. For the others, we deduced the musical notations from the simple piano versions of these rhymes and compositions available on YouTube.

Feedback on the Games

To obtain a preliminary sense of the acceptability of the games, we asked 15 pilot users (n=8, 53% male and n=7, 47% female) to provide feedback on the 3 aspects of the games. The users were recruited from the Indian Institute of Technology, Kanpur community, by word of mouth. Potential users who expressed interest were sent an email detailing the procedure to participate in the study and to provide feedback. They were also sent an informed consent form via email. They were required to include their name and signature in the informed consent form and email it back to the study team. These users rated the games on three aspects: (1) *The instructions on how to play the game were clear*, (2) *The game was fun to play*, and (3) *The purpose of the game was clear*. The users rated these aspects on a 5-point scale—(1) strongly agree, (2) agree, (3) neutral, (4) disagree, and (5) strongly disagree. These ratings were mapped to scores of 2, 1, 0, −1, and −2, respectively. For the game for learned helplessness, we asked the users an additional question, *In this game, you were presented with some unsolvable puzzles and some solvable puzzles. After you completed the game, the logic of the game was presented to you. After playing the game and reading the explanations, which of the following statements are true (tick all that apply)*?

The following options were provided: (1) *I have an understanding of learned helplessness*; (2) *I felt angry or frustrated while I was stuck with the puzzles*; (3) *After the logic of the game was explained, my frustration or anger reduced*; and (4) *After the logic of the game was explained, my frustration or anger did not reduce*. The feedback was collected as a preliminary pilot for a larger study.

Ethics Approval

Ethical clearance was provided by the Institutional Ethics Committee of the Indian Institute of Technology Kanpur (IITK/IEC/2019-20/II/4).

Analysis

We calculated the average value of the feedback received on the different aspects of the game. We also checked whether the feedback received was significantly different from 0 using the Wilcoxon signed rank test. Python (version 3.10.5; Python Software Foundation) and MATLAB R2020b (Mathworks) were used for data analysis.

Results

Design Philosophy

Our main design objectives were to make the games effective by using evidence-based paradigms and engaging by incorporating 6 out of the 7 core elements of gamification. The evidence-based paradigm used for the individual games is described in individual sections throughout the paper. CBM paradigms have been reported to be boring and repetitive [34-37]. We hypothesized that making the games fun and engaging would increase the likelihood of spontaneous gameplay and, consequently, increase the CBM dosage without external supervision. Studies have reported that the rationale behind some CBM interventions is not apparent to the users, which can contribute to the lack of engagement [34,38]. To tackle this, we added a brief section called *Science behind the game* to each game.

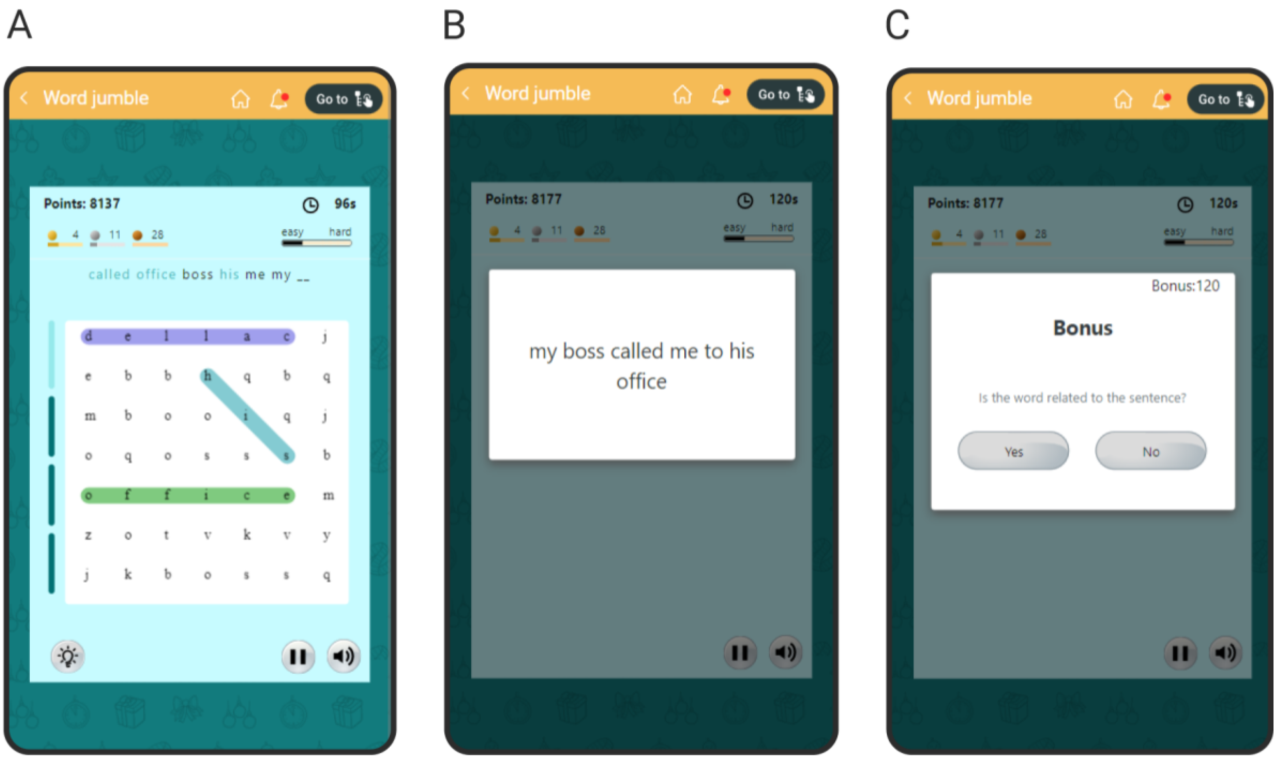
Individuals experiencing an episode of depression have decreased cognitive abilities [72]. Considering this, we designed the gameplay to be easy and intuitive, such that anyone with some experience in using smartphone apps and a basic familiarity with the English language could play the games. We also kept the hardware requirements for the games minimal so that they could be played on low-end smartphones. At the beginning of the games, we gave simple in-game instructions or in-game tutorials. To avoid an artificial limit on the practice of CBM, we designed the games to be never-ending (except for the game for learned helplessness, in which the design required a definite ending). The difficulty level of each game adapted to the skill level of the user to create the *flow* experience [73]. Apart from making the games intrinsically engaging, we also added some extrinsic motivators to play the games, such as badges and scores, or the sensory experience of a familiar musical tune. The badges served as short-term rewards for playing the games, and the scores served as in-game currency, which could be exchanged for lives or hints in the games. We describe how our games are based on the elements of gamification in the later section titled, *How game-like are our games?*

Game for Automatic Interpretation Bias Modification

People with depression have an automatic negative interpretation bias [74]. Cowden Hindash et al [21,75,76] used a modified word sentence association paradigm for participants with dysphoria to confirm and modify the automatic negative interpretation bias. The bias modification paradigm also showed a near-transfer effect on the Scrambled Sentence Task [77] and a far-transfer effect of increased resiliency on a laboratory stressor [21].

In the task of modified word sentence association paradigm for participants with dysphoria, a self-relevant ambiguous sentence (*My mom called me to tell me the news*) is shown for a short duration, followed by a positive or negative word. The user is asked whether the word is related to the sentence. The user can answer *Yes* (related) or *No* (unrelated). The user is trained, via text-based feedback, to associate positive words with ambiguous sentences; the feedback is *Correct* if the answer is *Yes* for a positive word or *No* for a negative word; otherwise, the feedback is *Incorrect*. We converted this paradigm into a serious game in the following manner: The game displays an alphabet grid. The user's goal is to find the words (that can be formed by connecting letters in the grid; Figure 1A) that form the ambiguous sentence. The game screen includes several empty bars, equal to the number of words to be found. As the user finds a word, a bar gets filled to provide the users with a sense of progress in the game and indicate the number of words found. Once the user finds 50% of the words, we reveal the full ambiguous sentence (Figure 1B), and then we show a positive or negative word and ask the user if the word and the sentence are related (Figure 1C). The user can answer by clicking on *Yes* (related) or *No* (unrelated) buttons. Quicker answers are given higher rewards to encourage the users to answer with the first thought they have. An incorrect answer receives 0 points. To prevent the users from clicking *Yes* for all positive words and *No* for all negative words, we used decoy sentence-word pairs, in which the sentence was unambiguous, and the negative word was related, while the positive word was unrelated [78].

Figure 1. Screenshots of the game for automatic interpretation bias modification. (A) The user finds words that are contained in the sentence by linearly connecting letters in the grid. (B) The ambiguous sentence is shown in full once the user finds 4 words. (C) The user is asked if the word (*Bonus* in the shown example) is related to the sentence on the previous screen.



The users earn reward points by finding words in the grid. Valid English words that are not parts of the sentence also earn points. The points, apart from being a short-term reward, also serve as an in-game currency to buy extra time or hints. Apart from points, the users also receive other short-term rewards in the form of bronze, silver, and gold badges for completing 4, 10, and 26 levels, respectively.

The game adapts to the user's level of competence by varying the number of words hidden and allotted time per difficulty level (Figure S1 in Multimedia Appendix 1). To help the user in learning to play the game, the initial 4 levels of the game keep the words of the sentence fully visible in a jumbled order and give the user 150 seconds (in the first 2 levels) or 120 seconds (in the next 2 levels) to find the words in the grid. A bar, ranging from *Easy* to *Hard*, indicates the game's current difficulty level.

There are 42 levels (sentence-word pairs) in the game. The difficulty of each level depends on the number of words to be found and the complexity of the grid. These, in turn, depend on the length of the sentence and the length of the longest word. The levels are arranged to gradually increase the difficulty level. After the completion of all the levels, the game loops back to the first level.

Game for Executive Control Training

Rumination, a core factor in depression, affects the duration [79] and intensity [80] of depressive episodes. Multiple studies have established that depressive rumination is associated with an inability to inhibit the processing of emotional information [81,82]. Executive control is one mechanism that regulates the ability to inhibit emotional information in healthy individuals [83-85]. Cohen et al [86] hypothesized that the difficulty in using executive control might be the factor behind impaired inhibition in ruminators. Cohen et al [86] designed a paradigm to train individuals to exert executive control before exposure to an emotional stimulus, followed by a discrimination task. They observed that individuals trained with this paradigm were less likely to engage in a state of rumination [86] and more likely to use reappraisal—an effective emotion regulation technique—more frequently and efficiently [87]. On the basis of this executive control training paradigm [87], we designed a 2D platform game to resemble the classic video game, Super Mario Bros. (Figure 2). The goal of the user is to keep a running avatar alive by jumping over obstacles (sitting or jumping frogs; Figure 2A) or pits (Figure 2B). The pits are of different types: some requiring a single jump, some requiring a double jump, and some including floating platforms in between (Figure 2C). The floating platforms are also of 2 kinds—some are stationary when the avatar lands on them, whereas others start to fall upon the landing of the avatar. The avatar sometimes passes through an underground tunnel, and on returning to the ground level, the background landscape changes to maintain a diversity of visuals. An in-game tutorial is shown to make the user familiar with the game's rules and controls. On a keyboard-based device, the arrow keys can be used to play the game. On a touchscreen device, buttons corresponding to the arrow keys are shown on the screen itself.

Figure 2. Screenshots of the game for executive control training. (A) The avatar faces an obstacle, a jumping frog. (B) The avatar faces an obstacle, a pit. (C) The avatar faces a longer pit with floating platforms. (D) The instructions for the cognitive bias modification paradigm. (E) An incongruent flanker task as a part of the cognitive bias modification paradigm. The user must press the button corresponding to the middle arrow in the flanker task. (F) A green circle as a part of the cognitive bias modification paradigm. The user must press the button (green button on the right side) corresponding to the circle in the center.

As time progresses, the speed of the avatar increases to increase the difficulty level. The score in the game increases over time as the avatar continues to run. Intermittently, the game screen presents coins, which can be collected by jumping. The coins serve as an in-game currency. Initially, the user is given 3 lives and 5 double jumps for free. Once the user exhausts the free double jumps, each double jump costs 10 coins. In addition, once the user exhausts the free lives, additional lives can be purchased with coins with gradually increasing difficulty: the first purchase costs 10 coins and each purchase after that costs twice the amount of the last purchase.

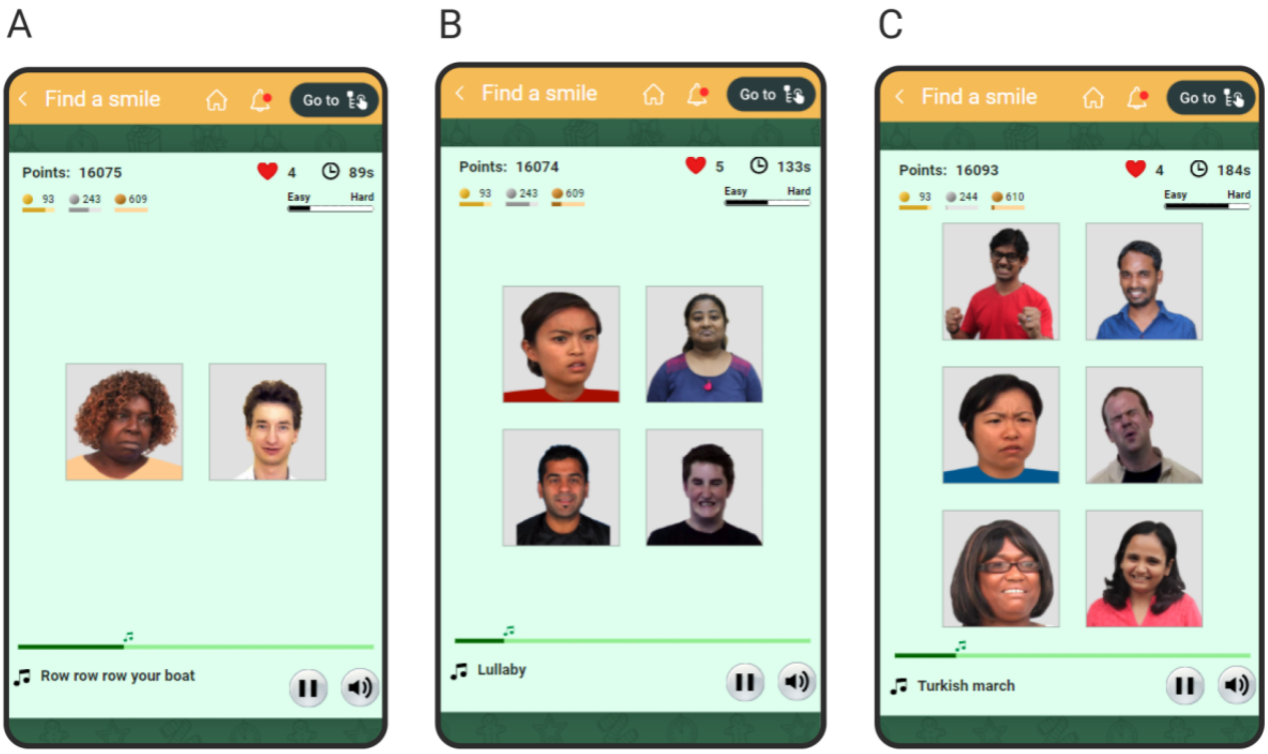
At predetermined points in the game, the avatar stops in front of a large pit with floating platforms. At this point, the executive control training task is shown to the user (Figure 2D). An incongruent or a congruent set of flanker arrows (Figure 2E) is shown with a 50:50 probability. The user is required to press an arrow key corresponding to the middle arrow in the set. The flanker arrows remain visible until the user responds or for a maximum of 1000 milliseconds. After the flanker set disappears, an image is shown for 100 milliseconds. The image is neutral or negative with an 80:20 probability following a congruent set and with a 20:80 probability following an incongruent set. After a further gap of 50 milliseconds, during which no stimulus is shown, a green or red circle is shown with a 50:50 probability (Figure 2F). The user is required to respond according to the color of the circle (up arrow for green and down arrow for red). The circle remains visible until the user responds or for a maximum of 2000 milliseconds (Figure S2 in Multimedia Appendix 1). These 3 steps—including the arrows, the image, and the circle—constitute 1 round of training. The next round of similar training steps begins after a delay of 2000 milliseconds. After 3 rounds of training, the gameplay begins again and continues for approximately 30 seconds before the next batch of training begins. The instructions for choosing the correct keys are shown before each round of training. If the user presses the correct keys for both the flanker task and the colored circle task in a round, it is considered a correct response. The users are incentivized to perform the task diligently, as correct choices reward them with double jumps or additional lives. The users can also earn short-term rewards in the form of bronze, silver, and gold badges for 6, 15, and 39 correct responses, respectively.

Game for Negative Attention Bias Modification

The vulnerability model of low self-esteem and depression states that low self-esteem increases the risk of future depressive episodes [88,89]. Accordingly, improving one's self-esteem should reduce the risk of depression. Individuals with lower self-esteem are more attentive to rejection cues, which in turn increases their tendency to interpret more and more social cues as rejecting, thus perpetuating the cycle of vigilance and low self-esteem [90,91]. Dandeneau et al [92] used an attention-training paradigm to modify this negative attention bias and observed that it led to a more resilient self-esteem against a laboratory-based rejection manipulation.

We designed a game based on the same training paradigm to overcome negative attention bias [92]. Images of human faces, one depicting a positive emotion and the others depicting negative emotions, are shown in a grid (Figure 3). The user is asked to click (or tap, when played on a touchscreen device) on the image with positive emotion as quickly as possible. Once the user clicks on the positive image, the next set of images is displayed in the same grid. To make this process fun and engaging, the game plays a musical note when the user clicks on a positive image. The musical notes, played sequentially, are taken from a popular song (or rhyme), and 1 song constitutes 1 level of the game. A click on a negative image results in an unpleasant beep. Therefore, in effect, the user can play the song by clicking on the faces with positive emotions—the more accurately they select the images with positive emotions, the fewer interruptions they hear during the song.

Figure 3. Screenshots of the game for negative attention bias training, showing (A) a 1 × 2 grid, (B) a 2 × 2 grid, and (C) a 3 × 2 grid of faces with different emotions.



To make the game challenging, the user is given a time limit to finish each level, calculated as $TT = N \times T$, where N is the number of musical notes in the song and T is the time allotted per note (initialized to 5000 milliseconds). The game adapts to the user's performance level by dynamically varying T between 1000 and 5000 milliseconds and the grid size between 1 × 2 (Figure 3A), 2 × 2 (Figure 3B), and 3 × 2 (Figure 3C) after the completion of each level. The algorithm of this adaptation is summarized in Figure S3 in Multimedia Appendix 1.

A bar, ranging from *Easy* to *Hard*, indicates the current difficulty level. To dissuade the user from clicking on images without paying attention, we penalize each click on a negative image by deducting 1 life (in addition to playing the unpleasant beeps). The user is given 5 free lives at the beginning of each game. Once the user runs out of lives, they have the option to replay the same level. Clicks on positive images earn points, which can be used to buy more time if the user runs out of time before the completion of a song. To give the user a sense of progress at each level, a progress bar on the screen indicates the fraction of notes in the current song that has been played.

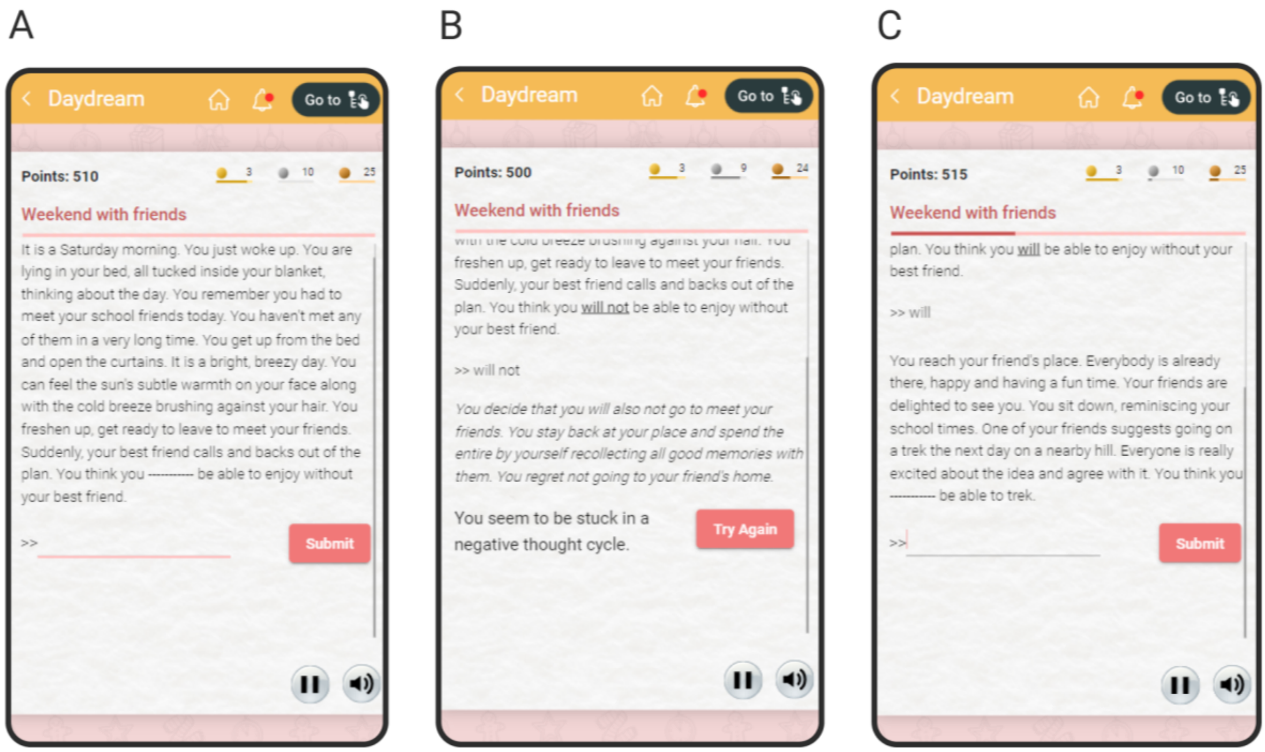
The users also receive badges as short-term rewards. They earn bronze, silver, and gold badges by clicking on 34, 60, and 156 positive images, respectively. The game has 20 levels (songs). Once the user finishes all the songs, the game loops back to the first song.

Game for Positive Imagery Training

Negative automatic thoughts can be verbal or imaginal [93]. Holmes et al [94] developed an interpretation bias training paradigm based on positive mental imagery. Multiple studies have demonstrated that the training has a positive effect on the participants' moods [25,94-96], although there are some exceptions [36,97]; the training also helped in targeting anhedonia [97].

We designed a serious game based on the combination of paradigms by Holmes et al [94] and Mathews and Mackintosh [98]. This game was developed as interactive fiction inspired by Zork [99]. At each level, the user is presented with an ambiguous scenario in the form of a paragraph with a blank space (Figure 4A). The user can fill in the blank with one or more words to resolve the sentence positively or negatively (eg, *You think you ______ be able to enjoy the meeting* can be resolved positively by adding *will* or negatively by adding *will not*). The game evaluates the phrase written by the user by comparing it against a comprehensive list of possible positive and negative completions for each sentence (occasionally, if the phrase falls outside the list, the game responds that it could not understand the input and requests the user to write a different phrase). If the user resolves the sentence negatively, it is considered an incorrect response and the user is asked to try again (Figure 4B). If resolved positively, the game moves forward and another ambiguous scenario appears in continuation with the previous one (Figure 4C). Once the user resolves the second part of the ambiguous scenario positively, the level concludes and a new scenario appears at the next level of the game. As vivid imagination is an active element [100], users are urged to imagine the situations vividly in the first person. No hints are provided in the game; however, if the user fails to answer correctly in 3 attempts, a list of potential answers is shown from which the user can select one. To encourage vivid imagination, we did not include a time limit in this game.

Figure 4. Screenshots of the game for positive imagery training. (A) A scenario is shown that can be resolved positively or negatively by providing one or more words to fill in the blank. (B) If the user resolves the scenario negatively, they are asked to try again. (C) If the user resolves the scenario positively, the game moves forward and another scenario is presented.



The game is designed to be never-ending. It includes 20 levels, and after the completion of all the levels, the game loops back to the first level. The user earns 5 points for resolving a scenario positively. The user also earns a bronze, a silver, and a gold badge after positively resolving 4, 10, and 26 scenarios, respectively.

Game for Learned Helplessness

Learned helplessness is a laboratory model of depression that emulates multiple aspects of clinical depression in animals [101,102]. The state of learned helplessness, reached after some experiences of inescapable aversive conditions, involves a generalized self-assumption of powerlessness, thereby reducing the effort to come out of difficult situations in the future. A reformulation of the theory in terms of attribution theory has also been extended to humans: individuals with learned helplessness attribute their failures to personal, pervasive, and persistent lack of abilities and their successes to luck [103].

We designed a puzzle-based game to help the users understand the ideas of learned helplessness and attribution style. We reasoned that an explanation after a game-based transient experience of the phenomenon would be more effective than simply explaining the concept using text or videos and is more likely to help users change their self-defeating attribution bias.

In the original experiments on learned helplessness, dogs failed to escape avoidable shocks after they had unsuccessfully tried to escape unavoidable shocks [104]. Very recently, a paradigm has been proposed to test learned helplessness in humans using loud audio tones as a stressor [105]. To allow the users to appreciate this phenomenon without a physical stressor, we devised the following approach: if a user can solve a puzzle initially but gives up on the same puzzle when it is shown after the failure to solve a hard and unrelated puzzle, the user would be able to see the parallel with learned helplessness and realize that it can happen in real life. At this point, the user is more likely to be receptive to the introspection of their own attribution bias.

We created a suite of 4 puzzle-based mini-games to achieve this objective. The first one, the circle-triangle mini-game, is a genuine puzzle game with multiple difficulty levels. The other 3 mini-games are designed to trick the user: each of them appears like a genuine puzzle game with easy puzzles in the first 1 or 2 levels but has unsolvable levels thereafter.

The user starts by playing the circle-triangle mini-game. The screen presents a pattern of squares, each containing a circle or a triangle (Figure 5A). If the user clicks on one of the squares, it flips (a circle becomes a triangle and vice versa). Simultaneously, the adjacent squares also flip (Figure 5B). The goal of the user is to change all the embedded shapes into circles. Once the user solves the puzzle, a message (*Great*) and auditory feedback (a pleasant *ding*) are provided to the user. Next, a harder level of the same mini-game is presented. This stepwise increase in the level continues until the user fails to solve the current level and clicks on a button labeled *I give up* (Figure 5C). When this happens, 1 of the 3 unsolvable mini-games is displayed to the user.

The 3 unsolvable mini-games are based on different types of puzzles (Figures 6A-C). For example, one is based on the popular *15 puzzle*, in which a 4 × 4 grid has 1 empty cell and 15 cells containing tiles numbered 1 to 15 and the goal is to move the tiles to arrange them in increasing order. The first level shown in the mini-game is kept very simple and easily solvable (Figure 6A1), which allows the users to become familiar with the puzzle. However, unbeknownst to the user, the second and third levels are unsolvable—we set the initial configuration of tiles in these levels by slightly reordering the tiles from solvable puzzles in such a way that they could not be solved anymore but looked normal otherwise (Figure 6A2). Thus, at the second level—just after the very easy first level—the user finds it impossible to solve the puzzle and has no choice but to accept failure by clicking on the button *I give up*. After this, the third level of the same mini-game appears, in which the user again gives up regardless of how hard they try.

Once the user gives up in both the levels of an unsolvable mini-game, the last solved level of the circle-triangle mini-game is shown again (Figure 7 presents the flow of mini-games). If the user gives up on this level, which they have previously solved, we take the opportunity to draw a parallel with learned helplessness and the game ends with the explanation. By relating to the game, we explain the ideas of learned helplessness and attribution bias, with an emphasis on personalization and pervasiveness. We expect that once individuals can appreciate their own susceptibility, they are more likely to engage in the introspection to identify real-life situations where they fall prey to dysfunctional attribution styles. A correct understanding helps one to evaluate each situation independently and not lose motivation in all areas of life upon experiencing failure in some.

Figure 5. Screenshots of the circle-triangle mini-game in the game for learned helplessness. (A) The initial state in level 4. (B) An intermediate state in level 4. (C) An intermediate state in level 6.

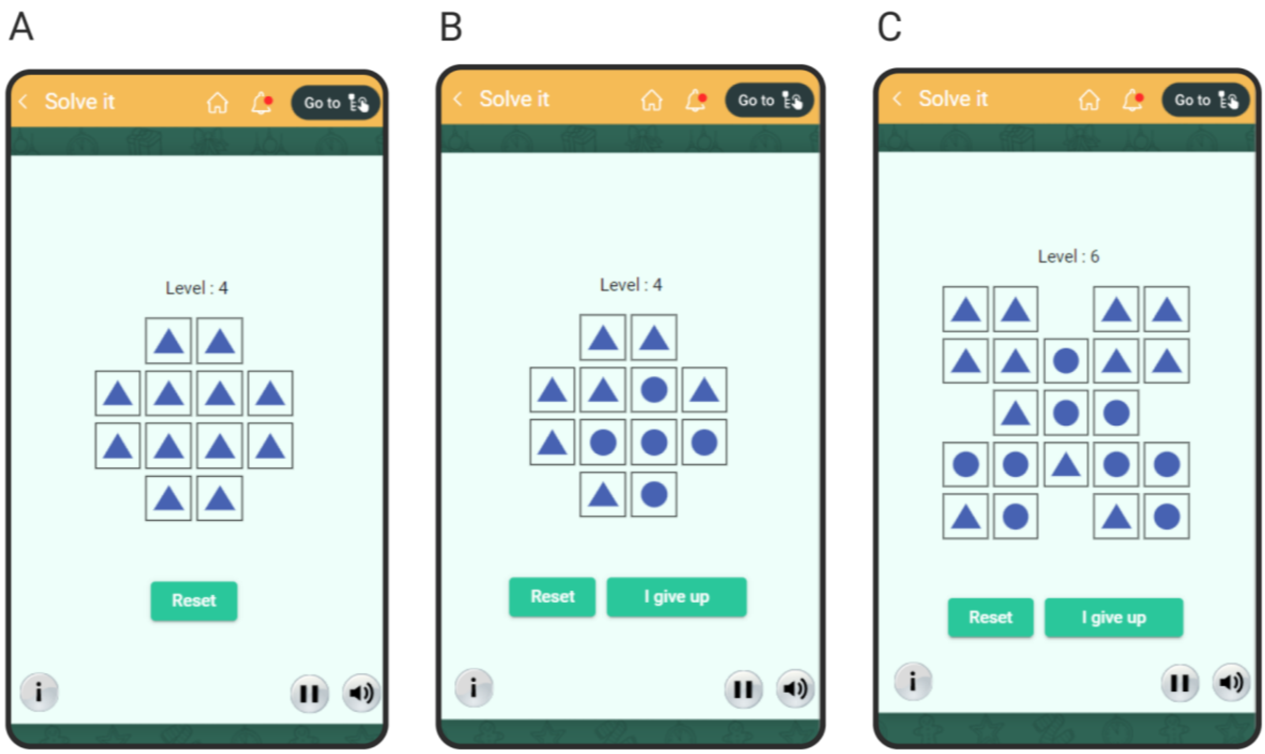


Figure 6. The 3 unsolvable mini-games within the game for learned helplessness. (A) The goal in this mini-game is to arrange the tiles in the increasing order of the numbers. Configuration A1 is solvable, and A2 is unsolvable. (B) The goal in this mini-game is to get the butterfly to sit on all the flowers. The butterfly can be moved forward and sideways using the cursor keys on a keyboard or the swipe action on a touchscreen device. Once a butterfly sits on a flower, the flower withers away and the butterfly cannot move to a position without a flower. B1 is solvable, and B2 is unsolvable. (C) The goal in this mini-game is to insert the small red arc into the big blue arc. The user can move the solid black ball using cursor keys or swipe action to the adjacent squares (if the square contains an arc open in the direction of the ball, the ball moves inside the arc). Once the ball is inside an arc, the arc can be moved along with the ball to an adjacent square that is empty or contains a bigger arc with an opening in the direction from which the smaller arc is coming. The ball comes out of the small arc if moved in the direction in which the arc is open. C1 is solvable, and C2 is unsolvable.

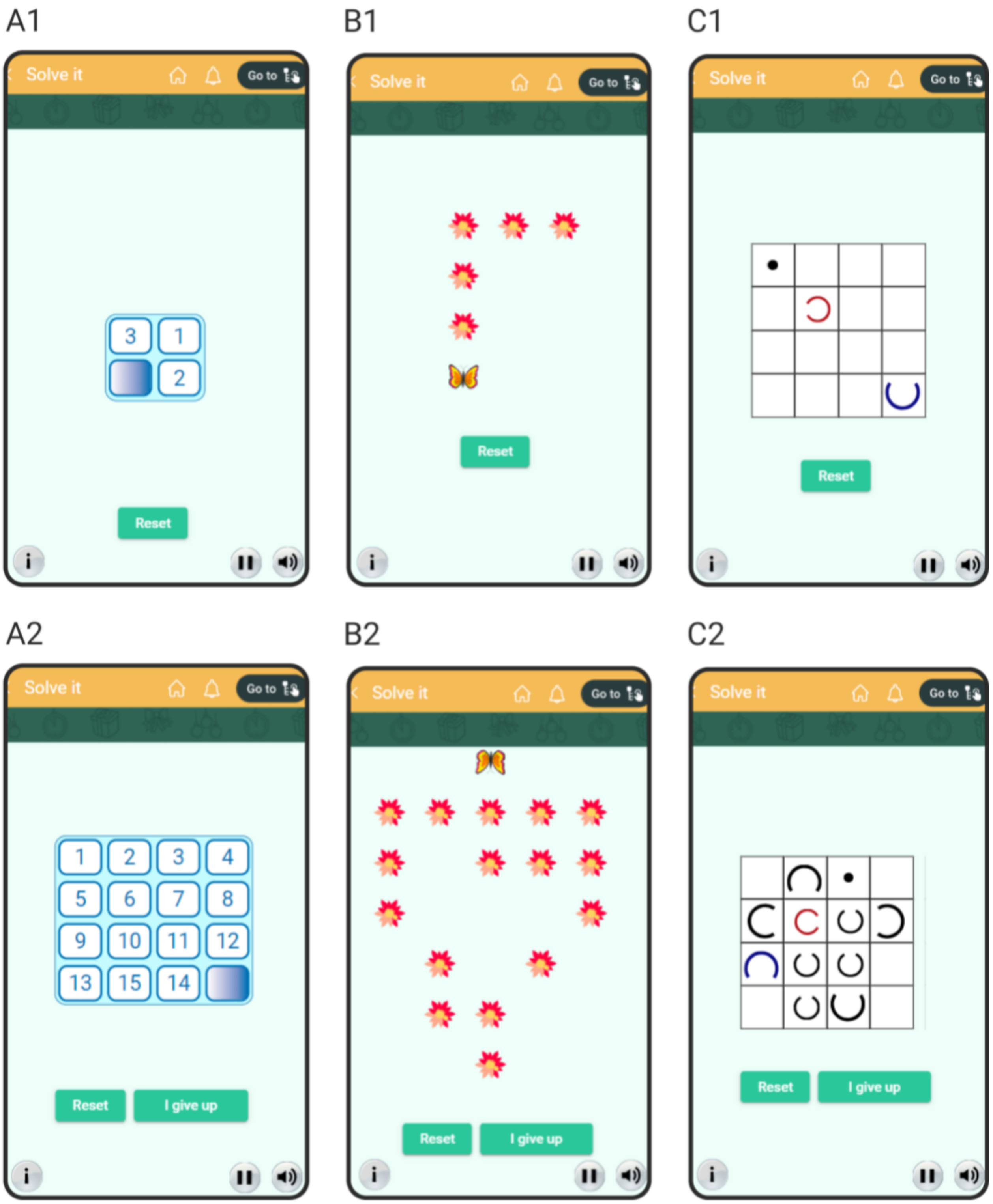
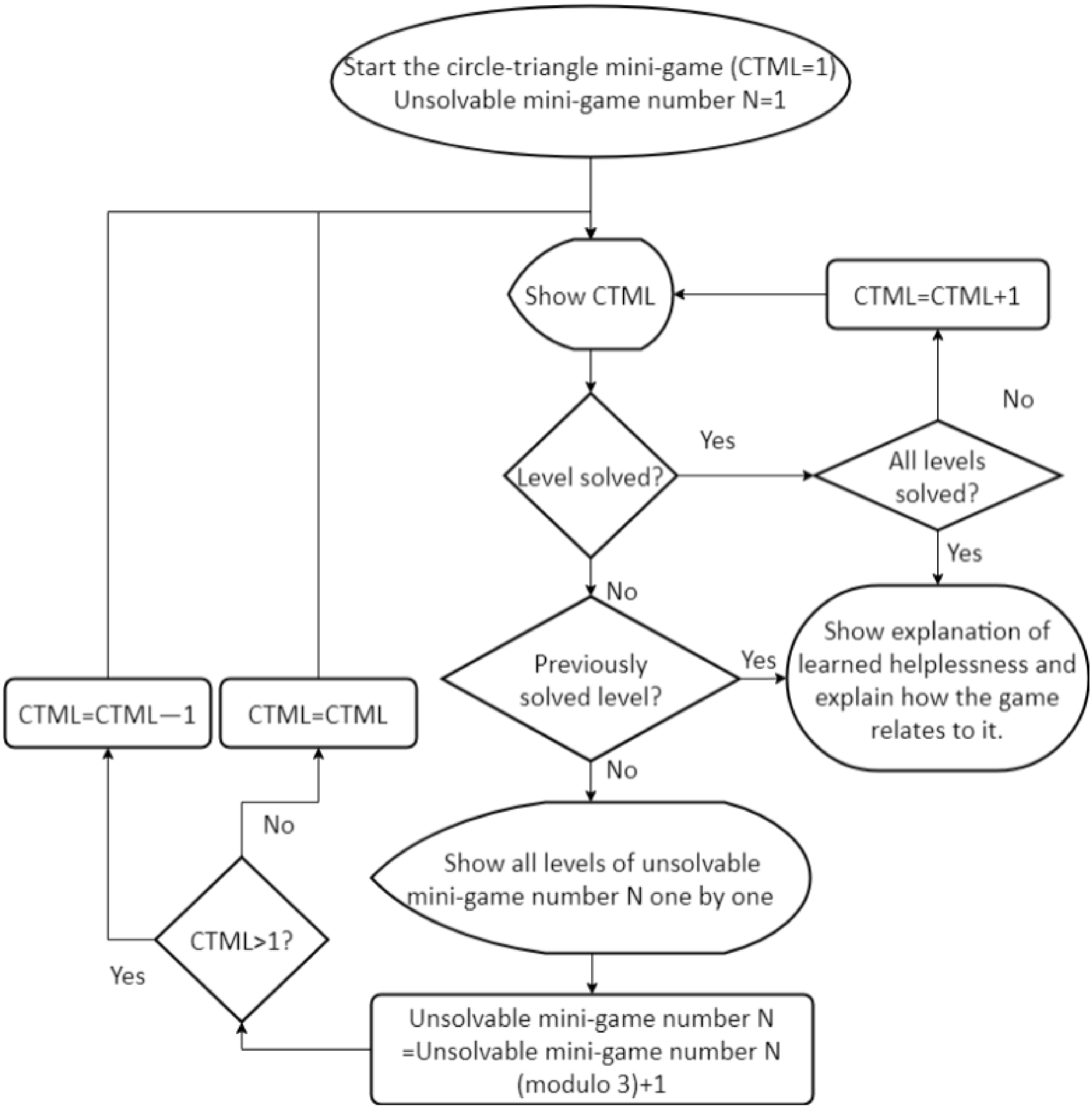


Figure 7. Flowchart describing the sequence of mini-games in the game for learned helplessness. CTML: circle-triangle mini-game level.



If the user does not give up on the last solved level of the circle-triangle mini-game, they reach the next level within the same mini-game, and the game continues as normal. Once they give up on a higher level of the circle-triangle mini-game, they are shown a different unsolvable mini-game. This cycle of alternating between the circle-triangle mini-game and a different unsolvable mini-game continues until the user gives up on a previously solved level of the circle-triangle mini-game or completes all levels in it (the difficulty of the higher levels ensures that the latter scenario is unlikely).

The 4 puzzle-based mini-games are designed to be engaging and challenging to play. The difficulty level in the circle-triangle mini-game adapts to the competence level of the users. The screen displays the current level to provide the user with a sense of progress. The user receives a gold badge on finishing the game. Unlike other games in TreadWill, this game was designed to be played for a limited time, until the explanation of learned helplessness and the idea of the game were shown; however, the users are free to play it again if they wish.

How Game-Like Are Our Games?

Cugelman [106] has suggested 7 core elements of gamification. Each of the games we had designed incorporated 6 of the 7 elements, including goals, challenges, feedback, rewards, progress, and fun; the only element not included in our games is social connectivity, as the games were designed to be played individually as part of a mental health intervention. Table 1 describes how the core elements are incorporated into each game.

Table 1. Core game elements incorporated in different games.

Game	Goals	Challenges	Feedback	Rewards	Progress	Fun
Automatic interpretation bias modification	Finding words in the alphabet grid to complete the sentence	Finding words from the grid within the allotted time	Points for finding words and positive interpretation	Points and badges	• In-level progress using progress bar • In-game progress using difficulty bar	Finding words in the alphabet grid
Executive control training	To keep the avatar alive as long as possible and collect coins	Avoid the obstacles at an increasingly faster speed	Points for keeping the avatar alive	Points and badges	• In-game progress via increasing avatar speed	Gameplay similar to *Super Mario Bros.*
Negative attention bias modification	To click on positive faces	To complete the song within the allotted time and avoid clicking on negative faces	Point and progress in level for clicking positive face and reduction in life for clicking on negative face	Points and badges	• In-level progress using progress bar • In-game progress using difficulty bar	The music along with the game play
Positive imagery training	To progress in the game by providing positive resolutions	Finding the right word	Points and progress in level for positive resolutions	Points and badges	• In-level progress using progress bar	Imagining the self-referent situations
Learned helplessness	Solving the puzzles	Solving the puzzles	Positive feedback for solving a puzzle	Badge	• For the solvable game, levels are shown	Solving the puzzles

Feedback on the Games

The feedback for all games obtained from the 15 pilot users (*Methods* section) is summarized in Figure 8. In most cases, there was statistically significant positive feedback on the clarity of instructions, fun in gameplay, and clarity of purpose (all $P<.05$; Table 2), showing that the games were acceptable to the users. According to the user feedback (Figure 8A-E), the games for negative attention bias modification (Figure 8C) and positive imagery training (Figure 8D) had the clearest instructions; the game for learned helplessness (Figure 8E) was the most fun to play; and the game for positive imagery training (Figure 8D) had the clearest purpose. The game for learned helplessness was able to achieve its purpose: 11 (73%) out of 15 users said that they had a better understanding of the idea of learned helplessness after playing the game. The game was able to induce anger or frustration in 6 (40%) out of 15 participants, of which 4 (67%) of the 6 mentioned that their anger or frustration reduced once the logic of the game was explained (overall, 7/15, 47% users reported a reduction in anger or frustration). Only 2 (13%) out of 15 participants reported that their anger or frustration did not reduce once the logic of the game was explained.

Figure 8. Acceptability results of the game for (A) automatic interpretation bias modification, (B) executive control training, (C) negative attention bias modification, (D) positive imagery training, and (E) learned helplessness. Overall (1) the instructions for the games were clear; (2) the games were fun to play; and (3) the purpose of the games was clear.

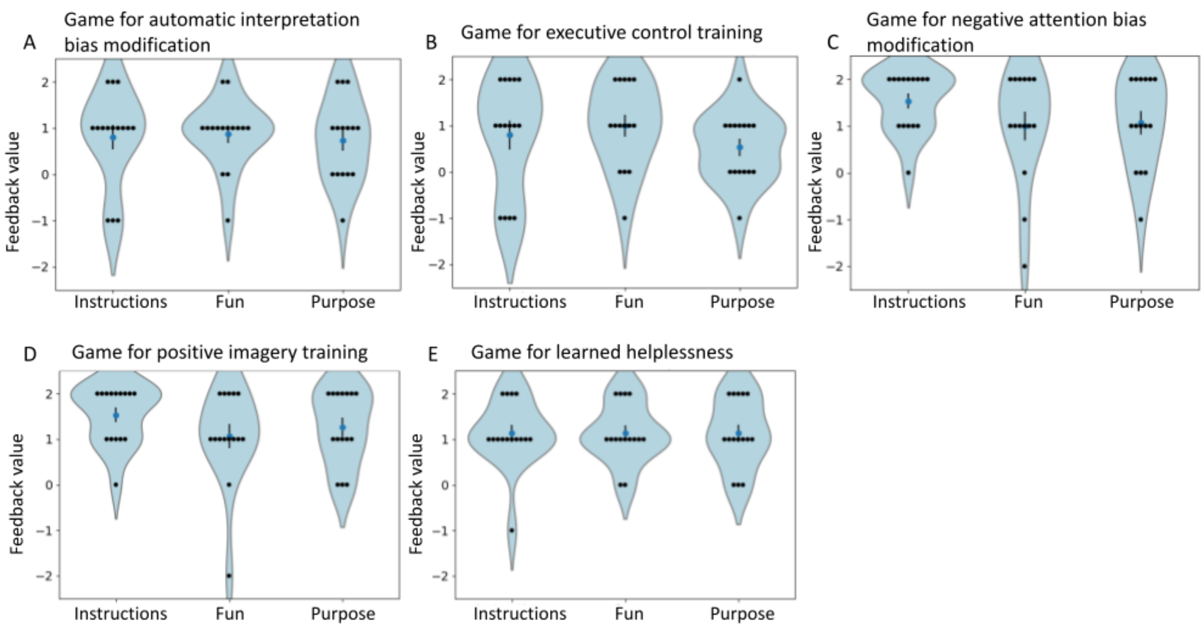


Table 2. Summary of feedback on the games from 15 pilot users. Each game was rated on 3 parameters on a 5-point Likert scale, in which 2=strongly agree, 1=agree, 0=neutral, −1=disagree, −2=strongly disagree. The *P* value corresponds to Wilcoxon signed rank test against 0.

	Values, mean (SD)	*P* value
Automatic interpretation bias modification		
Instructions	0.800 (1.014)	.02
Fun	0.867 (0.743)	.003
Purpose	0.733 (0.883)	.02
Executive control training		
Instructions	0.800 (1.207)	.03
Fun	1.000 (0.926)	.004
Purpose	0.533 (0.743)	.04
Negative attention bias modification		
Instructions	1.533 (0.639)	<.001
Fun	1.000 (1.195)	.01
Purpose	1.067 (0.961)	.003
Positive imagery training		
Instructions	1.533 (0.639)	<.001
Fun	1.067 (1.032)	.005
Purpose	1.267 (0.798)	<.001
Learned helplessness		
Instructions	1.133 (0.743)	<.001
Fun	1.133 (0.639)	<.001
Purpose	1.133 (0.743)	<.001

Discussion

Principal Findings

This paper describes the design of 4 serious games based on CBM paradigms and 1 serious game based on the learned helplessness theory. We expect that delivering the CBM paradigms in the form of serious games will increase the paradigms' engagement and consequent effectiveness. Currently, cCBT is the predominant digital intervention modality used for depression. Despite some early attempts at combining cCBT and CBM [23,32,33], no well-evaluated and widely available software intervention offers both. One likely reason is that users are not motivated to use the CBM paradigms in their raw forms. Incorporating game-based CBM paradigms in digital interventions might serve the following 2 purposes: increase engagement with the overall interventions and serve as a complementary therapeutic approach to CBT. Overall, all the games received positive feedback on all 3 aspects—whether the instructions were clear, whether the game was fun to play, and whether the purpose of the game was clear (Figure 8). In addition, the learned helplessness game was able to achieve its purpose of explaining learned helplessness via experiential learning.

Optimization of Game Paradigms

Two of the CBM paradigms described in this paper, the negative attention bias training [92] and the positive imagery training [94], were previously converted into serious games. In particular, the negative attention bias training paradigm has inspired many serious games. However, only a few have been evaluated in research studies [62,107,108], whereas the rest are commercially available without evaluation. The Bias Bluster game [109] was developed based on the positive imagery training paradigm.

We made slight modifications to 3 of the CBM paradigms to make them suitable for use in the games while keeping their active ingredients intact. In the original automatic interpretation bias modification paradigm, a sentence was shown for 1000 milliseconds [21]. However, during our internal testing, we observed that 1000 milliseconds was not appropriate for all sentences and, in general, too short for nonnative English speakers. Therefore, we showed the sentence for a duration dependent upon the length of the sentence, computed by *100 + (TC / ARS)* milliseconds, where *TC* denotes the total number of characters in the sentence and *ARS* denotes the average reading speed (estimated to be approximately 50 characters per 1000 ms).

In the original negative attention bias training paradigm, the images were presented in a 4 × 4 grid [92]. During the internal testing, we observed that a 4 × 4 grid on a smartphone screen makes the individual images very small and the emotions in the images indiscernible. Considering the higher penetration of smartphones than computers or tablets, we presented images in 2 × 1, 2 × 2, or 3 × 2 grids to ensure that the images and emotions could be seen easily.

In some of the previous implementations of the positive imagery training paradigms, the scenarios were presented in an auditory format and the positive resolutions were provided to the user by the program directly [25,94,95,97,100]. We presented the scenarios using a text-based format, similar to Mathews and Mackintosh [98], as the auditory format is less amenable to gameplay (eg, an audio clip is slower to scan back and forth compared with text). Furthermore, we designed the game such that the user was required to come up with a positive resolution to the ambiguous scenario. This modification was inspired by the observation that the training was more effective in changing the mood if the interpretation was actively generated by the user [98].

Limitations and Future Directions

Feedback from the users in this study indicates that serious games based on CBM paradigms are acceptable. However, this study had a small sample size. There is a need for more studies with larger, more diverse, and clinical samples to test the real-world engagement and effectiveness of the games. In the future, games can be made more engaging using virtual reality.

Conclusions

Serious game–based mental health interventions are acceptable to users and have the potential to increase their engagement with digital mental health interventions. The designs we have provided can also be adapted into other interventions for many other disorders in which cognitive biases are involved [110]. We expect that the inclusion of serious games based on the CBM paradigms will help in improving the effectiveness and engagement of digital interventions.

Acknowledgments

The authors thank the members of the NG laboratory for testing the initial versions of the games and providing feedback on the content and user experience. In addition, the authors thank professor Arjun Ramakrishnan and Abin Thomas for help in recruiting participants for the pilot trial. They also thank Arun Shankar and Ranjeet Kumar for labeling the images used in the game for the negative attention bias modification. Face images used in the game for negative attention bias training were collected from multiple sources: White—Psychological Image Collection at Stirling [111]; African and Asian—tarrlab [112] (courtesy of Michael J Tarr, Carnegie Mellon University; funded by National Science Foundation award 0339122); and Indian—photographed by us. This work was supported by the Cognitive Science Research Initiative (CSRI) of the Department of Science and Technology (DST; grant DST/CSRI/2018/102). The NG laboratory is supported by the DST Science and Engineering Research Board Swarnajayanti Fellowship (grant SB/SJF/2021-22/04-C). The funding agencies had no role in the design or implementation of the study and in the interpretation of the results.

Data Availability

The deidentified data analyzed in the pilot study are available from the corresponding author upon reasonable request.

Authors' Contributions

AG and NG conceptualized the project. AG searched the literature for cognitive bias modification paradigms and suggested the initial game ideas that were refined and finalized after discussion with NG and other authors. AG, JA, SB, BKS, LA, AA, ST, KM, SR, YA, and SG developed the games. AG and NG wrote the paper with inputs from all coauthors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Flowcharts describing game algorithms.
[PDF File (Adobe PDF File), 388 KB - games_v11i1e37105_app1.pdf]

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Abbreviations

CBM: cognitive bias modification
CBT: cognitive behavioral therapy
cCBT: computerized cognitive behavioral therapy

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Original Paper

Gamifying Cognitive Behavioral Therapy Techniques on Smartphones for Bangkok's Millennials With Depressive Symptoms: Interdisciplinary Game Development

Poe Sriwatanathamma[1], MFA; Veerawat Sirivesmas[1], PhD; Sone Simatrang[1], BFA; Nobonita Himani Bhowmik[2], MFA

[1]Doctor of Philosophy Program in Design Arts (International Program), Faculty of Decorative Arts, Silpakorn University, Bangkok, Thailand
[2]Department of Game Design, New York University, New York, NY, United States

Corresponding Author:
Poe Sriwatanathamma, MFA
Doctor of Philosophy Program in Design Arts (International Program), Faculty of Decorative Arts
Silpakorn University
22 Borommaratchachonnani Rd
Khwaeng Taling Chan, Khet Taling Chan
Bangkok, 10170
Thailand
Phone: 66 917655317
Email: poesriwatana@gmail.com

Abstract

Background: There is serious concern over the annual increase in depressive symptoms among millennials in Bangkok, Thailand. Their daily routine revolves around the use of their smartphones for work and leisure. Although accessibility to mental health care is expanding, it cannot keep up with the demand for mental health treatment. Outside Thailand, multiple projects and studies have attempted to merge gamification mechanisms and cognitive behavioral therapy (CBT) to create mobile health intervention apps and serious games with positive feedback. This presents an opportunity to explore the same approach in Thailand.

Objective: This study investigated the development process of gamifying CBT techniques to support game mechanics in a visual narrative serious game, BlueLine. The primary target of this research is Bangkok's millennials. In the game, players play as Blue, a Bangkok millennial who struggles to live through societal norms that influence his digital life and relationships. Through in-game scenarios, players will learn and understand how to lessen the impact of depressive symptoms via gamified interactions on their smartphones.

Methods: First, this paper follows each development step of solidifying BlueLine's game structure by integrating the Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches (ABCDE) model and narrative in games. Second, the approach to select CBT and related therapeutic elements for gamification is based on suitability to the game structure. Throughout the process, CBT experts in Thailand have reviewed these scenarios. The approach forms the base of the player's interactions throughout the scenarios in BlueLine, broken down into 4 types of gamified mechanisms: narrative, verbal interactions, physical interactions, and social media interactions.

Results: With the game structure based on the ABCDE model, BlueLine scenarios implement gamified mechanisms in conjunction with the following CBT and related therapeutic elements: behavioral activation, self-monitoring, interpersonal skills, positive psychology, relaxation and mindful activities, and problem-solving. In each scenario, players guide Blue to overcome his triggered dysfunctional beliefs. During this process, players can learn and understand how to lessen the impact of depressive symptoms through gamified interactions.

Conclusions: This paper presents the development process of gamifying CBT and related therapeutic techniques in BlueLine game scenarios. A scenario can harbor multiple techniques, including behavioral activation, self-monitoring, interpersonal skills, positive psychology, relaxation and mindful activities, and problem-solving. BlueLine's game structure does not limit the fact that the same combination of CBT elements ties each gamified mechanism.

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KEYWORDS
cognitive behavioral therapy; gamification; Bangkok's millennials; depressive symptoms; mobile phone

Introduction

Background

Nowadays, most millennials in Bangkok, Thailand, have adopted a long-hours working culture, which allows little time to relax and unwind. Social media has become the platform of choice, whether it is used to socialize with others or to catch up on public health warnings, such as those issued during the COVID-19 pandemic [1]. From 2016 to 2020, the number of social media users in Thailand jumped from 32 million to 52 million, approximately 80% of the population, with an average of 2 hours and 55 minutes of web-based social exposure per day [2]. After a long period of social media use, a possible side effect is social comparison, such as seeking acceptance and confidence from external sources [3]. Thus, it plays an essential role in influencing one to develop depressive symptoms [4].

A total of 20,685 Bangkok millennials responded to Thailand's Department of Mental Health survey in 2021 [5]. The risk of developing depressive symptoms in this group is frighteningly high at 48.97%, and, compared with provinces outside the capital, it is 4 times higher [6]. The survey was completed using the Patient Health Questionnaire (2-question version, 8-question version, and 9-question version) mental health survey system that is based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).

Since the outbreak of COVID-19, depressive symptoms have become more apparent among Bangkok's millennials [5-7]. During the pandemic, there were constant actions to promote mental health care awareness by hospitals and schools to provide quality and sustainable mental health care services [8]. Nonetheless, exposure to help is still limited, as was the case especially during the COVID-19–related lockdown period [9,10]. More services must therefore explore other approaches to reach patients experiencing depressive symptoms.

Smartphones are becoming a unanimous part of our daily routine, creating a window of opportunity to increase access to mental health care [11]. This can be in the form of serious games (designed for purposes beyond entertainment), which are part of applied games; games based on cognitive behavioral therapy (CBT) constitute 1 of the 6 major categories of tested games for mental health [12]. This approach can benefit players with favorable emotional treatment through awareness, behavior changes, and relief of symptoms [13,14]. Mobile mental health intervention is affordable and can be used adjunctively with the patient's existing treatment [15].

Integrating CBT Techniques Into Games

In recent years, studies have attempted to develop frameworks to create practical approaches to developing gamified apps. However, most still need to be fully established [16,17]. It is challenging to integrate CBT into different contexts of each game while ensuring that it achieves the intended experience and treatment goal for the players [18]. In this paper, the term *intended experience* refers to the expected gameplay experience of the player (ie, the quality of the gameplay interactions) [19]. It is plausible to integrate CBT techniques into games as multiple successful projects existing in different regions have shown (eg, a mobile health [mHealth] app for Māori [Indigenous New Zealand people] youth with emotional difficulties, Quest Te Whitianga) [20]. Night in the Woods (a winner of the British Academy of Film and Television Arts games award for narrative) is the story of Mae, who is dealing with depression and anxiety as she quietly returns to her hometown [21].

This paper breaks down the development process of a gamified intervention incorporating CBT techniques into BlueLine. The overall intended experience for BlueLine is for the player to live through scenarios as the main character where they are given choices and can perform actions that incorporate the following therapeutic components: behavioral activation, self-monitoring, interpersonal skills, positive psychology, relaxation and mindful activities, and problem-solving.

Methods

Overview

BlueLine is a visual narrative serious game where the player plays as Blue, a Bangkok millennial who struggles to live through societal norms that influence his virtual life and relationships. The game is inspired by Florence [22], in terms of the way the narrative expresses through visuals, and by We Should Talk [23], in terms of how the player's verbal choices affect their emotional state and lead to certain consequences in the game's world. This game primarily targets mobile platforms, and most Bangkok millennials use them, especially those who exhibit depressive symptoms. The game is also designed to be approachable to casual players. On release, BlueLine will be playable in both Thai and English to support the primary target group.

In the early stages of developing BlueLine, the focus was to create prototypes that could successfully integrate the gamification of CBT techniques into narrative design and harmoniously use visual design as the core gameplay. Our design process includes medical doctors and therapists who frequently care for Bangkok's millennials. It allows us to circumvent the limited studies on the use of CBT in Thai games available at the time of this research. We will conduct a randomized controlled trial of the complete BlueLine prototype to assess its efficacy, acceptability, and usability with the support of Thailand's Department of Mental Health.

First, we must understand the behavior of our primary target audience, the millennials of Bangkok. The behavior patterns of popular activities among this group establish statistics, especially the popular interactions in each social media application [24,25]. It also includes the time spent on each web-based activity. From a game design point of view, creating scenarios by researching and understanding the habits of the target audience can lead to better engagement and enable delivering of the intended experience [26]. Our design team has created these scenarios to be approachable even to people who do not have depressive symptoms. Through these CBT-gamified interactions, players can absorb information to become familiar with how to cope with depressive symptoms. They can fail safely without social consequences in real life. Each game scenario will also have its intended experience, aligning with its intended experience.

Second, we aimed to obtain insight from experts who have experience using CBT techniques to treat Bangkok's millennials. For a better understanding of the game design of this project, we created short scenarios in the form of storyboards and gameplay mock-ups in the form of animation to help the experts to express their opinion on how the game will affect their patients and to suggest details that can improve the effectiveness of the CBT-infused interactions. These short scenarios are experimental prototypes that explore how we can merge CBT techniques and gamification elements. Successful prototypes that deliver the intended gameplay experience will be compiled into the game later.

The feedback from monthly meetings with the experts is critical in developing future iterations. Playtests were held within the team frequently, followed by group discussions, which were also immensely invaluable for our developers with CBT-related experience. They shared opinions on aspects that they feel are beneficial and need improvement. This technique of verbalizing thought processes in usability testing is called *thinking aloud* [27]. At this stage, the emphasis was on ensuring that the prototype was complying with the intended experience while incorporating placeholder art assets. This was a standard game development process to prove that the participative elements in the gameplay can be practical without having to rely heavily on aesthetics.

Selecting CBT Techniques as the Game Structure

CBT is an evidence-based treatment for psychiatric disorders, including depressive symptoms. This treatment involves attempts to change ways of thinking and behavior patterns through understanding negative thoughts, emotions, behaviors, and physiological reactions, thereby relieving their symptoms [28]. This helps individuals learn to be their own therapists [29].

For BlueLine, the game's core structure implements the Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches (ABCDE) model. It is a simple mnemonic developed in the field of rational-emotive behavior therapy by Albert Ellis [30]. This model targets beliefs as a fundamental course of treatment. It guides the individual to break down the event and carefully examine the causes and effects so that they may respond to the situation in an improved manner if it recurs [31].

The core structure often integrates the ABCDE model in several CBT-based applications and serious games. One such application is Self-help, Integrated, and Gamified Mobile Phone Application, a gamified mHealth intervention, and it is used as an evidence-based theoretical structure for players to overcome their maladaptive beliefs [32], whereas REThink is a clinically tested therapeutic game for college students to manage distress efficiently [33], and ReWIND is a role-playing game that allows players to overcome their generalized anxiety disorder through anxiety-causing encounters [34]. Similar to BlueLine, they all use the ABCDE model to challenge dysfunctional beliefs in a safe virtual environment for their audience. Following this model, BlueLine's structure is divided into 5 steps (Textbox 1).

These 5 steps can match well with the narrative in a visual narrative game structure, as shown in Textbox 2. We can resolve the narrative tension by disputing beliefs and practicing new approaches. In addition, this allows other CBT and related therapeutic techniques to work in conjunction and still perform efficiently, including behavioral activation [35], self-monitoring [36], interpersonal skills [37], positive psychology [38], relaxation and mindful activities [39], and problem-solving [40].

Textbox 1. The Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches (ABCDE) model as a game structure from a player's point of view.

A: activating event

- Players identify their main character's trigger during a distressing scenario in the game.

B: beliefs

- Players understand the underlying dysfunctional belief as the scenario plays out by observing how the main character reacts.

C: consequences

- The impacts of the main character's beliefs influence physically within the game's world (character actions and surroundings) and psychologically (emotions).

D: disputation of beliefs

- The main character will attempt to challenge their dysfunctional beliefs through a series of player interactions in the game.

E: effective new approach

- The main character manages to transform their initial dysfunctional beliefs. The player will witness positive changes in the main character's mindset.

Textbox 2. A narrative scenario in the Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches (ABCDE) model.

Activating event

- Blue is forced to stay late at the office. Even after he gets home, he gets another call from work and has to stay up to work.

Beliefs

- He feels worthless. No matter how hard he works, the office is not happy.

Consequences

- He feels unappreciated, drained owing to lack of sleep, and loses interest in activities.

Disputation of beliefs

- He recognizes that the office is taking advantage of him and that he should not devalue his worth based on other people's words.

Effective new approach

- He discusses with the management his plan to not work after business hours and starts to perform recreational activities instead.

BlueLine simulates scenarios in safe virtual environments; players have the comfort of time to identify dysfunctional beliefs before they can happen. This way, they can see the consequences of their choices through self-monitoring the game character. The game allows players to challenge dysfunctional beliefs through its main character, Blue.

Following this structure, we aimed to scale up BlueLine because we plan the gameplay length to be approximately 1 hour and 20 minutes. We aimed to manage players' time on a single playthrough of BlueLine, thus lowering the risk of preoccupation with the game, which is one of the symptoms of internet gaming disorder in DSM-5, Text Revision [41]. Several factors are related to addictions, such as life satisfaction [42] and the types of games (on the web and offline) [43]. Statistically speaking, players who spend long weekly gaming hours (approximately 20 hours per week) are more likely to develop depressive and addiction symptoms [44].

BlueLine gameplay has 15 chapters, each lasting 5 minutes on average. The game will offer pause and resume features. Players do not have to finish a chapter in 1 session and have the option to resume from where they left off. Our players may not return to the game because a lack of motivation can be related to depressive symptoms [45]. This presents an opportunity for a reminder feature to encourage players to resume the game through timely notifications; for example, the game would deliver notifications during the evening but not late at night. This reminder feature also exists in internet-based CBT applications [46] and eHealth programs [47].

Storyboards are also developed during this process, with mock-ups created to test the composition of visual elements on a smartphone screen. While sketching the storyboards, many discussions arose about specific moments, leading to more inspiration to develop the narrative further. We can determine which CBT-infused action the main character could perform by seeing the sketched character in the scenario. We specifically designed the color palette and animation to ensure that players are not exposed to specific light patterns or flashing lights, which can lead to photosensitivity epilepsy or blackouts. Thus, storyboards guide the next step—the gamification of CBT techniques.

Approach to Gamification of CBT

The challenge is to gamify CBT techniques appropriately and fit them into each scenario. The chosen approach is based on case-by-case scenarios, with the end goal being that the interactions should be meaningful to the player. Meaningful play occurs when the player's action has immediate importance and affects the larger context of the game [48]. We were able to accomplish this by basing the content of BlueLine on Bangkok's millennials, including their daily routines, behaviors, and life experiences. This shapes the identity of Blue (the main character), who would face and overcome obstacles in the story.

Gamification Elements

We divide BlueLine's CBT gamification elements into 4 main components: narrative, verbal interactions, physical interactions, and social media interactions. We acknowledge that existing studies discuss gamification elements in CBT-based applications, such as scores, levels, and tokenized rewards [49,50]. However, there are difficulties implementing them in BlueLine because it is not in the nature of a visual narrative game to have repetitive elements. Table 1 shows the core structure of gamification mechanisms, and other use cases will be discussed in the *Results* section.

Table 1. Gamified mechanisms in BlueLine.

Gamification of CBT[a] in mechanics and description	Use in BlueLine
Narrative	
Growth of Blue as a representation of Bangkok's millennials	• The story is told from the perspective of Blue and his millennial daily routine, lifestyle, and life choices. Through the ups and downs in the story, Blue struggles with the triggering of his dysfunctional beliefs and overcoming them. • CBT techniques: self-monitoring, problem-solving, and interpersonal skills
Verbal interactions	
Engagement in conversation	• Blue participates in conversations with NPCs[b] throughout the game. Each NPC's reply contains therapeutic components depending on the player's verbal choices. • CBT techniques: self-monitoring, interpersonal skills, and behavioral activation
Physical interactions	
Activities that require Blue's physical action	• Blue participates in multiple activities that require him to perform the task physically. Interactions range from basic actions such as walking to complicated tasks such as grocery shopping and giving a love letter. • CBT techniques: relaxation and mindful activities and problem-solving
Social media interactions	
Scrolling through social media and likes	• This feature mimics a social app where players can scroll through the social feed in the game's world. The content in the feed is generated by design to match the intended experience of that scenario. It is not linked to any actual social apps. Generated posts are visual based to avoid negative trigger words. • CBT technique: self-monitoring
Photo mode	• This feature is a version of the camera app on mobile phones. The scenes that players see through the lens are generated by design, inspired by actual real-life locations. • CBT techniques: relaxation and mindful activities

[a]CBT: cognitive behavioral therapy.

[b]NPC: nonplayer character.

Results

Overview

This section details several scenarios where each gamification mechanism is integrated with CBT and therapeutic techniques. There is a degree of flexibility in which specific scenarios can have multiple gamification mechanisms and therapeutic techniques, whereas the core structure includes the ABCDE model.

Narrative

Depressive symptoms can recur, and that is the takeaway from BlueLine, which shows through player interactions that CBT and therapeutic techniques can reduce the risk of relapse as long as it is maintained [51]. BlueLine will take players through multiple scenarios built under the expanded ABCDE structure (Tables 2 and 3). This version adds a chapter column to support the upscaled story. A DSM-5 column is added to assess Blue's depressive symptoms at each stage of the story. This serves 2 purposes. First, it keeps the developers and consulting experts informed about exposure to depressive symptoms during the design and production stages. Second, it identifies moments in BlueLine where the game could encourage players to be open to seeking mental health care. This approach could circumvent the unwillingness of Asian communities to access help from mainstream services [52]. Throughout the game, visual keys are placed to subtly help the player gain confidence to reach out for help if needed; for example, a customized billboard of a real-life mental health care service will be placed far in the background but still legibly visible.

Table 2. BlueLine's Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches (ABCDE) structure with a narrative framework and a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) column.

BlueLine: Chapter 9, scenario 3	DSM-5 A1[a]-A9	ABCDE model
Blue and his partner have a minor quarrel over the photos he has taken.	__[b]	Activating event: Blue tries to apologize because the photos he took were not his best.
Line thinks that Blue is not trying hard enough and believes that he does not care.	—	Beliefs: Blue feels he has messed up. In the hope of being forgiven by Line, he keeps apologizing to her.
Line vents at Blue.	—	Consequences: Blue feels insignificant and worthless because she despises the photos he took.
The player stops Blue from panicking.	—	Disputations of belief: Blue stops apologizing (stays silent) so that Line can gather her thoughts.
Line realizes that Blue did try his best.	—	Effective new approach: Blue learns that by not panicking, he enables Line to understand his worth.

[a]A1 to A9: assessment of depressive symptoms at each stage of the story.

[b]To be filled in by the developers and consulting experts.

Table 3. An ABCDE[a] model breakdown of the conversation exchanged between Blue and Line in chapter 9 of BlueLine.

	Activating event	Beliefs	Consequences	Disputation of beliefs	Effective new approach
Narrative	• Blue and Line are having breakfast after the sunrise photo shoot. The couple begins to quarrel.	• Line thinks that Blue is not trying hard enough and believes that he does not care.	• Line vents at Blue.	Blue cannot continue to apologize because the game prevents the player from saying "Sorry" by fading out the "Sorry" button.	Line realizes that Blue does try his best and that the way she expresses herself has a negative effect on Blue.
Blue	• Blue tries to apologize because the photos he took were not his best. • Player begins self-monitoring.	• Blue feels he has messed up. In the hope of being forgiven, he keeps apologizing (achieved by the player pressing the "Sorry" button). • DSM-5[b] symptoms: • A7[c]: a sense of worthlessness • A8: impaired concentration	• Blue feels insignificant and worthless because she despises the photos. • DSM-5 symptoms: • A1: depressed mood • A2: lack of interest • A6: fatigue • A7: a sense of worthlessness • A8: impaired concentration	Interpersonal skills (using silence): Blue uses silence so that Line can gather her thoughts.	Behavioral activation: Blue learns that sometimes a moment of silence can help others to regain their minds.
Line	• Line is angry because the photos taken by Blue are not good enough.	• She thinks that the photos are bad because Blue does not care. She does not want to listen to any excuses or apologies.	• Line feels unappreciated and blames Blue. • DSM-5 symptoms • A2: lack of interest • A8: impaired concentration	Interpersonal skills (giving recognition): Line realizes that her words have hurt Blue.	Behavioral activation: Line learns to appreciate and give recognition when others are trying their best.

[a]ABCDE: Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches.

[b]DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

[c]A7 and so on: assessment of depressive symptoms at each stage of the story.

Act 1: Refresh

It is a new beginning for Blue, who has just returned to Thailand to start a new chapter in his life with a good office job and to be with family. The player will begin appreciating the sense of well-being radiated by a motivated office worker through self-monitoring Blue's daily routine. Blue will encourage the player to complete relaxation and mindful activities throughout the day by rewarding them with positive outcomes. This is achieved by engaging in physical interactions that some might consider mundane tasks (eg, waking up at 5 AM to leave for work early to avoid the traffic). At the same time, Blue will show appreciation for a beautiful sunrise. Eventually, the same routine begins to gray out as his surroundings slowly pressure him, such as being asked to work overtime. This will subtly trigger the activating event of the ABCDE model. The player's interactions at this stage consist of following Blue's attempts to find his way back to the well-being he once experienced.

Act 2: Reaching Out

After unsuccessful attempts at socializing, Blue meets Line, a girl who is an office worker just like him. They start to bond and become more and more close after each meeting via verbal interactions. Line's characteristics serve multiple vital purposes in the game. She serves as a source for Blue's development; at times, her actions and speech are similar to those of a therapist (to help reduce the anxiety the player might feel regarding their first therapeutic appointment). When Blue is feeling low, she helps him by performing therapeutic-infused actions (eg, using interpersonal skills). She also encourages Blue to participate in relaxation and mindful activities to reduce his negative emotions via positive psychology [38] (eg, visiting gardens and mountains). After some time, she will trigger a dysfunctional belief stemming from upward social comparison. This will allow Blue and the player to reciprocate her kindness and problem-solving proficiency using the therapeutic techniques they learn during the game.

Act 3: Reconnect

This act is set during the time frame of the 2020 COVID-19 pandemic in Thailand. Although the world changes, we want to present ways to handle mental health for our stakeholders. In the story, Blue's parents ask him to return home during quarantine. He is hesitant to leave Line's side because he only recently moved in with her, but she is supportive of his decision to go back home to take care of his parents. Slowly, however, distance begins to chip away at their bond. Depressive symptoms arise from activating events through social comparison in topics such as "It is safe to go on trips because there is no close contact if nobody goes on a trip," even as the lockdown intensifies in Thailand. Ultimately, the two work together to dispute their different dysfunctional beliefs to save their relationship. The last problem-solving session involves using the related CBT techniques throughout the game to unfold the final problem. The game rewards the player with a fulfilling climax—narrative, gameplay, visuals, and sound at their peak—making the final interaction memorable for players so that they may recall the way they used behavioral activation to handle the situation were it to happen in real life.

Verbal Interactions

Interactions with other nonplayer characters (NPCs) are essential in this game. Through their voices and actions, the NPCs aim to provide therapeutic components and gamification strategies, such as reinforcement of successful behavior, and provide feedback on the player's performance through prompts [53]. Players can make verbal decisions through the dialogue-crafting system (Figure 1).

The dialogue-crafting system is inspired by the sentence-spinner mechanic from the game *We Should Talk*. The game's use of sentence crafting creates different reactions. It focuses on using a designated combination of verbal choices for players to string together. In BlueLine, we have set up 2 types of sentence crafters: the single-choice sentence crafter allows the player to change 1 part of the sentence, whereas the dual-choice sentence crafter allows 2 parts to be changed.

CBT components will be integrated based on the verbal combination put together by the player and the feedback provided through the NPC, Line (Blue's partner); for example, as shown in Figure 2, this conversation aims to surround the player with a therapeutic interpersonal relationship to make them feel cared for in a supportive, nonjudgmental environment [54].

The gameplay screen shows Blue (the player) and Line (the NPC) at a cafe. Their conversation is shown in the bubbles positioned above their heads. At the bottom is the sentence crafter. The phrase "It does get crazy" is prefixed, as shown by the solid line, whereas the switchable portion is designated by a dotted line. Although the 2 choices are worded differently, they have the same underlying intention, which is to create positive emotions through evoking a sense of well-being [38]; for example, a player whose childhood was filled with joyous and noisy moments will be able to relate more to these good memories than players whose childhood was not as joyous and noisy. This follows the concept of piggybacking in game design, using what players already know instead of teaching them from scratch [55].

The example presented in Table 3 involves depressive symptoms experienced by both Blue and Line. Together, they review the photos Blue took. Line does not like the photos; hence, Blue tries to apologize to her in an attempt to calm her down. A "Sorry" chat bubble will appear when the player presses the "Sorry" button at the bottom of the screen. However, no matter how often the player presses the "Sorry" button, Line does not calm down. To resolve this issue, the player has to stop pressing the "Sorry" button. This would prevent Blue from apologizing and enable Line to gather her thoughts. Ultimately, Line realizes that her words hurt Blue; she appreciates this and says, "Sorry. Thank you for trying your best." Throughout this scenario, self-monitoring, interpersonal skills, and behavioral activation are used.

Figure 1. Dialogue-crafting system: single-choice sentence crafter.

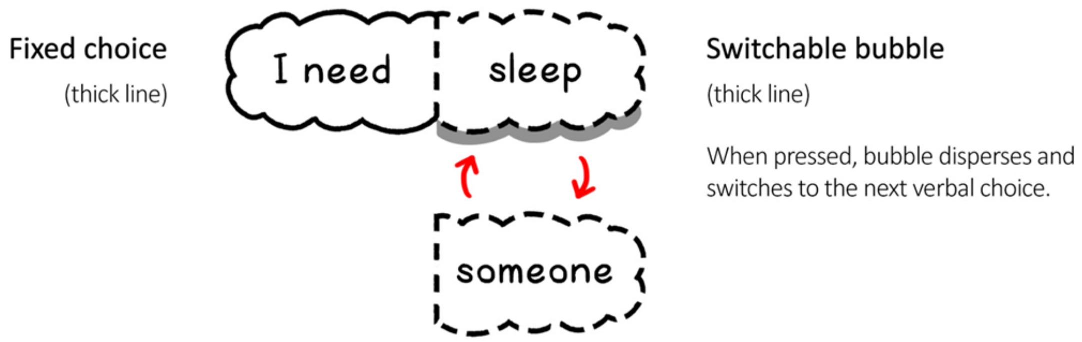
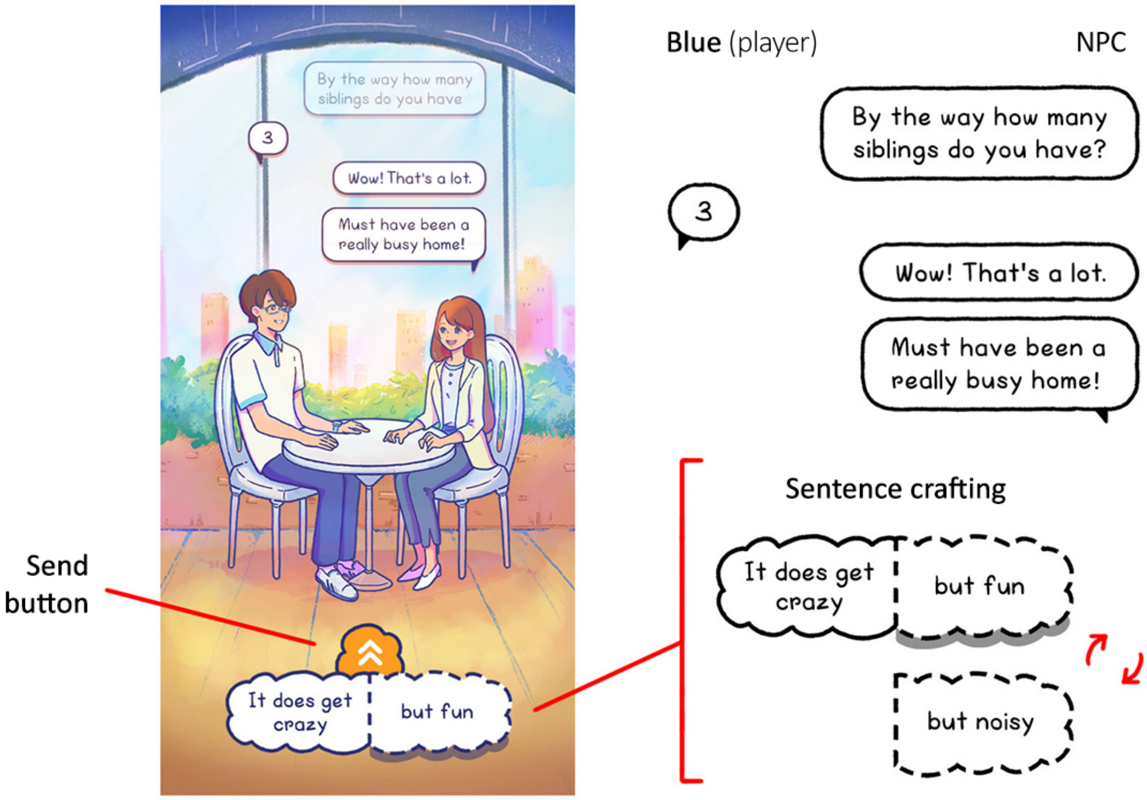


Figure 2. Breakdown of BlueLine's single-choice sentence spinner.



Physical Interactions

In BlueLine, physical activities expose players to therapeutic components through actions. This chapter presents 2 examples: one concerns implementing art therapy as relaxation and mindful activities, and the other concerns problem-solving.

The first scenario occurs when Blue stops by to purchase a bouquet of flowers on Valentine's Day. Instead of buying a premade bouquet, he makes one by hand (Figure 3). The goal is to teach the player that socializing is not the only means of engaging in relaxation and mindful activities. The process of art creation in art therapy also includes therapeutic elements such as self-exploration, which promotes an individual's self-awareness in terms of seeing a more positive self-image [56]. Art creation is not tied to a single medium and can vary depending on the culture concerned; some examples are painting, music, and knitting [57,58].

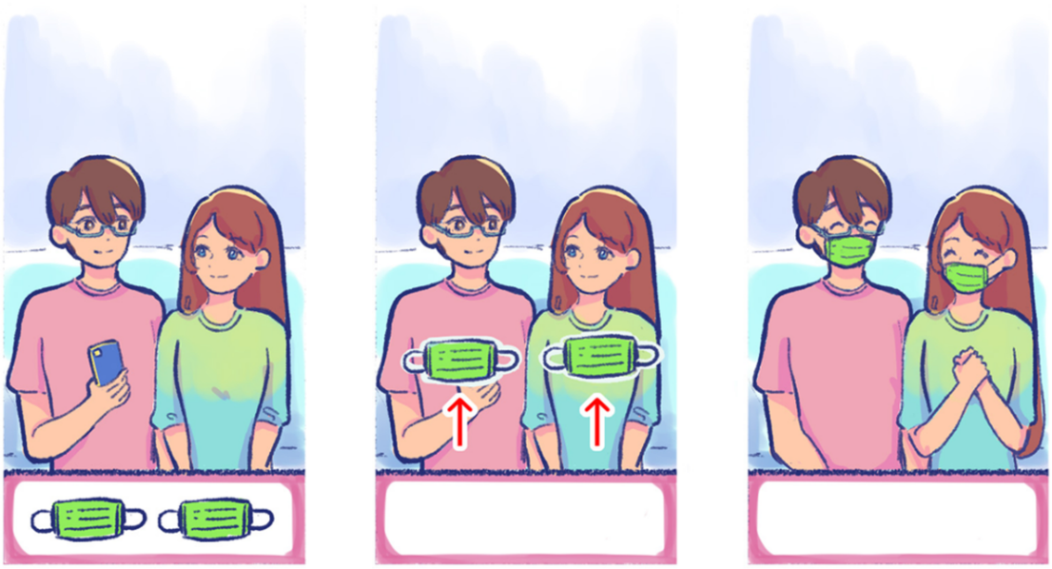
To make the experience feel tangible, the player can decorate the bouquet using their fingers to drag and drop each flower. There is a minimum placement limit before the game can proceed to the next scenario, but the player can take their time until they want to move on. We consider not tying in reward-centric game elements, such as keeping score or points for tokenized rewards, and instead allowing the journey of the interactions itself to be the reward. From our experience, this helps player engagement to last longer.

There is a moment in act 3 when Blue goes to a supermarket during the 2020 COVID-19–related lockdown in Thailand. He picks up face masks, alcohol, tissue rolls, and other necessities, but only so many items are available on the shelves.

The scenario at this stage of the game displays the risk of developing depressive symptoms during the COVID-19 pandemic in Thailand. As the population experiences more exposure to the disease and tunes in to information about COVID-19 on social media for at least 3 hours per day, there are more substantial effects on mental health in the form of anxiety and insomnia [7]. However, the process of problem-solving can be positively oriented. The solvable problem is set up for the player as a challenge and encourages their ability to resolve it effectively [40]. In Figure 4, the player will perform a swipe-up gesture with their finger to get both Blue (the player's character) and Line (the NPC) to wear masks. The players can see the progress through visually animated feedback from the 2 characters.

Figure 3. BlueLine's handmade flower bouquet: (A) before gameplay and (B) after gameplay.

Figure 4. Wearing face masks during the COVID-19 pandemic.



Social Media Interactions

According to the 2020 user behavior survey conducted by the Electronic Transactions Development Agency [59], Thai individuals spend 11 hours and 25 minutes on the internet daily, which is triple the amount compared with 2013. Instead of avoiding this topic, BlueLine uses it to visually compare a web-based lifestyle with a balanced one. Another objective is raising awareness of the players so that they can better understand the current lifestyles of Bangkok's millennials. Social media interactions are represented as social media apps and a photo mode.

The social media app in BlueLine focuses on the social feed aspect; it mimics existing social media apps, such as the Facebook, Instagram, and Twitter apps. However, the content of the feed is generated by our design team; none of it is taken from actual sources. To date, numerous studies point toward the impact of social comparison on social media on personal well-being and depressive symptoms [3,60,61]. Regarding this aspect, BlueLine intends to show players through self-monitoring that Blue's well-being improves after his fixation on social media reduces. This can be achieved through design-generated content (images, comments, and the number of likes) and controlling the time spent on social feed gameplay. Some posts do deal with social comparison to avoid players developing adverse mental health outcomes, such as a decline in psychological well-being [62], and making unfavorable social comparisons [63]; for example, a person may experience a lowering of self-esteem after they see someone showing off their material possessions in a post. In terms of duration, each social media gameplay session has been designed to last <1 minute to prevent players from engaging in heavy social media use and its associated adverse effects, such as self-harm behaviors [64] and a lowering of self-esteem [65].

As many social posts are accompanied by images, the interactive actions in the photo mode will be familiar ground for our target group. Players can use Blue's phone to take photos of various things, such as food in restaurants and natural scenery (eg, mountains; Figure 5). All the locations presented in BlueLine's photo mode are replicated from actual destinations in Thailand. This mode can catalyze players to venture outside and engage in relaxation and mindful activities (eg, visiting parks rather than shopping malls).

The player's photos will be saved into a digital photo album that acts as a gratitude journal so that players can look back at such moments and share the photos on the internet. In this album, there will be positive prewritten notations made by Blue to help remind players of the events that occurred in these scenarios (Figure 6). Gratitude reinforcement can improve daily mood and lessen adverse effects (eg, depressive symptoms) [66]. However, multiple studies suggest that combined social comparison and materialism can negatively affect subjective well-being [67-69]. Maintaining a high level of gratefulness can lessen materialistic behaviors [70]. To increase accessibility to Blue's gratitude journal, we have made it possible for players to access the album via 2 routes: the pause screen and the main menu.

Figure 5. BlueLine's photo mode.

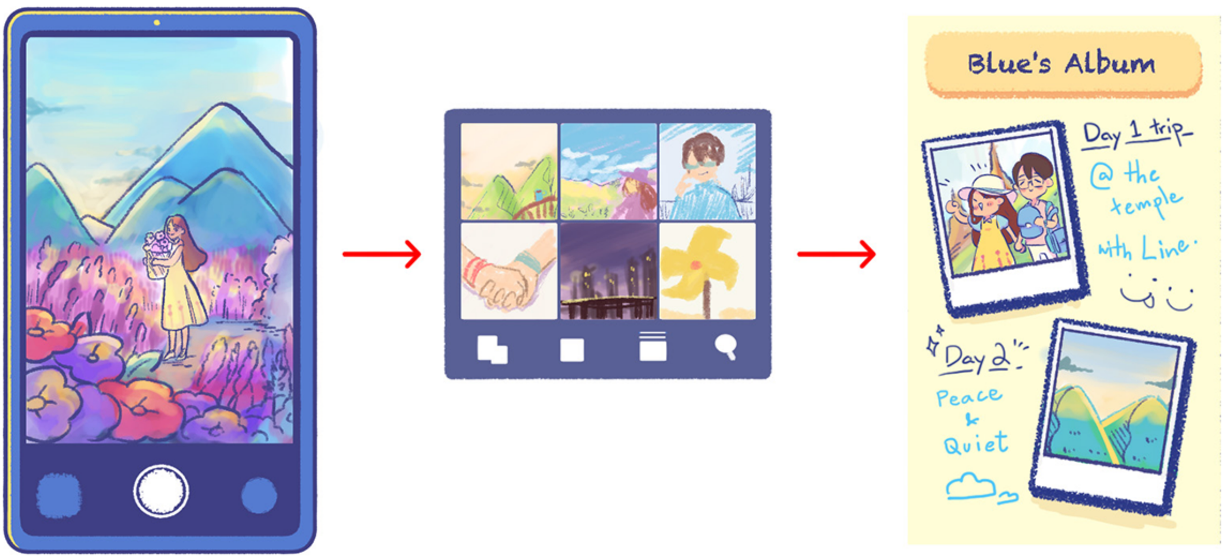
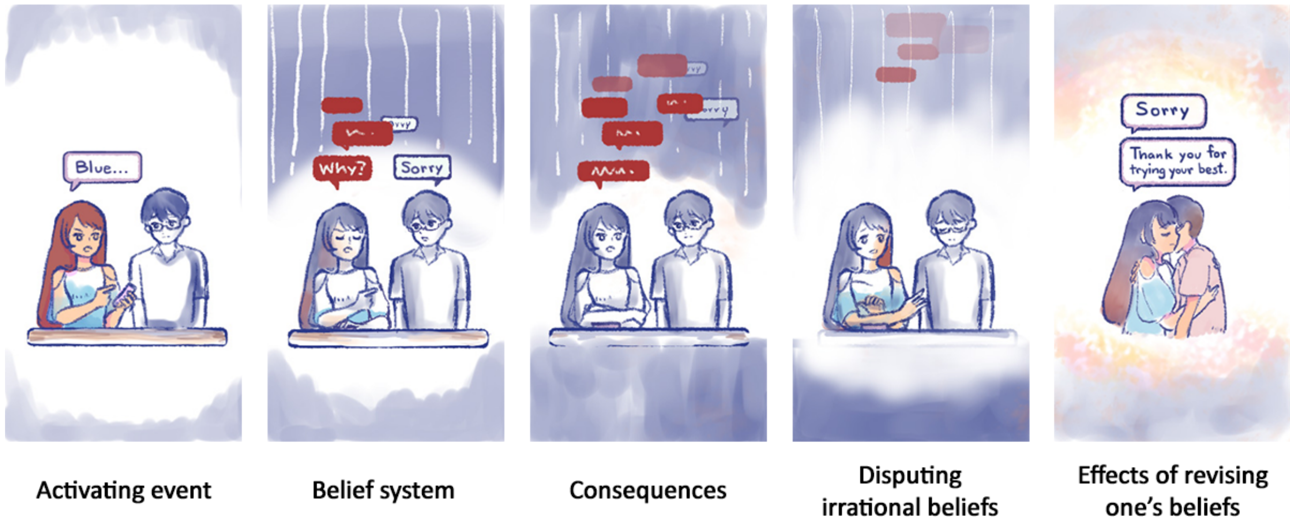


Figure 6. A breakdown of the conversation exchanged between Blue and Line in chapter 9 of BlueLine.



Discussion

Principal Findings

This study outlines the process of developing BlueLine, a gamified CBT intervention project on smartphones. BlueLine uses the ABCDE model as the game's core structure to present the gamified CBT components (Table 1). The core structure integrates the narrative structure before the gameplay with visual elements. The early development is iterative and experimental, and it involves collaboration with CBT specialists in Thailand who have expertise and knowledge in caring for Bangkok's millennials. Multiple playtests were set up with university students to help with the development process.

As a serious game, BlueLine falls into the visual narrative genre. Its gameplay lasts approximately 80 minutes, broken into 3 acts and 15 chapters. The game is split into short bursts to match a common habit of millennials—resorting to technology for a momentary escape from work—as well as their short attention span [71]. For the context to be meaningful to the target group, the daily routines, behaviors, and life experiences of Blue (the main character) reflect those of Bangkok's millennials. In addition, interactions in BlueLine are inputted using finger gestures that mimic those involved in the daily use of smartphones.

Primarily, we have designed BlueLine to be used in adjunct with the patient's primary treatment. It is not designed to tackle depressive symptoms entirely; instead, it focuses on enabling the player to understand the impact of depressive symptoms and learn how to lessen it. In most cases, our target group will not be playing the game while attending a session with their therapist; thus, BlueLine must be able to retain player engagement through gameplay. BlueLine's gamified CBT mechanics (narrative, verbal interactions, physical interactions, and social media interactions) have been created to be flexible enough to fit into many narrative contexts so that the game encourages repetitions of the following CBT techniques: behavioral activation, self-monitoring, interpersonal skills, positive psychology, relaxation and mindful activities, and problem-solving.

Strengths

Experience plays a crucial part in this project. Our members have experience making small-scale visual narrative games such as Yumi's Home [72], a first-person 2D narrative game about depression, familial obligation, and isolation. Furthermore, we have attempted to understand our target players and their behaviors in various ways. First, for 2 years, we were invested in researching the depressive symptoms experienced by Bangkok's millennials as well as preproduction prototypes. Second, the knowledge and experience of Thai CBT experts and the Department of Mental Health guided our design decisions in the development. There are 4 CBT experts, and each has >10 years of experience in psychotherapy; 2 experts are from the Department of Mental Health and a public psychiatric hospital, and 2 experts are faculty members of psychology departments at Thai universities. Thus, the project can scale up with confidence as we reach production.

To start with, we planned to localize BlueLine in both Thai and English. Those with Thai as their mother tongue can understand the nuances of the language and slang used by the characters, whereas English is meant for the increasingly international population in Bangkok. Players may switch the language at any given time via the options menu.

The story in BlueLine and the characters are based on the standard daily routines of Bangkok's millennials as well as the real-life stories of development team members. We have identified specific experiences that resonate through the spectrum of millennials' age range. The gameplay and visuals can be expressed on a deeper level in terms of attention to detail when non–game designers (artists and programmers) also participate in the design process [26].

Depressive symptoms can recur, and that is the takeaway from BlueLine, which shows players through interactions that CBT and therapeutic techniques can reduce the risk of relapse as long as it is maintained [51]. A game such as BlueLine is akin to an empathic listener. To empathize with another person is to understand their feelings, which is a level above mere acknowledgment. Serious games can make player more comfortable reaching out to the CBT-infused gameplay. Finally, BlueLine can enable players to learn by guiding the main character to challenge and overcome their dysfunctional beliefs.

Limitations

Currently, this project does not accept external funding. The project's scope is scaled to fit our current workforce, a team consisting of 5 members. Realistically, this is an ideal situation because we are able to maintain complete control over our design decisions. We intend all research and design processes to be free of external monetary influences (eg, investors). Once we complete the project, the app will be released in collaboration with the Department of Mental Health. We will consider a monetization model only after we have completed a randomized controlled trial of BlueLine with Bangkok's millennials.

Studies have shown the potential of gamification for depression care, but more data are needed to establish the effectiveness of this approach [73,74]. Many factors come into play when considering what gamification needs to accomplish in a serious game; each player may have different depressive symptoms, and the game cannot personalize the experience for each individual. An improper gamified element can have an adverse impact on individuals with mental illnesses [75].

Regarding game addictions, some studies have addressed their adverse effects on an individual's responsibilities (eg, education [76]) and personality (eg, adverse effects on self-esteem and behaviors [77]). In addition, BlueLine will be played on smartphones, which further extends users' total screen time. During the scoping phase, we established that the gameplay length is limited to <2 hours and is divided into small chapters to avoid long sessions. In the game, we have designed the interactions to be distinct from nonserious games and promote positive activities such as art therapy.

The BlueLine gameplay length of 1 hour and 20 minutes can be a little problematic, due to factors such as poor concentration, and can result in a higher likelihood of game addiction [44]. When a game loop is long, players can keep playing it repeatedly, which may result in long hours of screen time and addiction. However, BlueLine's *pause* and *resume* features allow players to take a break and return to the game later. In addition, it is within our scope to implement a feature to remind the player that they have been on the phone playing the game for too long. These features are used in internet-based CBT applications [46] and eHealth programs [47].

Of note, there are practical difficulties in developing mHealth apps in a higher middle–income country such as Thailand because of the lack of existing gamified mHealth apps for benchmarking. The lack of extensive statistical data on Bangkok's millennials makes it challenging to design specific scenarios in the game. To ensure that our design decisions can lead to the intended experience, we rely on creating multiple iterations of each scenario.

Growing up in Thailand, some of us have noticed that the general public, that is, those who belong to an earlier generation compared with millennials, have negative stereotypical misconceptions of games; they view games as childish activities and believe that a grown-up should not waste time playing games. Moreover, even today, seeking and receiving mental health care is stigmatized in many countries [78] and can lead to social rejection of patients as well as self-rejection experiences [79]. This aspect can hinder the reach of BlueLine to the target group. However, it is worth the attempt, considering the benefits of making CBT accessible to a substantial proportion of Bangkok's millennials. Thailand is one of many low- and middle-income countries looking at this technology as an opportunity [80].

Future Directions

In the future, we will collaborate with the Department of Mental Health to conduct a randomized controlled trial of BlueLine with Bangkok's millennials to assess its efficacy, acceptability, and usability. On the basis of the results, further adjustments will be made before BlueLine and its service avenues are completed.

Conclusions

In conclusion, the ABCDE model can be the structure of visual narrative games. The gamification of CBT and related therapeutic techniques are interchangeable based on the scenario and its intended experience for the player. To reinforce the same gamified combinations to the player while avoiding monotony in the gameplay, narrative context and visual representation can be used to retain player engagement through the game experience. However, BlueLine's development process is specifically focused on content related to Thai millennials; thus, its use may be less effective to other groups. BlueLine remains to be investigated in more detail regarding efficacy in adjunctive use with the patient's existing treatment in Thailand.

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Conflicts of Interest

None declared.

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Abbreviations

ABCDE: Activating Events, Beliefs, Consequences, Disputation of Beliefs and Effective New Approaches
CBT: cognitive behavioral therapy
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
mHealth: mobile health
NPC: nonplayer character

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Original Paper

Health Promotion in Popular Web-Based Community Games Among Young People: Proposals, Recommendations, and Applications

Philippe Martin[1,2,3,4*], PhD; Boris Chapoton[5*], MSc; Aurélie Bourmaud[1,3*], MD, PhD; Agnès Dumas[1,6*], PhD; Joëlle Kivits[1,7,8*], PhD; Clara Eyraud[1*], MSc; Capucine Dubois[9*], MSc; Corinne Alberti[1,3,7*], PhD, Prof Dr; Enora Le Roux[1,3,6*], PhD

[1]Université Paris Cité, Epidémiologie Clinique Evaluation Economique Appliquées aux Populations Vulnérables, Inserm, Paris, France

[2]Institut National d'Etudes Démographiques, UR14 – Sexual and Reproductive Health and Rights, Aubervilliers, France

[3]Assistance Publique des Hôpitaux de Paris, Hôpital Universitaire Robert Debré, Unité d'épidémiologie clinique, Inserm, Centre d'Investigation Clinique 1426, Paris, France

[4]GDID Santé, Paris, France

[5]Université Jean Monnet, Coactis UR 4161, Saint-Etienne, France

[6]Groupe de Recherche en Médecine et Santé de l'Adolescent, Paris, France

[7]Cité du Genre, Paris, France

[8]Réseau Francophone de Littératie en Santé, Paris, France

[9]Fil Santé Jeunes, Paris, France

[*]all authors contributed equally

Corresponding Author:
Philippe Martin, PhD
Université Paris Cité, Epidémiologie Clinique Evaluation Economique Appliquées aux Populations Vulnérables, Inserm
10 Avenue de Verdun
Paris, 75010
France
Phone: 33 0676606491
Email: philippe.martin@inserm.fr

Abstract

Background: Young people use digital technology on a daily basis and enjoy web-based games that promote social interactions among peers. These interactions in web-based communities can develop social knowledge and life skills. Intervening via existing web-based community games represents an innovative opportunity for health promotion interventions.

Objective: The aim of this study was to collect and describe players' proposals for delivering health promotion through existing web-based community games among young people, elaborate on related recommendations adapted from a concrete experience of intervention research, and describe the application of these recommendations in new interventions.

Methods: We implemented a health promotion and prevention intervention via a web-based community game (Habbo; Sulake Oy). During the implementation of the intervention, we conducted an observational qualitative study on young people's proposals via an intercept web-based focus group. We asked 22 young participants (3 groups in total) for their proposals about the best ways to carry out a health intervention in this context. First, using verbatim transcriptions of the players' proposals, we conducted a qualitative thematic analysis. Second, we elaborated on recommendations for action development and implementation based on our experiences and work with a multidisciplinary consortium of experts. Third, we applied these recommendations in new interventions and described their application.

Results: A thematic analysis of the participants' proposals revealed 3 main themes and 14 subthemes related to their proposals and process elements: the conditions for developing an attractive intervention within a game, the value of involving peers in developing the intervention, and the ways to mobilize and monitor gamers' participation. These proposals emphasized the importance of interventions involving and moderating a small group of players in a playful manner but with professional aspects. We established 16 domains with 27 recommendations for preparing an intervention and implementing it in web-based games by adopting the codes of game culture. The application of the recommendations showed their usefulness and that it was possible to make adapted and diverse interventions in the game.

Conclusions: Integrated health promotion interventions in existing web-based community games have the potential for promoting the health and well-being of young people. There is a need to incorporate specific key aspects of the games and gaming community recommendations, from conception to implementation, to maximize the relevance, acceptability, and feasibility of the interventions integrated in current digital practices.

Trial Registration: ClinicalTrials.gov NCT04888208; https://clinicaltrials.gov/ct2/show/NCT04888208

(JMIR Serious Games 2023;11:e39465) doi:10.2196/39465

KEYWORDS

health promotion; web-based community games; young people; interventional research; recommendations

Introduction

Background

Health promotion requires the creation of health-enhancing public policy with diverse and complementary approaches, particularly in the face of public health challenges (chronic diseases, social inequalities, and health systems issues) [1]. In this sense, health promotion is defined as the process of enabling people to increase their control over and improve their own health [2]. Areas for action include creating supportive environments, strengthening community actions, and developing personal skills. Health promotion interventions must then consider the importance of community and social dimensions, mobilizing social interactions as a lever for population health [3]. These social dimensions can reduce risk factors and increase the well-being of individuals.

Youth is a major period of empowerment and life evolution, with the formation of identity, social relationships, new responsibilities, and a professional future. It is also a period marked by health issues [4] that health promotion can address [2]. To do so, public health actors must understand the population's concerns, habits, and culture to adapt their intervention strategies. Describing and understanding the characteristics of an identified group and studying its behaviors, expectations, and preferences enables the development of health actions with greater impact on the target audience and society [5,6].

Web-based games are attractive and widely used by young people, involving an environment in which players can explore, interact, and follow scenarios in association with characters and stories [7]. Games present relevant challenges for players who require different types of effort to solve tasks (ludic activities) or share experiences [7,8]. The "community" aspect of some web-based games means that, as in social network sites, players can connect with others, build web-based relationships, and find a "peer-to-peer" environment and support around common interests and shared game codes [9]. The community aspect can be centered on specific ages, lifestyles, backgrounds, or thematic characteristics such as interests, hobbies, pastimes, or games [9,10].

Some game-based health promotion interventions are promising, with positive results in terms of feasibility and short-term effects on knowledge and attitudes related to diet, physical activity, and lifestyle [7,11]. However, there is a need to address some key challenges in terms of the process and optimal conditions of implementation to understand how games can be the site of effective health promotion (intervention mechanisms) and research. First, researchers must describe the implementation means of such interventions. Poor conceptualization or bad implementation of an intervention can have a direct impact on its effectiveness [12]. To be effective, web-based games created for health promotion should include the following characteristics or features: feasibility, ease of use, storytelling, feedback, fun, and a proven focus on the health topic addressed [7]. In the case of web-based games that were not originally dedicated to health promotion and research, such data are missing.

The Scott project aimed to deliver a health promotion and disease prevention intervention via an existing web-based community game for young people. Indeed, our hypothesis was that intervening via popular games might enhance the acceptability (user-friendliness) and scope of our actions. The Scott intervention consisted of facilitating small-group health discussions in the game. We chose the Habbo game (developed by the video game company Sulake Oy)—a free, popular, and web-based game with social interactions in which it was possible to intervene.

Goal of This Study

On the basis of the Scott concrete experience, the aim of this study was to (1) analyze players' proposals during the implementation of the intervention in the Habbo game, (2) elaborate on researchers' recommendations for conducting a health promotion intervention in existing web-based community games among young people, and (3) describe the application of these recommendations in new interventions in the same Habbo game.

Methods

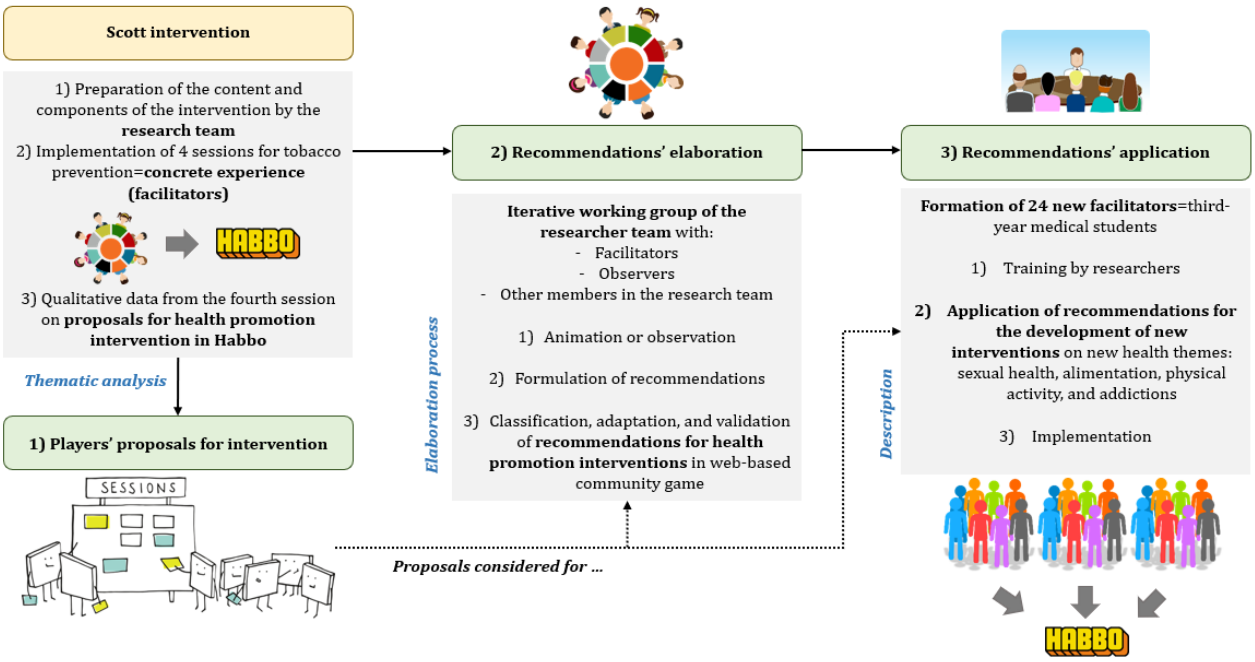
Overview

Our study is embedded in the Scott project, which is broadly a health promotion intervention research project aimed at implementing and evaluating an intervention in a web-based game. The first pilot study was conducted in 2020 [13]. The Scott project is registered on ClinicalTrials.gov (identifier NCT04888208).

During the implementation phase of the intervention, we conducted this qualitative study on the expectations and proposals of the participants in the first pilot study. Of all the pilot study participants, a panel of 22 participants were present to participate in the study.

We conducted a qualitative study nested in the Scott intervention implementation based on (1) a questioning of players' proposals for delivering health promotion within a web-based community game, (2) working groups with a multidisciplinary consortium of researchers for the elaboration of recommendations (based on our concrete experience), and (3) an application of these recommendations for new interventions in the same game. The stages and study processes are shown in Figure 1.

Figure 1. Stages and study process of the study.



Scott Intervention

The Scott intervention was a health promotion and prevention intervention, initially a tobacco prevention initiative, integrated into a popular web-based community game and thus targeting adolescent and young adult game players (the game is officially permitted to be played by an audience aged ≥14 years). During this experiment, we investigated players' proposals for pursuing health promotion within the game on any health themes.

Theory

The entire theoretical framework of the intervention is described in Multimedia Appendix 1 [14-20]. The theoretical framework is based on the notions of social support, group motivation, and social learning [21], as applied to small web-based groups [14]. The mobilized theories are the theory of planned behavior [15], social learning theory [16], peer education [17] (with a link between peer education and social learning theory [18]), and the notion of small-group behavior change in web-based communities [14]. The main premise is that group discussion fosters the development of collective motivation and sufficient knowledge, norms, and skills to promote favorable health behaviors.

Setting

We conducted the intervention in the French-speaking version of the web-based world Habbo. Habbo is an open-world web-based social network–type game with gamification elements. Habbo is a fun game with various activities with social interactions and different worlds in the game, allowing players to participate in discussion groups. The players can communicate with each other by sending limited character messages. The instant messages are limited to 50 characters. This results in many messages, a fast flow of messages, and multiple conversations in 1 space.

Ambassador players are players who are recognized for their attendance and good behavior. A team of moderators and a community manager ensure that the exchanges are fair. The developers of the Habbo game already allow external health actors to intervene in their game for health promotion interventions (not involving research) with the facilitation of the community manager and ambassador players. In the Scott project, we asked for the creation of a space in the web-based game (named a "room" inside the game) specifically for the project, with the appearance of a garden inside which a bus with a maximum capacity of 10 players (small group) was parked for the delivery of the intervention (Figure 2). A queue was set up to allow a limited number of participants to get access to the bus (10 players per session). We replicated the intervention framework of Fil Santé Jeunes (a French information service for young people [aged 12-25 years] in the field of health), which has been intervening in Habbo for several years. One of the research team members (CD) facilitated contact with Sulake and the transmission of needed experiences and skills. The relationship with Sulake was established entirely through the Habbo game's community manager. She helped us prepare the intervention (practical arrangements, recruitment, the dissemination of information notes, the implementation of the intervention, and the distribution of measurement tools).

Moreover, she acted as a unique intermediary between the developer and researcher, especially with regard to the following: the temporality of the intervention, the content of the sessions, questionnaires, data collected, and feedback.

Figure 2. Garden and bus for the project (place of intervention).

Facilitators

A pair of facilitators (PM and ELR) were in charge of the animation and moderation of action. This pair was composed of 2 public health researchers, identified in the game as woman and man, to ensure a gender mix. They had a pseudonym integrating the term "health" to assert their professional position.

Development and Preparation

We developed the intervention content with a pluridisciplinary research team consisting of prevention workers, a psychologist (already leading a support group centered on adolescents' issues in the Habbo game), the game's community manager, sociology and social marketing professionals, and researchers involved in health promotion and intervention research. Two researchers (the facilitators) were previously trained by one of the regular health professionals operating in the game, the community manager of the game, and 3 experienced players to facilitate the intervention. They were trained to test the game's commands (speak, exclude, silence, etc) before setting up the intervention.

Involvement of Peer Players

We worked with the ambassador players for the preparation of the first intervention (part 1) and application of the recommendations (part 3). These players were involved in the training of the facilitators (getting to grips with the features) and in the construction of the places of intervention in the game (Habbo players can create different spaces on the web).

In the game, players can collect badges (with no monetary value), which were used as incentives for this project. Badges were allocated to the participants before and after participation. To enhance novelty, we proposed the opportunity to create and provide original badges dedicated to this project (coconstruction vision) to some volunteer ambassadors.

Contents and Processes

We offered four 30-minute discussion sessions on 4 Thursdays in October 2020 at the proposed times of 11 AM, 3 PM, and 5 PM (12 sessions). We proposed different types of content concerning health issues and tobacco prevention (session 1: representations of tobacco, session 2: benefits of not smoking, session 3: resisting proposals from those around you, and session 4: helping others by making proposals for others' intervention). For the fourth and final session, we asked all 22 players (1 session per group; 3 groups=3 sessions) for their proposals and recommendations for pursuing health promotion actions in the game.

Participants

The participants were all volunteer French-speaking Habbo players. A preintervention survey was conducted in January 2020 to ensure that the average age of the given sample corresponded to that of a population of adolescents and young adults. Of the 83 responses, 75% (n=62) were from male participants, and the median age of the participants was 23 years, with a minimum age of 16 years and a maximum age of 32 years. The median age is in accordance with the World Health Organization's definition of young people's age range, which is 10 to 24 years [4].

Recruitment Process

We recruited study participants in October 2020. A week before the first session, we asked for a banner advertisement on the game's log-in page with all the information about the study (objective, facilitator's contacts, time, place, and subject). We also explained that not all players would be able to participate because of limited places and randomization. The participants were informed that they were participating in public health research. After inclusion, before the session integrating the qualitative study (session 4), the participants were informed that the purpose of this session was to collect their proposals for future interventions.

On the day of the first intervention, on the home page of the game, the participants had to fill in a questionnaire on baseline information (its completion constituted a criterion of eligibility for randomization). After the completion of the questionnaire, the participants were randomly provided either the intervention group badge or the control group badge. We planned 3 time slots for recruitment on the same day, at 11 AM, 3 PM, and 5 PM. For each time slot, a maximum of 10 participants received the intervention badge, which was valid for the 4 sessions (the day of randomization and the following 3 Thursdays). The control group, as well as the intervention group, had access to health information on preexisting websites posted in the project room.

Data Collected

Data were collected (1) from the qualitative study and the fourth session (focus group) on proposals, (2) from the working groups with a multidisciplinary consortium of researchers and feedback from the research facilitators, and (3) from observations of other interventions developed on the basis of the recommendations and applied by other facilitators.

1. Players' Proposals for Intervention

During the last (fourth) session, the players from the intervention group were asked about the attractiveness of the intervention and their proposals for health promotion in the game. We asked them to insert health promotion and prevention interventions into the Habbo game but beyond the Scott intervention. We asked the following questions: "Would you be willing to help us do prevention activities in Habbo? What would you consider important? What would you want to implement?" We collected verbatim testimonies from messages that illustrated players' proposals, elements of attractiveness, and the process of the intervention. No personal or identifying data (including pseudonyms) were collected for analysis. We collected the number of participants and number of messages sent during each session. Beyond these data, the facilitators collected personal feelings about the sessions, with field notes and points for animating and moderating interventions. We transcribed the participants' testimonies and associated them with a participant code (S1, S2, ..., Si) to preserve anonymity.

2. Recommendations' Elaboration

Iterative working group sessions were held among researchers (including facilitators) to share and analyze feedback from the intervention sessions and formulate recommendations for further interventions in the games. These data were in the form of raw notes and feedback reports.

3. Recommendations' Application

Three authors (PM, ELR, and CE) applied these recommendations during the training of new intervention facilitators in the same game. PM, ELR, and CE were responsible for training and supervising these facilitators. The facilitators were (third-year) medical students carrying out a practical initiation into prevention as part of their training. Eight different interventions over 2 weeks (4 per week), with 3 facilitators per intervention (24 facilitators [third-year medical students]) and new health themes (sexual health, addiction, physical activity, food, and nutrition), were developed. They conceptualized these new interventions based on the recommendations on diverse health themes, such as addiction, nutrition, sexual health, and physical activity.

Analysis

We conducted a qualitative analysis based on (1) the chat transcripts of the players, (2) a description of the recommendations elaborated by the researchers' working group, and (3) a description of the observation of the recommendations' application.

1. Qualitative Analysis of "Players' Proposals for Intervention"

We conducted a qualitative analysis of the participants' proposals regarding elements related to health promotion interventions: context, audience expectations, intervention components, and implementation modalities [22].

We conducted a thematic analysis focusing on the proposals and process elements related to the acceptability, attractiveness, and implementation of interventions in a web-based community game specifically. We allowed the participants' proposals to emerge during the sessions. The analysis was conducted based on raw proposals without predefined themes. The authors formulated proposals around the main themes and associated subthemes following these stages: initialization, construction, rectification, and finalization [23]. The initialization phase corresponded to the rereading of each session (thanks to the game's conversation history). The researchers EL and PM took notes on the emerging themes and their impressions. These 2 researchers then carried out the construction phase by classifying and describing the different expectations and proposals of the participants through a first classification and organization of the themes. For the analysis, we accumulated several messages from the same participant to relate all their proposals (only if they made several short messages in a row). The rectification phase corresponded to the distancing of the themes, notably by proposing them to the other researchers of the team, for adaptation and stabilization. This phase also allowed us to put forward the themes that brought real new scientific knowledge. Finally, the finalization phase focused on organizing the themes according to the link or distance between them (organization of the "storyline" of the proposals).

2. Recommendations' Elaboration

Following the intervention, the researchers provided feedback and developed recommendations for interventions specifically conducted in web-based community games. These recommendations were designed based on current recommendations for interventional research, on the experiences of the 2 researchers involved as facilitators (PM and ELR), and on the data from researchers who acted as observers during some sessions (BC, JK, and AD); discussed; adapted; classified; and validated by all the researchers associated with the project.

We analyzed domains and recommendations: the domains correspond to the important steps of preparation, conceptualization of the intervention, and realization of the intervention (implementation); the recommendations are concrete and detailed suggestions for how to meet the expectations for each domain.

3. Recommendations' Application

We observed and formulated a description of the recommendation-based interventions developed, centered on components and implementation modalities, to illustrate the concrete application of each recommendation.

Ethics Approval

The Inserm Ethics Review Committee and Inserm Institutional Review Board (IRB00003888, IORG0003254, and FWA00005831) provided a favorable opinion for our study and approved its information circuit on July 7, 2020.

Results

Overview

A total of 22 players participated in the session for the collection of proposals. Proposals were collected from groups of players (3 groups of 9, 8, and 5 players, named S1 to S22 in the following results), and 1715 messages were posted (an average of 572 messages per session), of which 1155 (67%) were posted by the participants and 560 (33%) were posted by the facilitators and researchers (PM and ELR). The facilitators and researchers (PM and ELR) who conducted the focus groups considered that the third group interviewed, in addition to the other 2 groups, provided no new information. Thus, they considered that data saturation had been reached.

Players' Proposals for Intervention

Thematic analysis of the participants' proposals revealed 3 main themes and 14 subthemes related to their proposals and process elements for health promotion action within the web-based community game. Textbox 1 presents these themes.

Textbox 1. Key themes and subthemes identified in the session.

Develop an attractive intervention in the game

- The need for varied and renewed health topics
- Entertainment components and formats for prevention
- Challenge as a motivation to participate
- An entertaining intervention that may be considered not serious enough
- The involvement of multiple stakeholders in the development and implementation of interventions

Involve peers in the development of the intervention in the game

- In favor of codeveloping the action
- Remaining anonymous for the fear of not being taken seriously
- Feeling of insufficient knowledge for delivering prevention themselves
- Experience as a skill for prevention
- Motivation and social support among peers as a lever for action

Mobilize and control gamer participation

- Limiting the number of participants to ensure the success of the action
- Trolls and essential moderation of exchanges
- In-game rewards as incentives
- Promote action outside the web-based game

Develop an Attractive Intervention in the Game

All the interviewed participants expressed an interest in contributing to the development of a prevention intervention in a web-based game. Through 5 subthemes, the analysis highlighted the themes, expected components, and formats, as well as the different stakeholders involved in the design and implementation of the intervention.

The Need for Varied and Renewed Health Topics

Initially, the participants mentioned the importance of addressing a variety of health topics. One of the participants (S2) suggested using a polling system to guide the topics addressed. Two participants mentioned the importance of including topics around “anything harmful” (S11) and health consequences by highlighting “impact features” (S2). One of the participants suggested a period for renewing topics, with “new themes each week” (S11).

Entertainment Components and Formats for Prevention

The participants proposed several action components, mostly participatory and interactive components, such as quizzes, games, and discussion groups (S11 and S12), to structure interventions. One of the participants (S11) explained the need to create places in the web-based game dedicated to prevention in the game, such as theaters or apartments. Another participant (S12) highlighted the importance of using animation and games as levers of participation:

> *There need to be animations and games. Those make it more engaging, and questionnaires are attractive too. You know, you can do everything and anything like that, with quizzes in the form of questionnaires.* [S12]

One of the participants mentioned the possibility of asking questions through a question box system (S11 and S12). Another suggested a system in which participants can ask questions through forums (S6). The same participant (S6) mentioned the possibility of introducing a prevention campaign in the game in connection with official institutional programs. Some also considered links to existing resources, with access to information summaries.

Challenge as a Motivation to Participate

One of the participants proposed a call for poster production in the form of a challenge to encourage the participants’ motivation and production:

> *...a poster competition within the game, with the results displayed in room galleries of the game.* [S8]

Another participant reminded us that there are already challenges in the game for players and that we only need to reuse this system for the intervention:

> *Actually Habbo has been doing competitions for years, so that means just re-using the same idea, and suggesting that players make a poster about smoking.* [S7]

In addition, one of the participants mentioned competitions with a prize to win:

> *Later we could set up animation games with a monthly ranking. For example, the top 5 players could be given a badge.* [S14]

An Entertaining Intervention That May Be Considered Not Serious Enough

When we asked whether an in-game prevention message is a good idea, we were told the following:

> *I am not sure, Philou [the facilitator], maybe they won’t take it very seriously.* [S3]

A participant (S1) warned that playful or entertaining elements may not lead players to consider the prevention message integrated into the action:

> *I think [the over-entertaining aspect of the prevention game] may be completely counter-productive and undermine the message it is supposed to convey.* [S1]

The Involvement of Multiple Stakeholders in the Development and Implementation of Interventions

When asked about the technical development of the action, some participants mentioned the help of the community manager, present and known to all. She is the one who grants permissions and accompanies the creation of new elements of the game. She would have the task of explaining the course of a multicomponent action (S12):

> *So organize animators let’s say once a week in addition to a discussion, with that a monthly ranking, with ‘the question box’ for the follow-up...the news of the community manager to explain the whole system.* [S12]

More generally, the participants suggested involving several actors in the game for intervention: the community manager, the health professionals, and the player ambassadors (S1, S12, and S14):

> *I think one of you two [facilitators] should be involved, with a Habbo representative, a player, and with an event on the welcome page. That makes it a real thing that’s being organised.* [S14]

As a result, the interviewed participants showed a willingness to take action with their fellow players.

Involve Peers in the Development of the Intervention in the Game

The thematic analysis highlighted the community dimensions within the game that can be levers of attraction to preventive action. These elements were organized into 5 subthemes.

In Favor of Codeveloping the Action

Most participants expressed a willingness to contribute to the development of preventive action within the game. Their role can be that of being a peer advocate or peer educator:

> *If it can have an impact on other people and can help them, I would be very happy to take part…I would hope to be able to take part or be a facilitator, to interact with the players and in fact help them with topics.* [S2]

Remain Anonymous for the Fear of Not Being Taken Seriously

If they were to be involved as peer educators in delivering actions, 3 participants (S8, S12, and S14) mentioned the need to be anonymous with a different pseudonym or avatar. Not being recognizable as a classical player would make other players listen to them more. One of the participants explained the need for a professional presence to be taken seriously:

> *In fact the worry is that if there are no professionals with us the players won't take us so seriously, because we know each other.* [S12]

Indeed, some are well known by their game peers, and it would be difficult for them to be taken seriously:

> *On the other hand if I appeared as a clone that would be fine, because I wouldn't be recognized. So long as there is anonymity I have no problem.* [S14]

Feeling of Insufficient Knowledge for Delivering Prevention Themselves

Beyond the players' self-projection as prevention actors, one of the participants emphasized his feeling of not being able to intervene on all health issues:

> *I don't feel I am capable of making a judgment about everything.* [S13]

He also pointed to his lack of experience in talking about certain topics:

> *Personally I don't think I am the best person [to do smoking prevention] since I have never smoked.* [S13]

Experience as a Skill for Prevention

Participants mentioned that experience then intervenes as a skill that can be mobilized by the players or professional facilitators (S1, S12, and S15):

> *Yes, when it's doing adapted prevention, which can also bring out your personal experience of the subject.* [S1]

> *...with people who have been affected by the subjects being discussed perhaps.* [S15]

> *I am not a good example although being a smoker myself I know all about the downsides.* [S12]

If mobilized for delivering prevention messages, a participant reported that his point of view would be more intelligible and impactful:

> *Our personal experience will make it more impactful...I would have more to talk about and have more impact in what I say.* [S2]

Motivation and Social Support Among Peers as a Lever for Action

For a participant (S6), the involvement of peers could take place through a social support system between gaming peers through sponsorship, similar to existing support strategies outside web-based games:

> *We could do it like our counterparts for alcohol, except that we are on Habbo...Yes, the units could be a series of badges and they can be used as tokens, like for alcoholism.* [S6]

This peer-to-peer social support can lead to web-based group challenges, such as the community challenge mentioned by one of the participants:

> *One could also think about a community challenge with ranking results.* [S8]

However, another participant (S11) highlighted the difficulty of motivating and mobilizing other players through digital means, especially for prevention:

> *Well, yes I would be happy to help someone stop smoking, but it's tricky sitting with a PC, isn't it?* [S11]

Mobilize and Control Gamer Participation

Beyond the involvement of web-based gaming peers as peer educators, the thematic analysis highlighted the ways in which players (the target audience) are engaged in prevention. In this regard, 4 subthemes were highlighted.

Limiting the Number of Participants to Ensure the Success of the Action

The participants expressed that it is more pleasant to play the game in small groups:

> *Yes, it's more pleasant in a small committee.* [S12]

Several participants emphasized the need to think about a prevention action that would mobilize small groups in the game (S2, S4, S5, and S12), especially to be able to debate properly (S2). One of the participants (S5) suggested limiting the number of participants to 10, always with 2 facilitators. It was also pointed out that several sessions are necessary (S2):

> *With a big group (100) it's likely to be more difficult because there will always be people to disturb others who really want to pay attention.* [S2]

> *I loved the once-weekly format.* [S14]

Trolls and Essential Moderation of Exchanges

Many players also talked about disrupters within the game (trolls). One of the participants said that there will always be "those who distract people who want to listen" (S2). A participant indicated that moderation is mandatory for the proper conduct of the action:

> *It's obligatory, Philou, you were in luck here, but in the bus there are usually trolls.* [S1]

This participant considered ambassadors (players with good behavior in the game) as people who could support this moderation:

> *with one or two ambassadors to moderate the players who come to provoke everyone in your INSERM sessions.* [S1]

In-Game Rewards as Incentives

The participants discussed how to reach players and enroll them in prevention action. Some participants (S1, S9, and S10) indicated the importance of rewards for engaging players:

> *To be very frank with you, if there aren't any rewards to be had, and it's just for prevention...you won't get many followers.* [S9]

The same participants pointed out that in the game, "badges" are collectibles and that many players want to acquire them:

> *Those who win get a badge, players really like badges.* [S6]

> *Then I also think there has to be a badge for each session depending on the theme (people will be more receptive).* [S1]

However, 2 participants (S3 and S11) suggested that players who come only for the incentives (badges) would be less influenced by the prevention action:

> *Many of them will come just for the badge.* [S3]

> *It's true that if there are incentives to win there will be more players, but we don't want them to come just for the badges.* [S11]

One of the participant (S12) expressed that not implementing these incentives would be a way to select the most motivated individuals:

> *Those who are prepared to attend knowing there is nothing to win are sure to be the most sincerely motivated.* [S12]

Promote Action Outside the Web-Based Game

A participant indicated the importance of taking action beyond the game, especially to reach more people:

> *To be honest, Habbo is not the way to mobilize the most people, you need to aim higher.* [S7]

Another way to get players to participate in action would be to promote the action inside and outside the game among the Habbo community (on Twitter [Twitter, Inc] and fan websites). One of the participants suggested putting billboards about the prevention action in the game (S2). Another participant (S11) suggested that the community manager could advertise on the game's home page and through alerts.

Yet another participant suggested recording the actions to replay them and reach more people:

> *in a public space in the game, with the Habbo viewing experience. Film it and replay it on fan sites [for fans outside the Habbo game itself].* [S1]

Another participant (S6) mentioned that the social networking site Twitter and game-related accounts can be used to advertise the action:

> *You can do ads on Twitter, on the Habbo news site, and in the bus you can work on themes around addictions like cigarettes.* [S6]

Recommendations' Elaboration and Application

Following the analysis of young people's proposals and professionals' experiences, we established 16 domains of 27 recommendations for health intervention in existing web-based community games (Multimedia Appendix 2). Each illustration describes the application of each recommendation during the development of new actions introduced in the game. Thus, Table S1 in Multimedia Appendix 2 integrates the fields, recommendations, applications of the recommendations in new interventions, and descriptions of specific new interventions. Multimedia Appendix 3 describes the interventions developed in response to these recommendations.

Discussion

Principal Findings

Our study highlights Habbo players' proposals for developing interventions within the web-based game. These proposals emphasized the importance of serious interventions that need to involve and moderate a small group of people in a playful way. Using a reflexive approach, we also proposed recommendations for application in different interventions in general web-based community games. These recommendations highlight numerous suggestions for preparing and implementing an intervention, correctly incorporating it into web-based games, and adopting the codes of the web-based community game culture.

Meaning of the Findings

Our study showed that it is possible to work in fields that are not commonly explored and exploited by intervention research, with important recommendations for making good use of them. This study shows that it is possible to integrate the intervention into games that the target population already plays instead of creating a new game for a health intervention. We knew that it was possible to intervene in the game (following the Fil Santé Jeunes experience). Nevertheless, this study wanted to delve further by collecting concrete proposals from the players. Recommendations based on the Fil Santé Jeunes experience completed these proposals. This made it possible to bring together the contributions of various stakeholders (target population and professionals) via a participatory research approach [24,25].

The players indicated the importance of addressing a variety of health topics, that is, being responsive and diverse in health promotion responses. The study participants highlighted the importance of addressing many of the associated themes in health promotion action in a web-based game. More generally, a large number of web-based games are used for individual health, mainly for cognitive training or indirect health education [26], physical activity [27], managing chronic disease [28], preventing bullying [29] or preventing tobacco use [30]. Health actors have developed a very large number of games, and these games are generally novel interventions delivered to individuals, with different degrees of acceptability, attractiveness, and feasibility.

The participants highlighted the need for different types of involvement (the involvement of peers and facilitators) and ways to conceptualize and implement interventions for health. Web-based games can play a major role in the adoption of positive health behaviors, particularly because they promote players' self-esteem, provide support and information, and facilitate interaction and communication [28] with a sense of community. The world of games can be a real support. For example, avatars are important among young people as an extension of the self or as a way to further experiment with social relationships safely. A previous study has shown that among trans or gender-diverse youth, the use of an avatar facilitates the expression and consolidation of gender identity, with powerful mental health benefits [31].

We proposed several recommendations on how to act in existing games, including the consideration of participants at several levels: personalization, solicitation, animation, and moderation. Furthermore, in the field of mental health, Fleming et al [32] made the following recommendations for using web-based games for interventions [32]: a user-centered approach requiring exploration of group preferences, engaging and effective interventions with a description of game dynamics, cross-sectoral and international collaborations to seek out and identify the skills required for game development, and rapid testing and implementation to keep interventions engaging.

From our perspective, we highlighted new elements to intervene in already existing web-based games. Nevertheless, the literature still has a few examples of interventions integrated into existing games that are popular with the target audiences. Few studies have focused on the added value of using games rather than creating them, whether in response to health issues or economic issues related to development [33]. One of the studies, however, highlighted the use of existing commercial video games as therapies, studying these games as potential health interventions [34]. Colder Carras et al [34] noted that there is a lack of research on the use of commercial games for health and highlighted the need to design standardized protocols, study best practices to identify which games work on which health conditions, and model the complex and dense data of games. In the future, it will be possible to understand the effectiveness of actions integrated into web-based games for health promotion by considering the influence of action implementation and processes in web-based community games.

Implications for Decision Makers and Practitioners

Decision makers and initiators of health promotion interventions must consider several approaches to intervene through web-based games beyond the community aspects described in this study. It is necessary to consider that it is possible to intervene by 3 means: fitting the intervention into an existing game, creating a game specifically to intervene, and reusing a game without modification.

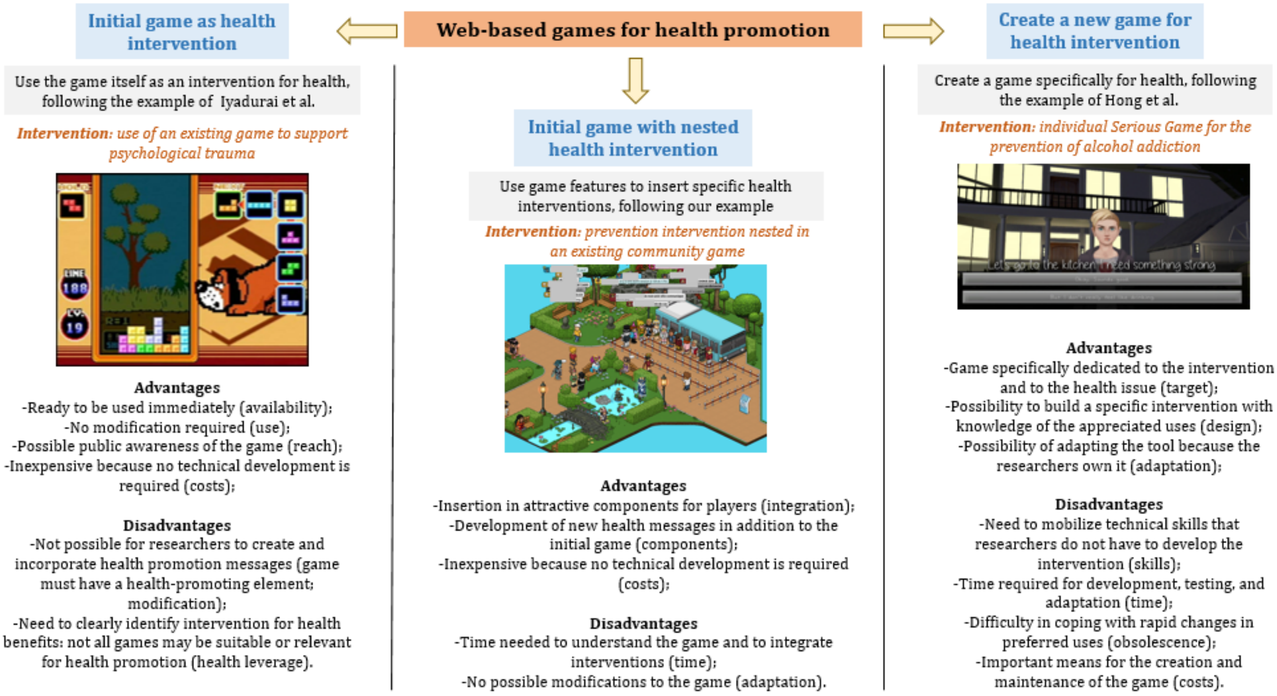
For interventions in existing games, it is necessary to consider what is practically possible (the potential of action). It remains necessary to understand the game's functioning to provide adapted interventions (functioning and adaptability). Some games do not allow for this kind of intervention because there is too strong a difference between the game objectives or gaming companies' culture and health objectives (real feasibility). If an intervention is possible, it is necessary to acculturate the intervention to the codes of the game without modifying the game. This requires the training and adaptation of external stakeholders (acculturation). Moreover, intervening in a game is only possible if there is a good link between the developers and stakeholders. It is important to establish a strong and trusting relationship with developers, particularly to integrate interventions in games (relationship). This relationship should also be considered from a research perspective, as it involves considering the data to be analyzed beyond the intervention to be implemented. On the one hand, the researchers must present to developers the real issues of research and the importance of collecting data that can be analyzed according to sometimes rigorous and complex methodologies (such as randomized controlled trials). On the other hand, the developers must explain how the game works (in a way that does not have health promotion as its initial goal) to anticipate both the best potential for action and the way in which the research can be carried out (eg, acceptability and accessibility of participants' data).

To develop a game for a health promotion intervention (similar to Hong et al [35]), it is essential to consider the levels of involvement needed. It is important to consider the need for technical skills to develop and maintain the game (technical skills). It is also important to consider the costs inherent to development and maintenance (costs). Moreover, it is essential to understand the uses of, expectations for, and attractions of the games (understanding), particularly the benefit of creating a new game (innovation). Developing a web-based game also takes time, with the risk of obsolescence of the game in the face of rapidly changing preferences (temporality and obsolescence). Creating a web-based game for health also raises the issue of reaching target audiences, who are already engaged with existing games.

According to the example set by some research [36], a third mode of intervention could be the replay of a web-based game as it is without inserting health content or even modifying the game's functionality. Although this would be inexpensive, it would require a clear identification of the actual health benefits that an unmodified, commercial web-based game could provide. The integration of these games with offline health practices or services is also generally required. These 3 modes that we discussed are illustrated in Figure 3.

In general, it is important for stakeholders to know which strategy is the most relevant to the target population, considering its accessibility and expectations (realism). The health intervention may have objectives that allow incorporation into existing games or require the creation of new web-based spaces. In any case, it is important to consider the implementation stages, stakeholders' roles (positions), and way to integrate populations. Incentives, elements of web-based games that can promote participation, can be used to integrate populations (incentives). In our experience, badges were attractive. The accomplishment of tasks and its valorization in game are sources of motivation for participation. For example, compensation with game's money can be discussed.

Figure 3. Illustration of the different possibilities to intervene through web-based games (Hong et al [35] and Iyadurai et al [36]).



Strengths, Limitations, and Future Directions

Our study is one of the few to investigate the potential of existing web-based community games for health promotion. It provides concrete methodological recommendations for the conceptualization and implementation of health actions in existing games. However, this study has limitations. We consulted the participants who were involved in our intervention, as the questions asked in this study occurred in the fourth session of the intervention, inducing a selection bias and not reaching the most distant players. In fact, we do not have information about the preferences of those who are more difficult to reach in the game. However, we collected the opinions of the most motivated players; they discussed the attractive elements of intervention for all players and how to develop and implement interventions for the most distant players. We developed our recommendations on 1 kind of web-based game (community based, with the possibility of development of elements in the game by the players).

We developed recommendations according to a structured methodology based on the experience and analysis of the project researchers. This methodology and the application of these recommendations in the development of new interventions demonstrated the internal validity of the recommendations. Recommendations must nevertheless be tested and validated in other games of this type, by other facilitators, with other intervention components, and for other health issues. Furthermore, the various functionalities offered by different web-based games require tempering the application of certain recommendations. Indeed, in our case, the game is mainly a place of web-based social interactions with gamification elements. Other web-based games might have features that are less community based. Therefore, our article focused on web-based community games with a socialization purpose. In addition, some of the recommendations may also be applicable outside existing games—not only to the development of new community health games but also to interventions using facilitation, communication, and participation techniques for health promotion.

Future research must continue to understand the processes involved in this type of intervention, depending on the audience and health issues being addressed. Indeed, interventions in web-based games can vary by topic (eg, differences in appeal between tobacco and mental health actions and differences in behavior change theories) and by participating audiences. It is still important to understand which population is using different popular web-based games to better understand whom we are reaching and what efforts need to be made. Knowing which population is attracted to health promotion activities remains important. Integrating target audiences (young people) into research processes remains essential in a community-based participatory research approach [24,25]. This will enable a better understanding of how to adapt and develop acceptable and attractive health promotion interventions in web-based games. Finally, research must involve evaluations based on complex intervention research recommendations to measure the effect of health promotion interventions in games on health determinants targeted by researchers and actors (information, attitudes, skills, and behaviors), taking into account context effects. To do this, the methodologies must be designed in an interdisciplinary manner and be based on existing recommendations [12,37].

Conclusions

Health interventions integrated in existing web-based community games represent a potential for promoting individual health and well-being. It is necessary to adapt to the changing preferences and uses of target populations by thinking of innovative means for intervention research (levers, brakes, and costs). This also requires a permanent acculturation of the interveners and researchers to correctly intervene and analyze the games as a place and potential for health promotion among the target audiences. Involving these audiences is of considerable help in designing and implementing innovative health promotion interventions.

Acknowledgments

The authors thank the Institute for Public Health Research for funding this study; the members of the Scott project for their contributions to the project, especially Bruno Giraudeau, Laëtitia Minary, and Anita Burgun; and Fil Santé Jeunes for their hospitality and training in good practices for conducting actions in the Habbo world. They particularly thank the community manager (anonymity preserved) for her indispensable support and the common management of this intervention. Finally, they thank the Habbo players for their opinions and advice on how to improve health promotion actions in web-based games, their translator Duncan Fulton for proofreading the manuscript, and the members of the Inserm U1123 and CIC-EC1426 teams for their support in the conduct of this project.

Authors' Contributions

ELR and PM wrote and submitted the protocol for the approval of this study. All the authors participated in the development of the intervention content. ELR and PM implemented the Scott intervention and collected the study data. CE, ELR, and PM applied new intervention sessions based on the recommendations. All authors participated in the analysis, generation of recommendations, application of the recommendations, and writing and validation of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Description of the theoretical framework of the Scott intervention.
[DOCX File , 21 KB - games_v11i1e39465_app1.docx]

Multimedia Appendix 2
Key recommendation elaboration and application for health promotion intervention in a web-based community game.
[DOCX File , 27 KB - games_v11i1e39465_app2.docx]

Multimedia Appendix 3
Description of interventions created based on the recommendations.
[DOCX File , 755 KB - games_v11i1e39465_app3.docx]

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Original Paper

Impact of a Serious Game (#RedPingüiNO) to Reduce Facial Self-Touches and Prevent Exposure to Pathogens Transmitted via Hands: Quasi-Experimental Intervention

Marta Arévalo-Baeza[1], PhD; Alejandro Viuda-Serrano[1], PhD; Carmen Juan-Llamas[2], PhD; Pablo Sotoca-Orgaz[1]; Iván Asín-Izquierdo[3,4], PhD

[1]Department of Education Sciences, Faculty of Medicine and Health Science, Universidad de Alcalá, Alcalá de Henares, Madrid, Spain

[2]Department of Biodiversity, Ecology and Evolution (Biomathematics), Faculty of Biological Sciences, Universidad Complutense de Madrid, Madrid, Spain

[3]Physical Performance and Sports Research Center, Department of Sports and Computer Sciences, Faculty of Sport Sciences, Pablo de Olavide University, Seville, Spain

[4]Department of Biomedical Sciences, Faculty of Medicine and Health Sciences, Universidad de Alcalá, Alcalá de Henares, Madrid, Spain

Corresponding Author:
Marta Arévalo-Baeza, PhD
Department of Education Sciences
Faculty of Medicine and Health Science
Universidad de Alcalá
Campus Universitario C/ 19, Av. de Madrid, Km 33,600
Alcalá de Henares, Madrid, 28871
Spain
Phone: 34 651569136
Email: marta.arevalo@uah.es

Abstract

Background: After the COVID-19 pandemic, society has become more aware of the importance of some basic hygienic habits to avoid exposure to pathogens transmitted via hands. Given that a high frequency of touching mucous membranes can lead to a high risk of infection, it is essential to establish strategies to reduce this behavior as a preventive measure against contagion. This risk can be extrapolated to a multitude of health scenarios and transmission of many infectious diseases. #RedPingüiNO was designed as an intervention to prevent the transmission of SARS-CoV-2 and other pathogens through the reduction of facial self-touches by thoughtfully engaging participants in a serious game.

Objective: Facial self-touches should be understood as behaviors of limited control and awareness, used to regulate situations of cognitive and emotional demands, or as part of nonverbal communication. The objective of this study was to ensure that participants become aware of and reduce these behaviors through a game of self-perception.

Methods: The quasi-experimental intervention was applied to 103 healthy university students selected by convenience sampling and put into practice for 2 weeks, with 1 control group (n=24, 23.3%) and 2 experimental groups (experimental group with no additional social reinforcement interventions: n=36, 35%; experimental group with additional social reinforcement interventions: n=43, 41.7%). The objective was to improve knowledge and perception and reduce facial self-touches to prevent exposure to pathogens transmitted via hands not only in health multihazard scenarios but also in ordinary circumstances. The ad hoc instrument used to analyze the experience consisted of 43 items and was valid and reliable for the purpose of this study. The items were divided into 5 blocks extracted from the theoretical framework: sociological issues (1-5); hygiene habits (6-13); risk awareness (14-19); strategies for not touching the face (20-26); and questions after the intervention (27-42), designed as a postintervention tool assessing the game experience. Validation of the content was achieved through assessment by 12 expert referees. External validation was performed using a test-retest procedure, and reliability was verified using the Spearman correlation.

Results: The results of the ad hoc questionnaire, which were analyzed using the Wilcoxon signed-rank test and McNemar index to identify significant differences between test and retest for a 95% CI, showed that facial self-touches were reduced (item 20, $P<.001$; item 26, $P=.04$), and awareness of this spontaneous behavior and its triggers increased (item 15; $P=.007$). The results were reinforced by qualitative findings from the daily logs.

Conclusions: The intervention exhibited a greater effect from sharing the game, with interactions between people; however, in both cases, it was helpful in reducing facial self-touches. In summary, this game is suitable for reducing facial self-touches, and owing to its free availability and design, it can be adapted to various contexts.

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KEYWORDS

self-touching; face; serious game; health; pathogen transmission; hazard scenarios; body language

Introduction

Background

The global pandemic caused by COVID-19 forced the World Health Organization and health care authorities to establish a series of fundamental measures to prevent the spread of infection, which have modified social behaviors [1,2]: social distancing, use of masks, frequent handwashing, and avoiding touching the face. Although the available epidemiological data and studies on environmental transmission factors have not defined fomite-mediated transmission through hand contact with the mucous membranes of the facial T-zone (eyes, nose, and mouth) as the main route, the risk of infection via this route by SARS-CoV-2 and other pathogens remains, as revealed by Marquès and Domingo [3], and rapid and direct recontamination can occur despite handwashing [4,5]. The survival of SARS-CoV-2 and other pathogens on surfaces is not known with accuracy, but we can take the influenza virus as a point of reference, which can survive for up to 10 minutes on our hands [6]. We can touch the mucous membranes of our face every 2 minutes [7], with a self-touching frequency of up to 50.06 times per hour [8], especially on the mouth, followed by the nose and eyes [9]. The frequency of hand-to-face contact shows great diversity; appears to be context dependent; is influenced by cognitive, attention, and emotional demands; and exhibits substantial individual and locational differences. It is difficult to establish an average [5,10], but given that a high frequency of touching the mucous membranes can lead to a high risk of infection, it seems essential to establish strategies to reduce this behavior as a preventive measure against contagions [11-13]. More importantly, this risk can be extrapolated to a multitude of health scenarios and the transmission of other infectious diseases.

Spontaneous facial self-touches (sFST) are defined as touches on one's own body, from the hands to the face, which include movements such as rubbing, scratching, stroking, or leaning on the hands, and which involve a proprioceptive activation of joints, muscles, and connective tissue, being able to activate skin sensitivity in a more or less conscious way, as pointed out by Spille et al [12]. These authors emphasize the importance of different triggers of sFST, distinguishing self-touches by self-regulation in situations where complex cognitive processes occur; by regulation of the intensity of emotions (anxiety, tension, clumsiness, uncertainty, discomfort, pleasure, and surprise); and finally, by the manifestation of emotions not expressed through words, which can be understood from nonverbal communication. Thus, we grouped the triggers of sFST by distinguishing compensation touches (as a manifestation of underlying emotions to adapt to a given context); warning touches (with prior warning such as itching, perspiration, tingling, hair brushing, imperfections, or lacrimation); and communicative gestures (without prior warning, with a triggering situation, and learned gestures, such as a hand on the chin while listening or waiting).

To reduce sFST, we can apply heuristics through specific interventions by avoiding errors of omission with signals and reminders; emphasizing the use of "if-then" plans; applying substitute or alternative behaviors; and developing an adequate and progressive reorganization of the brain [14], a process that requires observation and becoming aware of the trigger from a conditional strategy [15]. It could also be treated by consciously learning each touch action; differentiating it from its usual response chain; and replacing it with another action [16], such as using a handkerchief or touching another area of the face that is not a mucous membrane. In summary, the leading techniques for changing habits and behaviors seem to be repetition, the use of instructions and signals, action planning, the provision of instructions regarding how to carry out the behavior, and the establishment of behavioral objectives in the search for these self-control behaviors.

Objectives

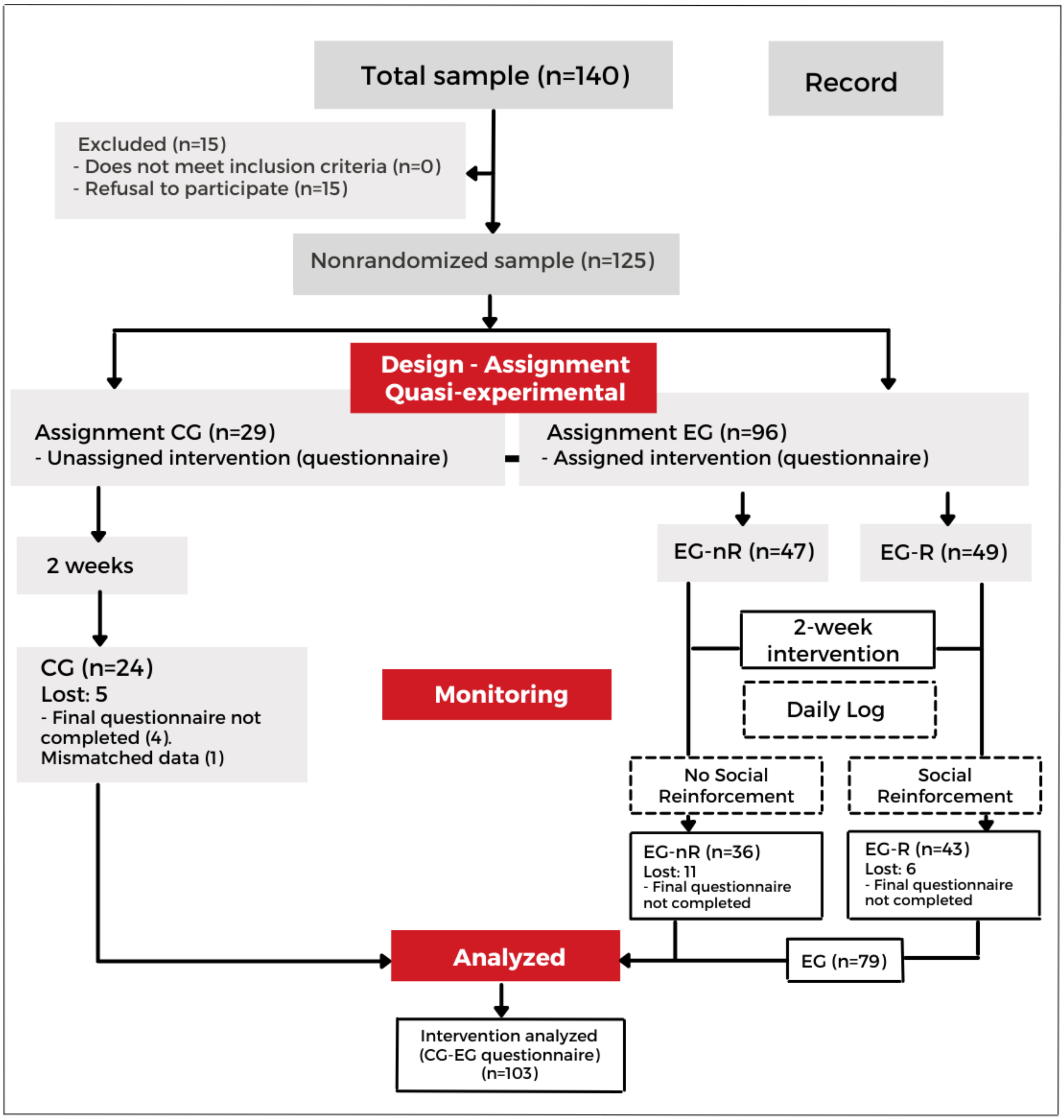
This study was based on the serious game. This concept is understood as a carefully planned playful framework, the main purpose of which is to provide not only the entertainment itself but also an engaging context that involves people who are playing in the learning process [17-19]. Research has resorted to the use of serious games to address health care content, in the context of training, preventing disease, rehabilitating, or seeking to improve quality of life and well-being [20-22]. A serious game like the one analyzed in this study is a tool with complex development but simple intervention, which favors its use in various contexts, such as health institutions, hospitals, community centers, schools, or similar entities, and by the entire population, adapting the research procedures and design to the characteristics of the participants. This intervention does not require complex procedures, tools, techniques, or specialized software; therefore, it is accessible, efficient, and possibly helpful in reducing and perceiving the behavior of not touching the face. The #RedPingüiNO methodological proposal is an intervention based on a serious game with the main objective of reducing facial self-touches as a preventive measure against exposure to pathogens transmitted via hands, such as SARS-CoV-2 and others. The foundation of its design is underpinned by the multidisciplinary theoretical framework, focused on a playful, engaging, and viral proposal that uses metaphors, humor, and a scoring system as drivers of the proposed game, using digital resources designed ad hoc that can be adapted to different contexts. Therefore, the objective of this study was to analyze the effects of the #RedPingüiNO intervention on the awareness and reduction of facial self-touches, especially in the T-zone, based on self-perception, given that a serious game seeks to positively impact the habits of participants.

Methods

Research Design

To design the research and the serious game, we have used Game-Based Intervention Reporting Guidelines given by Warsinsky et al [23]. Guidelines on conceptual issues, contributions of the study, related concepts, and definitions were taken into account; serious games were defined (*Introduction* section), the research stream was described (*Methods* section), the contribution of this study was clarified (*Discussion* section), and only core concepts based on the extant literature were used throughout the text. This study used a quasi-experimental design of involving a nonequivalent control group (CG) and a mixed approach. It is not possible to guarantee random assignment of the participants to the groups, but the educational center provides a predetermined distribution, ensuring limited homogeneity. This methodology is suitable for studying the potential causal effects of an intervention in open situations. The flowchart of the intervention is presented in Figure 1.

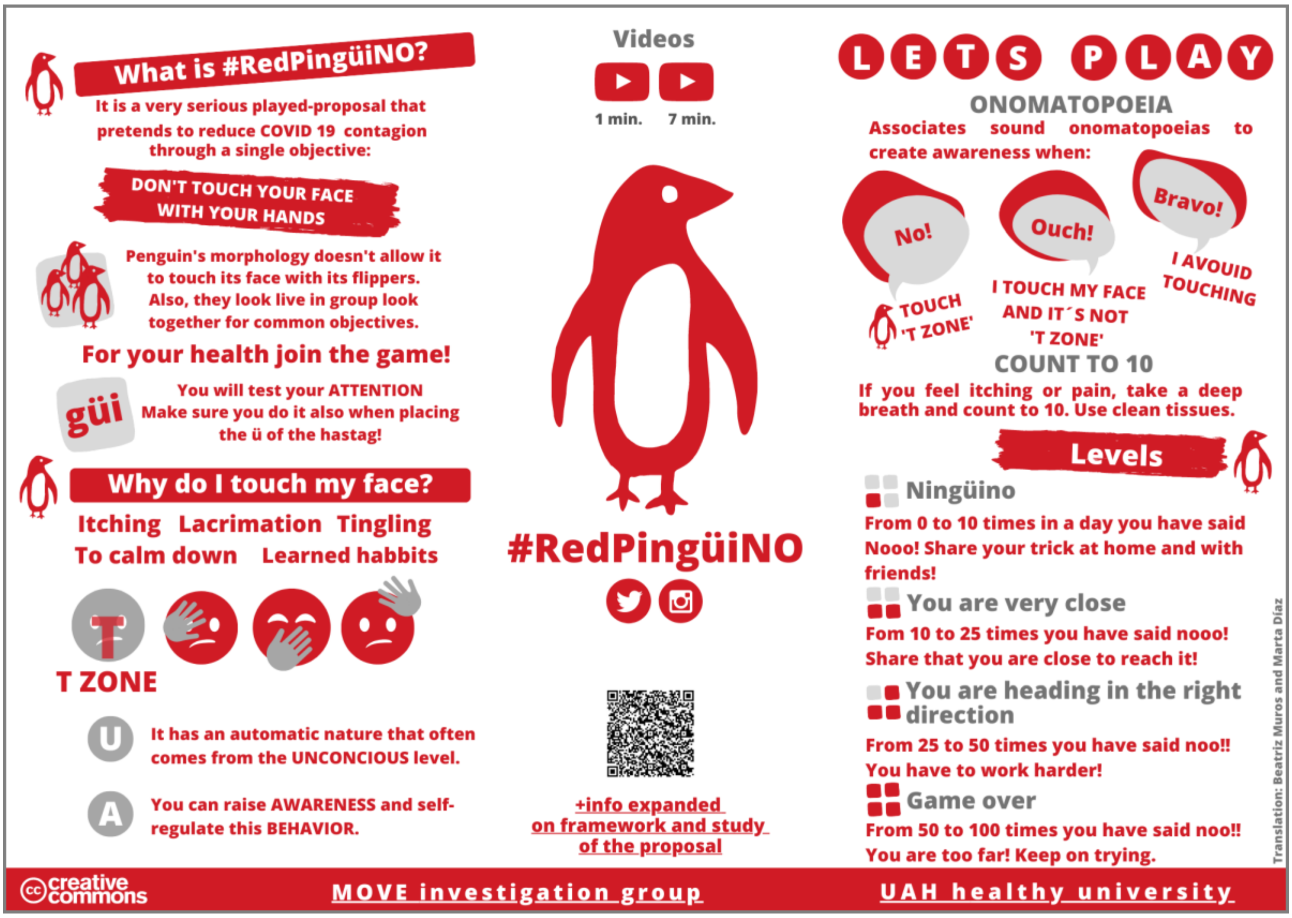
Figure 1. Flowchart of the intervention. CG: control group; EG: experimental group; EG-nR: experimental group with no additional social reinforcement interventions; EG-R: experimental group with additional social reinforcement interventions.



Serious Game Design

#RedPingüiNO is a project based on a serious game that aims to reduce the spread of COVID-19 and other diseases through strategies to avoid the act of touching the face with one's hands. The game uses penguins as protagonists because of their anatomy (they cannot touch their faces with their hands) and their social nature (collective and community behavior). The intervention platform has materials available in 8 languages. The game consists of associating sound onomatopoeias with behaviors: "No!" if the T-zone of the face is touched; "Ouch!" if another part of the face is touched; and "Bravo!" if the face is not touched at all. Descriptors and rankings are presented based on the daily frequency of self-touches (Figure 2). The rules of #RedPingüiNO were published on the #RedPingüiNO website [24].

Figure 2. Infographics and #RedPingüiNO website.



Participants

A total of 125 students taking the Primary Education Teaching Degree course from a public university in Madrid participated in this research. The sample was selected by convenience sampling with 103 healthy participants who completed the study, comprising 74 (71.8%) women and 29 (28.2%) men; 22 (21.4%) dropped out during the intervention, as they did not complete 80% of the proposed activities. The average age was 22.76 (SD 2.78) years and gender differences in the sample were due to the specific characteristics of the chosen degree, with a larger female representation. The participants were distributed into three groups via the use of the Telegram app (Telegram Messenger Inc): (1) the CG (n=24); (2) the experimental group with no additional social reinforcement (EG-nR; n=36); and (3) the experimental group with additional social reinforcement (EG-R; n=43). Participation in the study was voluntary and anonymous and required informed consent.

Ethics Approval, Informed Consent, and Participation

This study was approved by the Ethics Committee of the Universidad de Alcalá (reference: CEI/HU/2020/46). The research complied with all national regulations and followed the tenets of the Declaration of Helsinki. The data of the participants were treated confidentially, and no personal information was accessed. Privacy was respected, and no personal information has been published. All the participants provided informed consent.

Instruments

An ad hoc self-administered questionnaire about facial self-touches and the game #RedPingüiNO was administered to the participants using an easy survey platform before and after the intervention (the items in the instrument are listed in Multimedia Appendix 1). The instrument was made up of 43 items that were divided into 5 blocks and prepared from the following theoretical framework: (1) sociological issues (1-5), (2) hygiene habits (6-13), (3) risk awareness (14-19), (4) strategies for not touching the face (20-26), and (5) questions after the intervention (27-42). The fifth block was designed as a postintervention questionnaire and was administered only to the participants of the experimental groups (EGs). The items were closed ended, except for 1 open-ended question that collected considerations regarding the game (item 43).

The content validation of the questionnaire was conducted by expert judges [25]. A total of 12 judges (8 women and 4 men) assessed the content and form of the questionnaire. Their professional experience ranged from 11 to 35 years in scientific research related to the study, coming from various universities and heterogeneous fields of interest (body language, health, psychology, and didactics). The experts performed an overall assessment of the questionnaire and rated the degree of adequacy (relevance and wording). They were also asked about a set of aspects associated with the elaboration processes (appearance, clarity and length of the instructions, item format, and question order); data collection (completion time); and data interpretation (objectivity and absence of biases). The psychometric analysis of the content validity criteria of the instrument was performed using the V coefficient given by Aiken [26], considering the proportion of judges who express a positive assessment as a criterion for revising or eliminating items. An intervention pilot test and the registration were conducted by 4 teachers over a period of 5 days, during which they played the game and provided their assessments.

The participants of the EGs had to complete a daily self-compliance record of occurrence with 6 questions about the evolution of the intervention using the Microsoft Forms (Microsoft) tool and had to provide the following via Telegram: anonymous identification; frequency, prevention, and main reason for self-touches; motivation; and additional information. In the web space created for the EG-R, social reinforcement actions were carried out, freely sharing, among the participants, experiences during the intervention, daily achievements, difficulties, and additional information.

Procedures

This research was coordinated and developed by faculty members and research staff who specialized in body language, with at least 10 years of experience. The questionnaires were administered by evaluators who were unaware of which group the participants belonged to, and the participants were unaware of the existence of other intervention groups.

The participants continued their daily routines throughout the intervention without supplementation of any other activity. The intervention was carried out for 2 weeks (November 23, 2020, to December 7, 2020) during the school term to foster the existence of a normalized context and to avoid the effect of holiday periods on the variation of routines. During this period, an attempt was made to modify the behavior of facial self-touches of the participants of the 2 EGs, EG-nR and EG-R, compared with that of the participants of the CG through the use of serious play. The reminders, sent via Telegram, occurred at the beginning of the day and around lunch time. At the end of the afternoon, a link to the registry was sent. The social reinforcement in the EG-R was in the form of praise, support, and approval, with tangible rewards and individual and collective reinforcement. The communication strategies used included cooperation, participation, interaction, and comparison.

Data Analysis

Statistical analyses were performed using SPSS package (version 25.0; IBM Corp). The types of variables in the questionnaire, namely, categorical and dichotomous, made it necessary to use nonparametric tests. To study the reliability of the questionnaire, different statistics were used to assess test-retest reliability. To analyze whether there were statistically significant differences between the answers given to the same items in the test and retest, the Wilcoxon signed-rank test was used, except for dichotomous variables, which were analyzed using the McNemar index. In addition, the degree of correlation between the test and retest items was determined using the Spearman rank correlation coefficient for nonparametric samples. To demonstrate the reliability of items 27 to 42, which were answered only by the participants of the EGs, the Cronbach α was used. Furthermore, to analyze the significant differences between the different groups, the following was used: for groups taken 2 by 2, the Mann-Whitney *U* test for 2 independent samples and (2) to compare the 3 groups, the Kruskal-Wallis test for 3 independent samples. Finally, content analysis was used to analyze the open-ended questions in the questionnaire [27].

Results

Reliability and Validity of the Instrument

The V coefficient by Aiken [26], which was used to determine validity, was interpreted using the score method [28], and it showed a very positive and adequate result for the use of the questionnaire. This procedure was developed based on the expert method, assuming a 95% CI (*P*=.05). The value of the test was V=0.99 for the adequacy of the items and V=0.96 for the wording, with minimum values of 0.88 and 0.87, respectively. Table 1 shows the reliability of the instrument for items 6 to 26. The test-retest values were adequate because they were .05; therefore, it was not necessary to remove any of the items. The Spearman rank test for nonparametric samples confirmed these results, because no correlations .05 were observed.

Items 12 and 13 of the yes or no responses regarding the frequency of facial self-touches with a mask and knowledge of the facial T-zone did not show statistically significant differences (*P*=.45 and *P*=.53, respectively). The participants of the CG showed a higher frequency of facial self-touches with a mask (13/24, 54%), and 75% (18/24) knew about the facial T-zone before filling out the questionnaire. The reliability of the instrument for items 27 to 42 related to the intervention was analyzed using the Cronbach α (.723). The Cronbach α coefficient showed a value .70, which is the usual acceptance limit [29]. In summary, the questionnaire was valid, reliable, and therefore suitable for use.

Table 1. Reliability analysis of the questionnaire for the control group (n=24).

Construct and item	Test values, mean (SD)	Retest values, mean (SD)	Wilcoxon sign-rank test or McNemar index (*P* values)	Spearman rank coefficient (*P* values)
Hygiene habits				
6	2.63 (0.92)	2.71 (0.81)	.21	.80
7	2.33 (0.70)	2.54 (0.78)	.36	.46
8	2.92 (1.06)	2.79 (1.06)	.16	.54
9	2.67 (0.82)	2.58 (0.83)	.77	.46
10	2.83 (0.87)	2.88 (0.74)	.76	.70
11	3.92 (0.41)	3.83 (0.38)	.10	.35
Risk awareness				
14	3.54 (0.51)	3.42 (0.58)	.08	.81
15	3.63 (0.49)	3.54 (0.51)	.37	.41
16	3.58 (0.58)	3.58 (0.50)	>.99	.23
17	3.42 (0.58)	3.54 (0.51)	.16	.54
18	3.58 (0.50)	3.58 (0.50)	.76	.33
19	2.17 (0.64)	2.38 (0.65)	.16	.73
Strategies for not touching the face				
20	1.83 (0.70)	2.04 (0.75)	.21	.65
21	3.54 (0.51)	3.54 (0.51)	.48	.46
22	3.54 (0.51)	3.38 (0.49)	.56	.26
23	3.71 (0.55)	3.46 (0.51)	.25	.38
24	2.96 (0.69)	2.75 (0.74)	.48	.47
25	3.42 (0.65)	3.29 (0.55)	.16	.60
26	2.46 (0.66)	2.50 (0.78)	.54	.33

Hygiene Habits, Risk Awareness, and Strategies to Avoid Touching the Face

The significant pre- and postintervention differences in the participants of the EGs in terms of hygiene habits, risk awareness, and strategies to avoid touching the face are shown in Table 2. As Table 1 shows that there are no statistically significant differences in the CG, this information is omitted from Table 2.

Hygiene habits showed significant differences ($P<.05$) at pre- and postintervention time points in several items, as shown in Table 2. The 2 EGs showed coincident positive significant differences in item 9, which is related to the disinfection of objects. Item 6, regarding the frequency of handwashing, establishes a significant positive difference in the EG-R and a negative difference in the EG-nR. In addition, the participants of the EG-nR improved the behavior of avoiding touching the facial T-zone (item 7). Items 12 (EG-R, $P>.99$; EG-nR, $P=.73$) and 13 (EG-nR; $P>.99$) did not show significant differences at pre- and postintervention time points, with the exception of the EG-R for item 13, knowledge of the facial T-zone ($P=.01$). The participants of the EGs showed a higher frequency of facial self-touches with a mask (45/79, 57%), and 77% (61/79) knew about the facial T-zone before filling out the questionnaire. Risk awareness establishes pre- and postintervention differences (EG-nR and EG-R) in item 19, showing a perception toward greater ease in avoiding the behavior of touching the face. Moreover, the EG-nR showed higher values in the perception of the risk of touching the face (item 15).

By contrast, regarding the strategies for not touching the face, as the main objective of this study, consistent significant differences were observed. In the pre- and postintervention analysis, both EGs showed a reduction in the perception and frequency of facial self-touches (items 20 and 26). However, the EG-R established a positive significant difference in the perception of the magnitude of this behavior (item 26); this result is possibly related to an increase in perceptive capacity. In addition, a clear improvement was observed in the perception of the possibility of reducing facial self-touches with training and the importance of awareness of the behavior among the participants of EG-nR (items 22 and 23) and in seeking a simple solution to avoid a risk behavior among the participants of EG-R (item 24). The significant differences between the groups are shown in Table 3.

Regarding hygiene habits, there were differences between the CG and the 2 EGs, and the comparison of the 3 groups in relation to the ability of avoiding touching the facial T-zone favored the EGs (item 7).

With respect to risk awareness, positive significant differences were only observed between the CG and EG-nR, the CG and EG, and among the 3 groups in 2 items, 15 and 16, related to touching the face and handwashing. Finally, regarding the strategies for not touching the face, differences were observed between the CG and the 2 EGs, with higher rates observed in the EGs. These differences were observed for items 20, 24, and 25 in the EG-nR; for all items except 21 in the EG-nR; and for all except 21 and 23 in the full EG. In addition, differences were observed among the 3 groups for items 20 and 24. No significant differences were observed between the 2 EGs in any section.

Table 2. Significant differences between pre- and postintervention measures in the experimental groups.

Construct and item	Experimental group with no social reinforcement (n=36)			Experimental group with social reinforcement (n=43)		
	Test values, mean (SD)	Retest values, mean (SD)	Wilcoxon sign-rank test (*P* values)	Test values, mean (SD)	Retest values, mean (SD)	Wilcoxon sign-rank test (*P* values)
Hygiene habits						
6	2.67 (1.06)	2.58 (1.02)	.005[a]	2.49 (0.88)	2.79 (0.77)	.04[a]
7	2.56 (0.65)	2.94 (0.79)	.008[a]	2.65 (0.84)	3.02 (0.67)	.08
8	3.03 (0.97)	3.03 (0.81)	.93	2.72 (1.12)	2.74 (0.93)	.85
9	2.44 (0.81)	2.92 (0.73)	.001[a]	2.58 (0.98)	2.98 (0.96)	.03[a]
10	2.72 (0.85)	2.94 (0.63)	.28	2.93 (0.83)	3.16 (0.92)	.10
11	3.75 (0.50)	3.58 (0.69)	.13	3.86 (0.41)	3.79 (0.47)	.41
Risk awareness						
14	3.56 (0.61)	3.64 (0.59)	.41	3.44 (0.67)	3.48 (0.66)	.52
15	3.67 (0.53)	3.86 (0.35)	.04[a]	3.60 (0.58)	3.72 (0.63)	.20
16	3.81 (0.40)	3.86 (0.42)	.53	3.65 (0.48)	3.72 (0.59)	.35
17	3.58 (0.55)	3.72 (0.51)	.23	3.53 (0.55)	3.67 (0.61)	.14
18	3.75 (0.50)	3.78 (0.42)	.76	3.44 (0.55)	3.58 (0.76)	.18
19	2.11 (0.75)	2.47 (0.84)	.02[a]	2.05 (0.92)	2.44 (0.85)	.007[a]
Strategies for not touching the face						
20	2.11 (0.98)	1.44 (0.73)	.004[a]	1.91 (0.89)	1.49 (0.69)	.002[a]
21	3.61 (0.49)	3.72 (0.45)	.16	3.63 (0.49)	3.56 (0.73)	.82
22	3.42 (0.65)	3.64 (0.49)	.03[a]	3.44 (0.59)	3.58 (0.66)	.23
23	3.50 (0.61)	3.72 (0.45)	.02[a]	3.40 (0.54)	3.49 (0.63)	.25
24	3.08 (0.81)	3.28 (0.61)	.14	2.91 (0.84)	3.23 (0.78)	.02[a]
25	3.36 (0.59)	3.61 (0.55)	.05	3.42 (0.59)	3.56 (0.63)	.22
26	2.58 (0.91)	2.00 (0.79)	<.001[a]	2.47 (0.91)	3.67 (0.61)	.04[a]

[a]Statistically significant differences (*P*<.05).

Table 3. Statistically significant differences among the control group (CG), experimental group with no additional social reinforcement (EG-nR), and experimental group with additional social reinforcement (EG-R).

Construct and item	Mann-Whitney *U* test for CG and EG-R (*P* value)	Mann-Whitney *U* test for CG and EG-nR (*P* value)	Mann-Whitney *U* test for EG-nR and EG-R (*P* value)	Mann-Whitney *U* test for CG and EG (*P* value)	Kruskal-Wallis test for CG, EG-nR, and EG-R (*P* value)
Hygiene habits					
6	.69	.66	.38	>.99	.67
7	.01[a]	.047[a]	.71	.01[a]	.04[a]
8	.80	.43	.16	.80	.38
9	.08	.10	.59	.06	.15
10	.12	.81	.11	.29	.17
11	.81	.18	.17	.39	.26
12	.48	.34	.76	.36	.63
13	.57	.54	.94	.50	.79
Risk awareness					
14	.48	.10	.26	.20	.24
15	.054	.007[a]	.34	.007[a]	.02[a]
16	.14	.009[a]	.17	.02[a]	.03[a]
17	.17	.12	.78	.10	.24
18	.49	.11	.34	.21	.29
19	.88	.61	.75	.73	.89
Strategies for not touching the face					
20	.003[a]	.001[a]	.61	<.001[a]	.002[a]
21	.49	.15	.43	.25	.37
22	.06	.05[a]	.97	.03[a]	.09
23	.62	.04[a]	.08	.18	.09
24	.008[a]	.003[a]	.98	.002[a]	.008[a]
25	.04[a]	.03[a]	.77	.02[a]	.051
26	.11	.03[a]	.40	.04[a]	.08

[a]Statistically significant differences (*P*<.05).

#RedPingüiNO Intervention

The intervention showed that 94% (74/79; EG-nR: 34/36, 94% and EG-R: 40/43, 93%) of the participants in both EGs achieved greater awareness of the times they touched their faces (item 27), and 95% (75/79; EG-nR: 34/36, 94% and EG-R: 41/43, 95%) of the participants perceived that they had managed to reduce the number of facial self-touches (item 28). There were no significant differences between both groups (*P*=.51 and *P*=.86, respectively). The intervention improved the awareness of the reasons why the participants touched their face in each situation (item 42), with a rate of 3.53 (SD 0.60) (mean 3.47, SD 0.56, for the EG-nR and mean 3.58, SD 0.63, for EG-R) on a 4-point Likert scale (1=totally disagree and 4=totally agree). Table 4 shows the results of the strategies, materials, and evaluation of the #RedPingüiNO intervention.

Table 4. Significant differences between experimental groups (EGs).

Item	EG, mean (SD)	EG-nR[a], mean (SD)	EG-R[b], mean (SD)	Mann-Whitney *U* test score for EG-nR and EG-R (*P* value)
29	3.13 (1.15)	3.33 (1.07)	2.95 (1.19)	.09
30	2.92 (1.2)	2.78 (1.24)	3.05 (1.15)	.36
31	3.05 (1.1)	3.11 (1.21)	3.00 (1.00)	.26
32	2.53 (1.34)	2.33 (1.33)	2.70 (1.34)	.25
33	2.77 (1.25)	2.44 (1.34)	3.05 (1.11)	.07
34	3.05 (1.02)	2.83 (1.13)	3.23 (0.90)	.13
35	3.04 (0.85)	3.08 (0.87)	3.00 (0.85)	.60
36	2.94 (1.23)	2.72 (1.30)	3.12 (1.16)	.18
37	3.57 (0.61)	3.44 (0.61)	3.67 (0.61)	.045[c]
38	3.48 (0.64)	3.39 (0.60)	3.56 (0.67)	.13
39	3.49 (0.62)	3.39 (0.60)	3.58 (0.63)	.10
40	3.16 (0.72)	2.89 (0.71)	3.40 (0.66)	.001[c]
41	3.63 (0.58)	3.53 (0.56)	3.72 (0.59)	.054
42	3.53 (0.60)	3.47 (0.56)	3.58 (0.63)	.27

[a]EG-nR: EG with no additional social reinforcement.

[b]EG-R: EG with additional social reinforcement.

[c]Statistically significant differences (*P*<.05).

Strategies and Materials

On a 4-point Likert scale, where 1 was “Little” and 4 was “A lot,” the intervention groups showed high rates in the perception of the different materials, highlighting recording (31) and video (item 36) over infographics (item 32). The strategies in the game of saying “No!” (item 29) and saying “Bravo!” (item 30) had high and similar results in both the groups. The follow-up strategy (item 33) was assessed by the participants of the EG-R at a higher rate than those of the EG-nR, without it being significant (*P*=.07). The Telegram strategies with high rates in both groups also did not establish significant differences between the 2 EGs (items 34 and 35).

Evaluation of the Intervention

The intervention was assessed by the participants of the 2 EGs as engaging (item 37), helpful (item 38), and motivating (item 39), with high rates; however, the EG-R showed a higher rate than the EG-nR in the perception of the appeal of the intervention (*P*=.045). In both groups, the duration was perceived as sufficient, with high means (item 40) and a higher rate in the EG-R than in the EG-nR (*P*=.001). In addition, the serious game proposed as an intervention strategy was perceived as suitable for use within the school context (item 41), with high rates in both groups. Therefore, although the results are satisfactory in both groups, social reinforcement seems to have an impact on the perception of the intervention with higher means in the EG-R in all cases, regardless of whether they establish significant differences. This highlights the perception of the intervention as an engaging way to train awareness to not touch the face long enough to achieve changes in this behavior.

Development of the Daily Intervention Log

In the analysis of the development of the daily log, a significant positive difference is observed in relation to the times that the participants of both EGs consciously stopped their hand before touching their face with a “Bravo!” (EG, *P*<.001; EG-nR, *P*=.01; and EG-R, *P*<.001), as well as a significant negative difference in relation to the frequency in which the facial T-zone was touched, and they realized it with a “No!” (EG, *P*<.001; EG-nR, *P*=.049; and EG-R, *P*<.001), possibly due to the significant reduction in facial self-touches. These data must be understood as the perception of a decrease in the frequency of facial self-touches. The reasons for facial self-touches were not modified among participants throughout the intervention. The participants of the EG-nR and EG-R established the reasons for touching their face as itching, lacrimation, and tingling (EG-nR: 17/36, 47%, preintervention and 16/36, 44%, postintervention; EG-R: 26/43, 61%, preintervention and 21/43, 49%, postintervention); restlessness, discomfort, and boredom (EG-nR: 13/36, 36%, preintervention and 12/36, 33%, postintervention; EG-R: 10/43, 23%, preintervention and 9/43, 21%, postintervention); and learned gestures (EG-nR: 6/36, 17%, preintervention and 8/36, 22%, postintervention; EG-R: 7/43, 16%, preintervention and 13/43, 30%, postintervention). The motivation perceived by the participants throughout the intervention showed a significant improvement, on a 5-point Likert scale, in the EG-nR (3.47, SD 0.87 at preintervention and 4.06, SD 1.09 at postintervention) and in the full EG (3.59, SD 1.25 at preintervention and 3.93, SD 1.16 at postintervention). This difference is not established in the EG-R (3.65, SD 1.40 at preintervention and 3.86, SD 1.21 at postintervention), owing to the perceived high motivation at the start of the intervention.

Discussion

Principal Findings

The main objective of the #RedPingüiNO intervention was to reduce facial self-touches as a preventive measure against SARS-CoV-2 and other pathogens in various health contexts. The newly constructed tools developed for analyzing the intervention established adequate validity and reliability. After the 2-week intervention, the participants perceived improvement in their hygiene habits strategies, such as handwashing; disinfection of objects; the use of a handkerchief; and the action of avoiding touching the eyes, nose, and mouth. After the intervention, the perception of the risk that facial self-touches entail increased within the EGs, but at the same time, touching the face was noticed as an easier behavior to avoid. The participants in the 2 EGs perceived that they had reduced the number of facial self-touches following the intervention. Participants' perception of the specific number of times they touched their faces also increased. They became more aware of the reasons why they touched their faces on a daily basis, the frequency of this behavior, and the importance of this awareness for self-regulation and avoiding self-touches. #RedPingüiNO was considered an appropriate and fun experience. More than half of the people who participated rated the game with qualifiers like "satisfactory," "rewarding," "positive," "fun," "useful," or "surprising"; moreover, during the intervention, motivation increased as they perceived the achievement.

Comparison With Prior Work

This study seems to reinforce that changes in health behaviors are possible with appropriate tools. This need is based on the idea that the most effective steps to reduce infection and death rates during the pandemic have been based on changes in individual behavior [2]. After the intervention, touching the face was noticed as an easier behavior to avoid, which coincides with the approach of Heinicke et al [30]. These authors indicate that reducing or stopping facial touching is a habitual and prevalent behavior that is unlikely to decrease unless we train with specific strategies for self-regulation, which implies awareness and the establishment of effective responses. Facial self-touches seem to increase in frequency and duration in emotionally or cognitively challenging social situations. This may be due to the attention states, working memory processes, and emotion-regulating functions [12] associated with such situations, which are developed and maintained based on the body language used in interactions with oneself and other people. Itching, lacrimation, and tingling were the most noted triggers of this behavior among the participants who subsequently experienced restlessness, discomfort, and boredom; the participants were somewhat less alert to the learned gestures.

The increased perception of a reduction in the number of facial self-touches seems to respond to the fact that during serious play, there was an improvement in awareness of this behavior that involved limited cognitive effort, control, and intention [31]. This can be seen in the progressive increase of "No!" in the log and how the positive reinforcement also increased with the passage of time when stopping self-touches with the "Bravo!" strategy. These game dynamics respond to the need for control over self-touches, which must be trained through habits to block, divert, or perceive the act through attention and anticipation, as well as from the reflexive capacity of movement [2]. Although we perceive the touch when it has already occurred, with repetition, there is a possibility of anticipating and paying the necessary attention to stop the action before it happens.

Although the effectiveness of strategies using mindfulness [32] or using technological means, such as software [33], camera and sensor networks [34], and smartwatches [35], to reduce facial self-touches is being investigated, specific strategies should be provided to reduce self-touches, ranging from awareness to easily understanding triggers and mechanisms to regulate one's own behavior, if possible, from everyday contexts [8,9,15,36]. This was the case in this intervention. One participant said as follows:

> *The most important thing in this experience is to consider each situation that causes me to touch my face or the situations that do not. I have questioned every detail (makeup, fringe, daily face washing, piercings, glasses, hot-cold, allergies, etc.)* [participant 14]

Thus, awareness is understood as a mental activity of the individuals that enables them to feel, have a reflexive knowledge of their actions, and know about themselves in particular, including actions less regulated by consciousness.

This serious game was considered useful, satisfactory, and fun—an intrinsic aspect of the act of playing [37]. This shows the positive balance of game design by providing a state of well-being, pleasure, and enjoyment, as described in flow theory [38], reinforcing the notion that serious games can be a playful and effective methodological framework for learning [39,40]. In a game aimed at learning, the media and materials are fundamental and enable its development [41], and if they are technological, they can be relevant allies for interaction [42], as the highly valued video tutorials, infographics, daily logs, and the Telegram group proved to be in this study. In summary, a game like #RedPingüiNO is based on its design and implementation, and therein lies its potential, taking care of the aspects of the mechanics, dynamics, and aesthetics framework. This mechanics, dynamics, and aesthetics framework is a formal approach to understanding games, which attempts to bring together game design and development, criticism, and technical research [43].

Starting from these elements, the intrinsic motivation of the participants was sought from Marczewski theory [44], valuing autonomy in game development, the mastery that enabled the participants to be aware of the progress they were achieving, the purpose for which they were playing, and their relationships. Regarding the latter, the participants from the groups both with and without reinforcement managed to be more aware of the times they touched their faces and perceived a reduction in self-touches. However, the participants in the EG-R considered the game more appealing, believed more firmly that the allotted time was sufficient, and presented higher frequencies of self-touch awareness and restraint during the recording. In summary, the game without this accompaniment was helpful, although the collective support and reinforcements promoted among those who played it may have a relevant supporting role. Regarding playing with other people, a significant number of participants indicated that they had shared it with their families and friends, seeking out that social reinforcement themselves but within their own environment:

> *[W]hat has struck me the most in this intervention has been the fact that I shared it with my family. They have helped me to be much more aware of the number of times I touch my face.* [participant 8]

> *I have learned a lot, in fact, I have encouraged my family and friends to do it with me and together we have greatly reduced how much we touch our faces. When we sat down to eat, we talked about it and we kept a family ranking too.* [participant 17]

Limitations and Future Directions

#RedPingüiNO resulted in a significant and helpful serious game that increased the perception of face self-touch avoidance. However, this study had some limitations. First, the sample used was a small number of university students, and it would be expedient to conduct future research with larger and more diverse samples. Second, owing to the specific characteristics of the university groups of students, there was a certain difference between the number of male and female participants in the different groups, and the CG had a smaller number of participants, which could bias the results. However, no significant gender differences were found in the study. Third, data on whether participants touched their face were not obtained from recordings. As not touching the face is a self-controlled behavior, these data were collected via a questionnaire and the daily logs of participants, and the results could be overestimated or underestimated. Therefore, as this behavior was not directly observed, these results must be understood as participants' perceptions of the decrease in the frequency of facial self-touches.

However, these limitations may present an opportunity because self-control itself has been one more strategy for reducing facial self-touches, with people taking a more active role in being aware of it and playing the game in their daily environments, not under laboratory conditions or in simulations. The perception of automated behaviors serves as a mechanism for self-control, which is facilitated by the awareness generated through conscious observation. Moreover, the perceived efficacy of the game invites to demonstrate its potential among other populations, such as health care workers and susceptible people, or within other environments.

Conclusions

This study provides evidence on the possible impact of the serious game #RedPingüiNO in reducing the behavior and perception of touching the face and its mucous membranes and may have an effect on the prevention of infectious diseases in different health contexts, such as those caused by SARS-CoV-2 and other pathogens. Being able to exert some control over this transmission path from within a game has allowed for better conscious control beyond verbally warning people not to touch their faces. The implemented tools were considered valid and reliable. Participants perceived a reduction in facial self-touches after the intervention and became more aware of their risk behaviors. The play strategy of #RedPingüiNO is simple and motivating in its format, precisely because it deals with a complex behavior that has a high degree of unconscious movement and automatic action, which is regulated by various contextual internal and external communication situations for the individual. Challenge-oriented mechanics, levels, and humor-based onomatopoeia reinforcement, as well as accessible and free gameplay components, make this serious game adaptable to other contexts such as health institutions, hospitals, community centers, schools, or similar entities. We also noted that the game could have a greater effect if it is shared, and the experience is reinforced by the interactions between the participants. #RedPingüiNO can help control risk behaviors against infectious diseases or in exceptional health situations. In summary, this study can be presented as a precedent for the self-control of behaviors related to health at different levels.

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Authors' Contributions

MAB designed and directed the study. MAB, PSO, and AVS performed the bibliographic review. MAB, PSO, AVS, and IAI structured the theoretical bases and developed the project. AVS organized the development of the instruments. MAB, PSO, and AVS performed the interventions. CJL developed the statistical analysis and structured the results. MAB, PSO, AVS, CJL, and IAI wrote the manuscript. MAB, AVS, and IAI reviewed the draft manuscript. MAB, PSO, AVS, CJL, and IAI approved the latest version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey instrument.
[PDF File (Adobe PDF File), 216 KB - games_v11i1e45600_app1.pdf]

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Abbreviations

CG: control group
EG: experimental group
EG-nR: experimental group with no additional social reinforcement
EG-R: experimental group with additional social reinforcement
sFST: spontaneous facial self-touches

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Original Paper

Eating Behavior and Satiety With Virtual Reality Meals Compared With Real Meals: Randomized Crossover Study

Alkyoni Glympi[1], MSc; Dorothy Odegi[1], MSc; Modjtaba Zandian[1], PhD; Per Södersten[1], PhD; Cecilia Bergh[2], PhD; Billy Langlet[1], PhD

[1]Division of Clinical Geriatrics, Center for Alzheimer Research, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Huddinge, Stockholm, Sweden

[2]Mandometer Clinics, Stockholm, Sweden

Corresponding Author:
Billy Langlet, PhD
Division of Clinical Geriatrics
Center for Alzheimer Research, Department of Neurobiology, Care Sciences and Society
Karolinska Institutet
Alfred Nobels allé 23
Huddinge, Stockholm, 141 52
Sweden
Phone: 46 086905826
Email: billy.langlet@ki.se

Abstract

Background: Eating disorders and obesity are serious health problems with poor treatment outcomes and high relapse rates despite well-established treatments. Several studies have suggested that virtual reality technology could enhance the current treatment outcomes and could be used as an adjunctive tool in their treatment.

Objective: This study aims to investigate the differences between eating virtual and real-life meals and test the hypothesis that eating a virtual meal can reduce hunger among healthy women.

Methods: The study included 20 healthy women and used a randomized crossover design. The participants were asked to eat 1 introduction meal, 2 real meals, and 2 virtual meals, all containing real or virtual meatballs and potatoes. The real meals were eaten on a plate that had been placed on a scale that communicated with analytical software on a computer. The virtual meals were eaten in a room where participants were seated on a real chair in front of a real table and fitted with the virtual reality equipment. The eating behavior for both the real and virtual meals was filmed. Hunger was measured before and after the meals using questionnaires.

Results: There was a significant difference in hunger from baseline to after the real meal (mean difference=61.8, P<.001) but no significant change in hunger from before to after the virtual meal (mean difference=6.9, P=.10). There was no significant difference in food intake between the virtual and real meals (mean difference=36.8, P=.07). Meal duration was significantly shorter in the virtual meal (mean difference=–5.4, P<.001), which led to a higher eating rate (mean difference=82.9, P<.001). Some participants took bites and chewed during the virtual meal, but the number of bites and chews was lower than in the real meal. The meal duration was reduced from the first virtual meal to the second virtual meal, but no significant difference was observed between the 2 real meals.

Conclusions: Eating a virtual meal does not appear to significantly reduce hunger in healthy individuals. Also, this methodology does not significantly result in eating behaviors identical to real-life conditions but does evoke chewing and bite behavior in certain individuals.

Trial Registration: ClinicalTrials.gov NCT05734209, https://clinicaltrials.gov/ct2/show/NCT05734209

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KEYWORDS

exposure therapy; eating behavior; anorexia nervosa; bulimia nervosa; binge eating disorder; overweight; obesity; immersive virtual reality; VR; virtual reality

Introduction

Eating disorders and obesity constitute severe health problems in Western society. Globally, the prevalence of eating disorders has increased recently by 25% [1], and for obesity, it is estimated that, by 2030, 20% of the world's adult population will be obese [2]. Both health conditions considerably impair physical health, disrupt psychosocial functioning [1,3], and are risk factors for depression and anxiety disorders [3,4]. Both are expensive disorders, with the overall cost of eating disorders in the United States in 2018 estimated at $64.7 billion per year [5] and of high BMI worldwide in 2017 estimated to be $802 billion [6].

Although both health problems are related to food consumption, their commonalities are seldom discussed. For instance, the same eating behavior parameters (ie, eating rate and food intake) have been identified to increase the risk of developing anorexia and obesity [7,8]. A majority of these individuals have lost the ability to experience satiety during and after meals [7]. A key characteristic of anorexia nervosa is a slow eating rate, which stems from an effort to prevent weight gain by restricting food intake [7]. People with bulimia nervosa try to restrict their food intake to control their body weight but eventually become sufficiently hungry that they consume large amounts of food rapidly before purging [9]. Binge eaters have the bulimia intake pattern without purging [9]. Those who become obese often try to restrict their food intake, but their efforts are typically transitory and ineffective. Finally, a high eating rate is associated with increased food intake [8], excess body weight [8,10], and a larger bite size [8,11].

Eating disorders and obesity constitute severe health problems, and although their prevalence has increased over the years, there is still no consensus for their treatment [1]. The effectiveness of conventional eating disorder treatments, such as family-based therapy, psychopharmacological treatment, and cognitive behavior therapy, are weak [7], with most studies reporting poor long-term treatment outcomes [12]. Conventional treatment for obesity includes lifestyle modification (diet and exercise), medication, and bariatric surgery. The weight loss associated with lifestyle modification and medication interventions is also limited, due to poor adherence rates [13], and although bariatric surgery is the most effective weight loss treatment, it is associated with multiple health complications [14].

High relapse rates are reported for both eating disorders and obesity, with only some people with anorexia nervosa reaching full recovery [15] and people with obesity often regaining most of the lost weight [16]. Last, high dropout rates are another issue that affects the treatment outcomes. For instance, it is estimated that, for people with anorexia nervosa, the dropout rates range from 20.2% to 49.6% [17] and, for people with obesity, from 10% to more than 80%, depending on the treatment program [18]. Therefore, there is an urgent need to explore effective alternative treatments to address these health problems.

Virtual reality devices have been used in many areas of health care for a variety of applications from professional health care education to disease treatment [19]. Examples of conditions that have been treated successfully with virtual reality are anxiety disorders, phobias, stress management, posttraumatic stress disorder, acute and chronic pain management, autism, and physical rehabilitation [20,21]. An especially promising area of use may be for the assessment and treatment of eating disorders and obesity, for which virtual reality devices can be used as an adjunctive treatment tool [20,22,23].

Recent technological advancements have significantly decreased the cost of virtual reality, making the technology more accessible for medical treatments [24]. The ability to customize and control the virtual reality environment makes the application of this technology easier in a treatment context, since triggering certain fears may be difficult to reproduce in real life [25]. The scripted nature of a virtual reality app prevents the occurrence of unexpected situations and provides patients with a safe environment where they can experience specific aspects of life, allowing them to be "emotionally present" within the virtual environment [26]. Immersive virtual reality provides an even more intense experience for the user, using a virtual reality headset or multiprojected environments to generate realistic images, sounds, and other sensations [25].

Virtual reality exposure therapy has been successful in modifying body image distortions in people with obesity, binge eating disorder, and eating disorders not otherwise specified, leading to a reduction in inappropriate behaviors related to food and social relationships [27].

Besides modifying body image distortions, virtual reality studies of eating disorders have focused on exposure to virtual food stimuli [23]. Some of these studies aimed to assess emotional reactions or craving while using virtual reality, while others had therapeutic objectives [23]. The results suggest that the participants perceived the virtual reality environment as real and that it was able to elicit emotional responses (eg, anxiety, food-related thoughts) [23]. More specifically, for binge eating disorder and bulimia nervosa, studies indicate the potential utility of virtual reality in improving motivation for change, self-esteem, and reducing binge eating and purging behaviors [20].

In obesity, besides modifying body image distortion, virtual reality studies were successful at improving self-control, mood, and weight loss [28-30]. Another area of focus was to increase physical activity using "exergaming" as a potential treatment for obesity and diabetes. Exergaming's fundamental concept is to use vigorous body activity as the input for interacting with digital game content, in the hopes of replacing the sedentary activity that is typical of traditional keyboard, game pad, and joystick inputs [31,32].

In addition to these findings, a study that investigated the perceived usability of a virtual reality app that promoted normal eating behavior suggested that clinicians have a positive attitude toward using virtual reality when treating people with an eating disorder [33]. Considering the advantages provided by this technology, virtual reality could be a useful tool to address eating disorders and obesity via exposure therapy and behavioral training.

Although interest in using virtual reality for treating eating disorders and obesity has increased over the last 2 decades, there is a lack of studies examining the effect of behavioral training via virtual reality on eating behaviors and satiety [22,23]. It has been proven that better treatment outcomes are obtained when the treatment normalizes eating behavior [34]. Similar methods may be successful in treating other eating behavior problems. Thus, a behavioral training approach via virtual reality could provide a new adjunctive tool to the existing treatment of eating disorders and obesity.

Both the method (eg, virtual reality and immersive virtual reality) [23] and aim (eg, normalizing body image and food exposure) [22,23] of virtual reality studies in eating disorders and obesity have been inconclusive, and further work is required to clarify these findings. Another reason to investigate the effectiveness of virtual reality further is that clinicians have expressed concerns that people with anorexia nervosa could substitute virtual meals for real meals to reduce feelings of hunger without ingesting any food [33].

Therefore, the main aim of the study was to determine whether eating in an immersive virtual reality environment reduces hunger among healthy adults. The secondary aim was to describe any eating behavior differences between the consumption of virtual reality meals and real-life meals.

Methods

Participants

General inclusion criteria were women, 18 years to 28 years of age, a BMI from 18.5 kg/m^2 to 29 kg/m^2, not pregnant nor breastfeeding, and normal physical activity (<1500 metabolic equivalent of task min/week of moderate-to-vigorous physical activity level from the International Physical Activity Questionnaire). Health inclusion criteria were nonsmokers, the absence of temporomandibular disorders or recent serious dental surgery, not undergoing treatments known to affect appetite (eg, some psychotropic drugs, acetazolamide), and no previous history of eating disorders. Only nonvegetarians with no aversion to the food that was to be served were allowed to participate in the study.

Recruitment

Recruitment of participants started in October 2020 and ended in April 2022. Participants were recruited via digital meeting platforms, by contacting potential participants in person, and by hanging flyers around the university campus.

Instruments

BMI

To measure BMI, weight was measured using a body composition analyzer (Tanita BC-418), and height was measured using a stadiometer (Seca 216 1814009). To collect data on eating behavior (ie, chews, bites, forkfuls) a home security camera (Mi 360°, Xiaomi) was used. To display and interact with the virtual meal, we used a virtual reality headset (HTC VIVE Pro), which consists of a head-mounted device and accompanying handheld controllers. The headset provides 110 degrees of viewing at a resolution of 1440 x 1600 pixels per eye (2880 x 1600 pixels combined) and a refresh rate of 90 Hz.

Food Intake

To measure food intake throughout the real meal, a digital food scale (Mandometer version 4) was used. The Mandometer is a medical device that consists of a scale that is connected to a computer; the scale measures the weight of the food on the plate at a sampling frequency of 1 Hz [35]. Before starting a meal, a plate was placed on the food scale, and the weight of the plate was subtracted from the meal. Food was then served on the plate, and the weight of the food was registered throughout the meal.

Subjective Data

Subjective data were collected via a tablet (Samsung Galaxy Tab A7) using an in-house developed app containing all questionnaires to ensure that participants fulfilled inclusion criteria, and it also contained 1 questionnaire to collect outcome data.

Inclusion Questionnaires

The short form of the International Physical Activity Questionnaire was used to evaluate participants' physical activity and to exclude those with too high moderate-to-vigorous physical activity levels [36]. The questionnaire consists of 7 questions, for example "During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?" The Health questionnaire was used to exclude individuals who were not healthy enough to participate or did not fulfill the inclusion criteria. The questionnaire consists of 25 questions about the general health of the participants (eg, "Do you often have infections like cough or sore throat?"). The Dutch Eating Behavior Questionnaire was used to assess 3 distinct eating behaviors (external, emotional, and restrained eating) [37]. The questionnaire consists of 33 questions, such as "If you have put on weight, do you eat less than you usually do?", "Do you have the desire to eat, when you are emotionally upset?", or "If you see others eating, do you also have the desire to eat?"

Outcome Questionnaire

Subjective appetite, mood, and taste of the food were rated using a meal questionnaire, which consists of 25 questions divided into 2 parts. The first part, "before meal," consists of 6 questions about mood (eg, "Are you feeling tense right now?") and 6 questions about appetite (eg, "How hungry do you feel?"). Mood and appetite questions were rated on 100-mm visual analog scales ranging from 0 to 100, with the verbal anchors "Not at all"=0 on the left side and "Extremely"=100 on the right side. The second part, "after meal," consists of 6 questions about appetite (same as before the meal) and 7 questions about the taste of the food (eg, "How fatty did the food taste?") on visual analog scales identical to that presented before the meal.

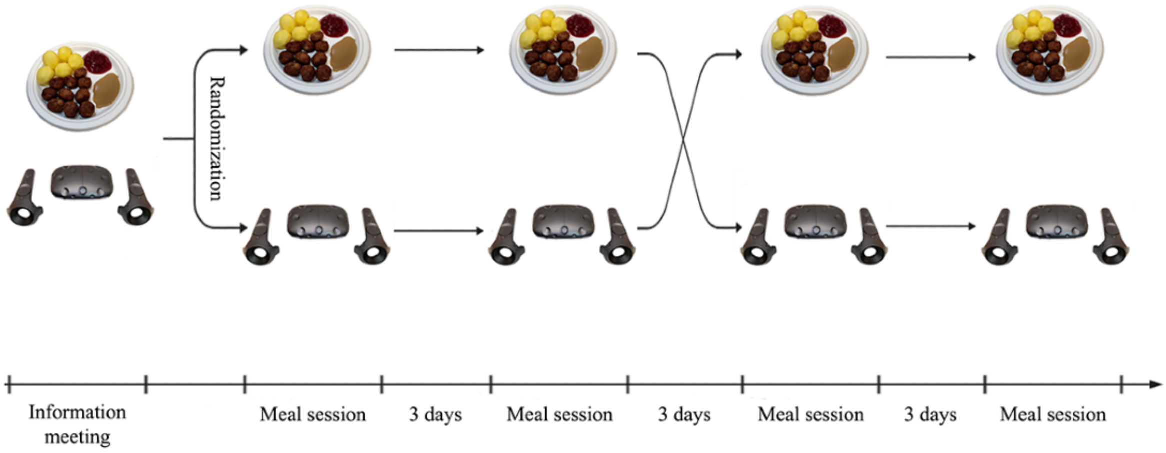
Ethical Approval

The research protocol was approved by the Swedish Ethical Review Authority (D.nr: 2019-04249).

Procedure

The study consisted of 5 meetings in a randomized crossover design, in which participants acted as their own control with 2 conditions, each with 2 repeats. Respondents first attended an information meeting where they ate an introduction meal. During the remaining 4 meetings, participants were either served a virtual or a real meal in a randomized order (Figure 1). All 5 meetings, including the information meeting, were held on weekdays (Monday to Friday) during lunch hours (11 AM to 1 PM) and had a wash-out period of at least 3 days. Both the real-life and virtual reality meals were recorded using a video camera.

Figure 1. Study design.



The day before each meeting, participants received an email with information regarding the type of meal (virtual or real) that they would have. To control for satiety, participants were reminded to eat the same breakfast the day of the meeting, at least 3 hours before, and to refrain from high-intensity physical activity 24 hours before the meeting. All the real meals were prepared by the researchers in the clinic 30 minutes to 60 minutes before the participants' arrival. All the prepared meals were kept in the oven at a temperature of 80 °C to ensure proper serving temperature. In the virtual world, the size of utensils, food containers, and food items were equivalent to the matching real-world item. Size-to-weight of food items in the virtual world was calculated, and corresponding meatballs and potatoes were purchased for the real-world meals, resulting in meatballs weighing 14 g each and potatoes weighing 60 g each.

Information Meeting

During the information meeting, respondents were provided with detailed information about the study, data collection, handling and secrecy, and the potential risks associated with participating. Besides informing them, the purpose was to ensure their eligibility to participate in the study, familiarize them with the study procedures, and provide a baseline food intake value for the rest of the meals. Each participant signed a written consent form and proceeded to answer the Health and the International Physical Activity Questionnaires. Once the questionnaires were reviewed and approved, the participant's height and body composition were measured.

Afterward, the introduction meal was served. In total, 1.2 kg of food was served, consisting of meatballs (400 g) and boiled potatoes (800 g). Brown sauce and lingonberry jam were placed in separate ceramic bowls on the table with a glass of water (200 mL). After the food had been served, the participant filled in the "before meal" part of the meal questionnaire. Once completed, the participant was instructed to put food on the plate that had been placed on the food scale and to eat the meal as they normally would, with no time nor intake restriction (ad libitum). Finally, instructions were given for the participant that they could add food to the plate or leave food on the plate and to refrain from using a mobile phone or other distracting elements while eating. Once the participant was finished putting food on the plate, the food scale and the video camera were turned on. After meal termination, the participant filled in the "after meal" part of the meal questionnaire.

The next step of the procedure was the virtual meal, for which the participant was taken to the virtual reality room, seated on a real chair in front of a real table, and fitted with the virtual reality equipment. The virtual reality room showed a kitchen that included a table, chair, and windows that revealed a natural scene. In the virtual reality environment, the controllers were represented by hands. The introduction meal consisted of several steps, teaching the participant how to serve themselves and consume food in the virtual reality environment [33]. A virtual tablet presented what tasks to perform to proceed to the next step. Each step ended by pressing the "next" button. In every step, a new "object" appeared on the table starting with a plate and continuing with meatballs in a pan, potatoes in a pot, brown sauce in a sauceboat, lingonberry jam, a jug of water, a glass, and cutlery [33]. After completing all previous steps, the participant could freely "cut" and "eat" the food.

Real-life Meal

The meeting for the real-life meals started by measuring the participant's body composition and filling in the "before meal" part of the meal questionnaire. The participant was then led to the room where they would eat. The room was designed to be as neutral as possible, with only a table and a chair (Figure 2). The meal was served on a plate that was placed on the food scale, with a glass of water alongside. The quantity of food on the plate was the same as the amount of food that the participant consumed during the introduction meal, plus an extra 50% portion on the side (Figure 3). The same instructions as in the introduction meal were provided. Once the participant was done eating, they filled in the “after meal” part of the meal questionnaire.

Figure 2. Research room.

Figure 3. Food was served, and 50% of the portion was placed on the side.

Virtual Meal

The meeting started by measuring the participant’s body composition. Afterward, the participant was taken to the virtual reality room (Figure 4), filled in the “before meal” part of the meal questionnaire, and was fitted with the virtual reality equipment. The meal served in virtual reality was the “same” as the real meal; the portion of the virtual meal was equivalent to the portion that was consumed during the introduction meal. There was extra food in the containers placed on the table, enabling free addition of food to the plate (Figure 5). Once the participant was ready to eat the virtual meal, the video camera and the acquisition software from the computer were initiated by the researcher. The purpose was for the meal to be eaten normally with no time restriction. Once the participant was done, the “after meal” part of the meal questionnaire was filled in.

Figure 4. Virtual reality room.

Figure 5. Virtual reality environment.

Data Formatting

Video recordings from both virtual and real meals were annotated using The Observer XT 16 (Noldus). The eating-related behaviors annotated were forkful, food addition, bite, and chew. Forkful was annotated as a point event when the fork touched the plate to pick up food. Addition was annotated as a state event, starting when food was added to the plate and ending when no more food was added and food ingestion started again. Bite was annotated as a point event when the mouth was closed around the fork. The virtual food did not require bites, as the food was "eaten" by putting it close to the headset. Chew was annotated as a point event when teeth occlusion and activation of masseter and temporalis muscles occurred.

Statistical Analysis

Statistical analyses were carried out using R software version 4.2.1 [38]. Since participants conducted 2 meals for each eating condition (2 real and 2 virtual meals), the average of every measured outcome (eg, food intake, hunger) was calculated. Thus, for each eating condition, 1 value (the mean) was created and was used in the analysis. For example, the food intake of the virtual reality meal refers to the mean food intake from the first and the second virtual reality meals.

The Shapiro-Wilk test and visual inspection of a Q-Q plot were performed to ensure normal distribution of the data. For the parameters that were not normally distributed, a Wilcoxon signed rank test and a paired Student *t* test were performed. Since the interpretation (ie, rejection or nonrejection of the null hypothesis) to both tests were identical for all investigated parameters, only *t* tests are presented in the results. The relevant parameters tested were hunger before and after the virtual and real meals, food intake, meal duration, eating rate, forkfuls, and additions, between the real and virtual meals. A subgroup was created from the participants who took chews and bites in the virtual meals. Additional *t* tests were performed for this subgroup, comparing chews and bites in the virtual meal to the real meal. Last, the same test was performed for all participants to evaluate the effect on hunger and meal duration between the first and second meals in both eating conditions. Pearson product-moment correlation was used to examine the association between hunger after the meal and meal duration and chews, as well as the correlation between meal duration and chews and food intake. Caution is required when interpreting all correlation analyses including chews from the virtual reality condition as a parameter, since in more than one-half of the measurements, the number of chews was 0. A significance threshold of $P \leq .05$ for all statistical tests was used. Unless otherwise specified, values are expressed as mean (SD). For the power calculation, a sample size of 20 was found to be sufficient for the study, using the effect size between real meal conditions of previous studies, an α cutoff of .05, and power of 0.80.

Results

Participants

Of 24 participants, 20 finished all parts of the study (Table 1); 2 participants dropped out due to scheduling difficulties, 1 participant was excluded due to corrupt data, and 1 participant was excluded due to suspected conformity bias, based on low food intake. No participant was excluded based on questionnaire responses.

Table 1. Demographic data of the participants (n=20).

Demographic characteristics	Results, mean (SD)
Age (years)	23.9 (2.5)
Weight (kg)	61.2 (9.6)
Height (cm)	165.3 (7.4)
BMI (kg/m^2)	22.4 (2.8)
Body fat (%)	27.5 (5.1)

Hunger Before and After Meals

For the virtual meal, participants rated their hunger before and after the meal at 66.9 and 59.9 (out of 100), respectively, resulting in no significant difference in hunger before and after the virtual meal (*P*=.10). For the real meal, participants rated their hunger before and after the meal at 68.6 and 6.9, respectively, resulting in a significant reduction in hunger after the real meal (mean difference=61.8, *P*<.001). One participant had a reduction in hunger similar in size to what was expected for a real meal as a result of eating a virtual meal, with a rated reduction of 59.

There was no significant difference in hunger before the meal between the virtual and real meals (*P*=.79), but hunger was significantly higher in the virtual condition after the meal (mean difference=–53.1, *P*<.001).

Eating Behavior Characteristics

There was no significant difference in “food” intake between the virtual and real meals (*P*=.07). Meal duration was significantly shorter with the virtual meal (mean difference=–5.4, *P*<.001), which led to a higher eating rate (mean difference=82.9, *P*<.001) for the virtual meal. When the chewing time (burst interval) was removed from the virtual and real meals, there was no significant difference in meal duration between the virtual and real meals (*P*=.06). The number of forkfuls and number of additions were significantly lower with the virtual meal than with the real meal (mean difference=–13.0, *P*<.001 and mean difference=–2.0, *P*=.005, respectively). The results are presented in Table 2.

Table 2. Eating behavior characteristics from the virtual and real meals (n=20).

Eating behavior	Virtual meal, mean (SD)	Real meal, mean (SD)	*P* value
Food intake (g)	375.6 (140.9)	338.9 (108.3)	.07
Meal duration (min)	3.6 (1.7)	9.0 (3.0)	<.001
Meal duration without chews (min)	2.8 (1.3)	2.4 (1.2)	.06
Eating rate (g/min)	124.0 (52.9)	41.1 (16.9)	<.001
Forkfuls (n)	25.9 (9.8)	38.9 (14.8)	.002
Additions (n)	0.6 (0.8)	2.5 (2.9)	.005
Bites (n)	10.0 (11.7)	40.0 (15.8)	<.001
Chews (n)	28.9 (68.0)	419.0 (162.9)	<.001

Chews and Bites

For participants who took bites and chews in the virtual meal, the numbers were significantly lower compared with the real meal (n=14, mean difference=–28.1, *P*<.001 and n=6, mean difference=–387.4, *P*=.004, respectively). The results are presented in Table 3.

Table 3. Mean values from participants who took bites (n=14) and chews (n=6) in the virtual meal.

Eating behavior	Responding (n=20), n (%)[a]	Virtual meal, mean (SD)	Real meal, mean (SD)	*P* value
Bites	14 (70)	15.4 (11.2)	42.4 (16.1)	<.001
Chews	6 (30)	82.4 (97.5)	469.8 (193.0)	<.001

[a]Number included in the analysis, based on the participants who took bites or chews in the virtual meal.

Familiarization Effects

There was a significant reduction in meal duration from the first virtual meal to the second virtual meal (mean difference=0.4, *P*=.03) but no significant change in meal duration between the first real meal and second real meal (*P*=.07). There was no significant difference in hunger before the meal between the first virtual meal and second virtual meal and between the first real meal and second real meal (*P*=.40 and *P*=.22, respectively).

Association Between Hunger and Chews and Meal Duration

In both the virtual and real meals, a low correlation was found between hunger after the meal and number of chews (r=–0.10, *P*=.68 and r=–0.18, *P*=.44, respectively). A low correlation was also found between hunger after the meal and meal duration in both the virtual and real meals (r=–0.12, *P*=.60 and r=–0.12, *P*=.62, respectively).

Association Between Meal Duration and Chews and Food Intake

In both the virtual and real meals, a low correlation was found between meal duration and food intake (r=0.22, *P*=.35 and r=0.14, *P*=.56, respectively). A high correlation was found between meal duration and chews in the virtual and real meals (r=0.69, *P*<.001 and r=0.75, *P*<.001, respectively).

Discussion

Principal Findings

To our knowledge, this is the first study to investigate the effect of a virtual meal on hunger and to explore the differences in eating behavior between real and virtual meals. The findings of this study indicate that eating a virtual meal does not affect hunger in healthy women. The results demonstrated that participants consumed approximately the same amount of real and virtual "food," but the virtual meal was significantly shorter, resulting in a higher eating rate. Participants also had lower numbers of chews, bites, forkfuls, and additions in the virtual meal.

Comparison With Prior Work

It is expected for hunger to decline throughout a real meal, which was the case for the real meal condition. Meanwhile, eating a virtual meal did not significantly reduce hunger. The nonsignificant difference in hunger before and after a virtual meal suggests that such meals can be used for people with anorexia nervosa without the risk of having them replacing real meals with virtual meals. This finding is in contrast with a study in which participants were found to decrease their consumption of a particular food (eg, cheese) by repeatedly imagining eating it [39]. Since this study was conducted with healthy women, care will be required when implementing this method for eating disorders or obesity.

The extent to which a virtual meal represents realistic eating conditions was also examined, although the aim of the virtual reality app was not to mimic real-life eating behavior. Interestingly, even though the meal duration of the virtual meal was shorter than that of the real meal, the amount of "food" consumed was approximately the same. The reason for this phenomenon was that most of the participants did not chew during the virtual meal, resulting in an approximately 3 times higher eating rate compared with the real meal. These data support previous research, which showed that eating rate was inversely related to the number of chews [40]. Changing the virtual reality protocol to elicit a more realistic eating behavior or providing virtual reality eating training may result in a satiety response. However, findings suggest that this approach would not be beneficial as an intervention for obesity or bulimia nervosa.

A serendipitous finding of the study was that, although it was not required nor requested, participants took bites and chews during the virtual meals, indicating that the virtual reality environment was perceived on some level as being real. The display of eating behaviors similar to real life is in line with the findings that cue exposure in virtual environments is effective for inducing food craving in healthy control participants [41].

The familiarization effect observed in the virtual meals suggests more meals are required to reach a stable behavior since several participants experienced difficulties. Examples of those difficulties were placing the food in their mouth and grabbing or serving the food on their plate. People are less accustomed to eating virtual meals than real meals, and that conclusion is also supported by a study that examined the impact of the environment on eating behavior using virtual reality [42].

Based on previous findings, we expected longer meals (ie, longer exposure to food "images") [43] and more chews (ie, more oral processing) [44] to be negatively associated with hunger. However, the correlation was low in both cases. These correlations should be interpreted with care, since they were not part of the initial hypothesis (we did not know participants would chew virtual food) and the fact that more than one-half of the participants did not chew in the virtual meal.

Strengths and Limitations

The main strength of this study was the use of immersive virtual reality equipment, as this technology increases the feeling of being present in the environment [20]. Other strengths were that many confounding covariates were controlled through the deployment of a random crossover design [45], narrow inclusion criteria, a strict study protocol [42], a familiarization meal, and objective data collection methods. For the introduction meal, a larger portion (1.2 kg of food) than what is typically ingested was offered to the participants to make them realize they did not have to consume everything. For the coming meals, they were provided with the same portion size as they ate during the introduction meal with extra food on the side. The artificial manipulation of portion size ensured similar meal sizes, making hunger, eating rate, and other eating behavior parameters comparable [46].

The main limitation of the study was the novelty of immersive virtual reality. Participants unused to immersive virtual reality require practice and concentration to understand the "game" mechanics [42]. It was observed that, in the introduction meal, several participants experienced difficulties handling the food (eg, placing the food in their mouth and grabbing or serving the food on their plate). Some participants expressed surprise or amusement during their encounter with virtual reality equipment (especially the first time), which may have influenced the results. Another limitation was that the virtual reality app required food on the plate and in containers to start, which resulted in alterations to the real meal protocol as well. Ideally, participants would have only received food on the plate for each session.

Other limitations include a lack of effect size measurements from previous virtual reality meals for the power analysis and potential low generalizability to people with eating disorders or obesity, because the study enrolled only healthy women. Moreover, the recruitment location (university campus) may have resulted in a convenience sample, in regard to education, socioeconomic status, technological literacy, and availability (workdays from 11 AM to 1 PM). In addition, the subjective methods used to quantify hunger are vulnerable to demand bias, in which the participants provide responses that they believe the researchers are looking for [43]. However, there are no reliable biological markers to evaluate appetite [47].

Future Perspectives

Further investigation is necessary to confirm the safety of virtual reality for patients, as they may respond differently than healthy control participants. Future studies should aim to include other demographic groups (eg, men, children, vegans, and other groups prone to eating disorders or obesity) to evaluate the generalizability of the findings. The effect of a virtual meal should also be investigated in different settings (eg, at home, at a restaurant, lunch with friends) and with a variety of foods. Moreover, future studies should provide additional virtual meals to reduce the familiarization effect observed in this study. Looking to the future, further attempts at incorporating chewing in the virtual meal (eg, with chewing gum to mimic food mastication) and using more advanced equipment that allows the involvement of all the senses (eg, sounds and olfactory information) might prove beneficial in evoking physiological responses similar to those of real meals.

Conclusions

This study investigated the effect of virtual reality on hunger. Eating in an immersive virtual reality environment has no significant effects on hunger in healthy individuals, suggesting that virtual reality can be used for patients (eg, with anorexia nervosa) without the risk of having them replace real meals with virtual meals. Due to the lack of chewing, the virtual meal was consumed in less time, while the food intake was approximately the same as in the real meal. Surprisingly, some participants took bites and chews in the virtual meal, although they were not instructed to nor was it required to "eat" the food.

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Conflicts of Interest

PS and CB own shares in Mandometer AB, the company that financed the development of the virtual reality app. Other authors have no conflicts of interest to declare.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 359 KB - games_v11i1e44348_app1.pdf]

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Original Paper

Developing a Game (Inner Dragon) Within a Leading Smartphone App for Smoking Cessation: Design and Feasibility Evaluation Study

Justin S White[1,2,3], PhD; Marie K Salem[1], MPH; Séverine Toussaert[4], PhD; J Lee Westmaas[5], PhD; Bethany R Raiff[6], BCBA-D, PhD; David Crane[7], PhD; Edward Warrender[7]; Courtney Lyles[8], PhD; Lorien Abroms[9], ScD; Johannes Thrul[10,11,12], PhD

[1]Philip R Lee Institute for Health Policy Studies, University of California, San Francisco, CA, United States
[2]Department of Epidemiology and Biostatistics, University of California, San Francisco, CA, United States
[3]Department of Health Law, Policy & Management, Boston University School of Public Health, Boston, MA, United States
[4]Department of Economics, University of Oxford, Oxford, United Kingdom
[5]Population Science, American Cancer Society, Atlanta, GA, United States
[6]Department of Psychology, Rowan University, Glassboro, NJ, United States
[7]23 Limited, London, United Kingdom
[8]Department of Medicine, University of California, San Francisco, CA, United States
[9]Department of Prevention and Community Health, George Washington University, Washington, DC, United States
[10]Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States
[11]Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, MD, United States
[12]Centre for Alcohol Policy Research, La Trobe University, Melbourne, Australia

Corresponding Author:
Justin S White, PhD
Philip R Lee Institute for Health Policy Studies
University of California
490 Illinois Street, Box 0936
San Francisco, CA, 94158
United States
Phone: 1 415 476 8045
Email: Justin.White@ucsf.edu

Abstract

Background: Several stand-alone smartphone apps have used serious games to provide an engaging approach to quitting smoking. So far, the uptake of these games has been modest, and the evidence base for their efficacy in promoting smoking cessation is still evolving. The feasibility of integrating a game into a popular smoking cessation app is unclear.

Objective: The aim of this paper was to describe the design and iterative development of the Inner Dragon game within Smoke Free, a smartphone app with proven efficacy, and the results of a single-arm feasibility trial as part of a broad program that seeks to assess the effectiveness of the gamified app for smoking cessation.

Methods: In phase 1, the study team undertook a multistep process to design and develop the game, including web-based focus group discussions with end users (n=15). In phase 2, a single-arm study of Smoke Free users who were trying to quit (n=30) was conducted to assess the feasibility and acceptability of the integrated game and to establish the feasibility of the planned procedures for a randomized pilot trial.

Results: Phase 1 led to the final design of Inner Dragon, informed by principles from psychology and behavioral economics and incorporating several game mechanics designed to increase user engagement and retention. Inner Dragon users maintain an evolving pet dragon that serves as a virtual avatar for the users' progress in quitting. The phase-2 study established the feasibility of the study methods. The mean number of app sessions completed per user was 13.8 (SD 13.1; median 8; range 1-46), with a mean duration per session of 5.8 (median 1.1; range 0-81.1) minutes. Overall, three-fourths (18/24, 75%) of the participants entered the Inner Dragon game at least once and had a mean of 2.4 (SD 2.4) sessions of game use. The use of Inner Dragon was positively associated with the total number of app sessions (correlation 0.57). The mean satisfaction score of participants who provided ratings (11/24, 46%) was 4.2 (SD 0.6) on a 5-point scale; however, satisfaction ratings for Inner Dragon were only completed by 13% (3/24) of the participants.

Conclusions: Findings supported further development and evaluation of Inner Dragon as a beneficial feature of Smoke Free. The next step of this study is to conduct a randomized pilot trial to determine whether the gamified version of the app increases user engagement over a standard version of the app.

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KEYWORDS

smoking cessation; mobile app; games for health; gamification; software design; feasibility; mobile phone

Introduction

Background

Cigarette smoking is a leading preventable cause of death and disease in the United States [1]. Although many clinic-based and phone-based smoking cessation treatments are effective, most people who try to quit smoking do so without any aids and are successful <5% of the time [2]. The recommended cessation treatment, which combines counseling with medication, is used by <5% of those who attempt to quit [3].

Smartphone apps for smoking cessation have become increasingly popular among smokers who want to quit. As of 2020, English-language smoking cessation apps had been downloaded 33 million times [4]. The low cost and convenience of smartphone-delivered support makes them an appealing alternative to clinical treatments for many smokers, especially those disproportionately affected by the harms of smoking such as low-income, less educated, and racially minoritized subgroups [5]. In addition, the widespread availability of smartphones—85% of US adults owned one as of 2021—has helped extend the reach of smoking cessation apps to a large number of people [6]. Thus, smartphone-based interventions hold great promise for reducing the high burden and disparities in smoking-related cancer risk and mortality. Although many cessation apps do not follow evidence-based guidelines [7-9], a few are now being developed using established behavior change theory and existing clinical guidelines.

A perennial challenge for mobile health (mHealth) apps is their low engagement and retention rates [10]. Overall, <5% of users actively use a downloaded mHealth app daily, and <5% of users continue to use the app after 10 days [11]. Approximately half of the participants in studies of app-based mHealth interventions drop out, and studies of app-based smoking cessation interventions have found similarly high dropout rates [12-15]. Given the potential for smartphone apps to reach millions of smokers and reduce tobacco use, it is important to find ways to engage app users and increase retention and efficacy.

Behavioral researchers have suggested using serious games and gamification techniques to promote behavioral health [16-18]. Serious games are games with a primary purpose other than entertainment, such as health promotion. Gamification is a related motivation tool that uses nonmonetary rewards to make nongame activities fun or challenging. Gamification is designed to increase users' motivation and engagement, which in turn may increase exposure and adherence to a smoking cessation program [19]. A study found that approximately 75% of the adult smokers surveyed played video games [20], and many smokers believed that game-based interventions for smoking cessation would be motivating [20,21].

Several gamified apps have been developed to help people quit smoking, such as Cigbreak [22], Crush the Crave [23,24], Inspired [25], QuitIT [26,27], Quittr [28,29], and Tobbstop [30,31]. A small number of randomized controlled trials of these apps have been conducted, and they have generally found that users were satisfied with the gamified app, but most did not experience significant increases in smoking abstinence [23,27,29,31]. User engagement and retention of these apps also varied, with each study adopting a different approach to measurement (eg, number of game "episodes" completed or minutes played). Nonetheless, nonrandomized studies have suggested that elements of gamification, such as achievement badges, may increase users' self-efficacy and motivation or intention to quit [32,33]. Taken together, these findings demonstrate limited and conflicting information regarding the effectiveness of gamified apps for increasing smoking cessation relative to quitting without assistance, and additional efforts are needed to improve user engagement and retention.

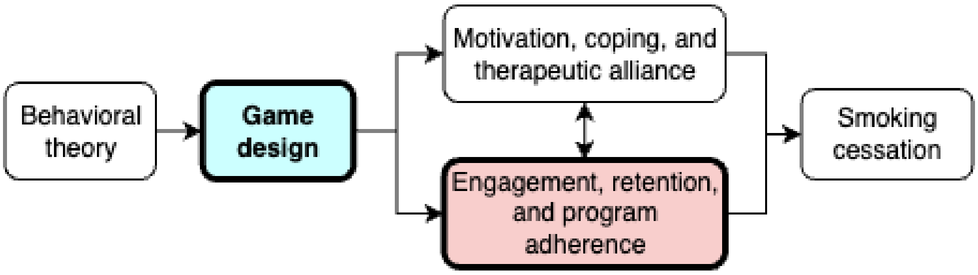
The Smoke Free App

Our team of academics and software developers sought to design and integrate a game into the Smoke Free smartphone app. Developed by London-based 23 Limited, Smoke Free is one of the most downloaded smoking cessation apps in the Apple and Android stores, with >800,000 downloads per year and 6 million downloads so far [34,35]. A preprint of a pragmatic randomized controlled trial reported that, although being randomized to receive an offer to use the Smoke Free app did not increase smoking abstinence compared with no intervention, the app increased continuous abstinence at 6 months when smokers who were randomized to receive the app downloaded it (12.7% intervention vs 7% comparator) [35]. The app leverages behavior change techniques that have proven to be effective in face-to-face behavioral support programs [36]. Key features of the app include (1) a calculator that tracks the total amount of money saved by not smoking; (2) a calendar that tracks the time elapsed since the user quit smoking; (3) a scoreboard that awards badges to users for not smoking; (4) progress indicators that inform users about health improvements that the user can expect because they started their quit attempt; (5) daily missions that assign evidence-based tasks to help users avoid and resist urges to smoke; (6) a diary and cravings log that track the frequency, strength, and location of cravings to smoke; and (7) a text-based chatbot that delivers quitting guidance in a friendly, conversational tone. In randomized trials, a full version of the app with chatbot was shown to increase user engagement compared with a reduced version of the app [37], and the daily missions were shown to increase user retention and self-reported smoking abstinence at 3 months [34]. The current standard version of the Smoke Free app does not contain gamification features apart from the virtual badges noted previously.

The Inner Dragon Game

Our team designed a theory-informed game called Inner Dragon and integrated it into the Smoke Free smartphone app. Inner Dragon uses game elements that incorporate behavioral insights to increase user engagement and retention. This increased engagement is expected to increase exposure and adherence to the smoking cessation program, which should improve the chances of quitting smoking (Figure 1). The process of developing Inner Dragon and the game design is described in the *Methods* section.

Figure 1. Conceptual model.



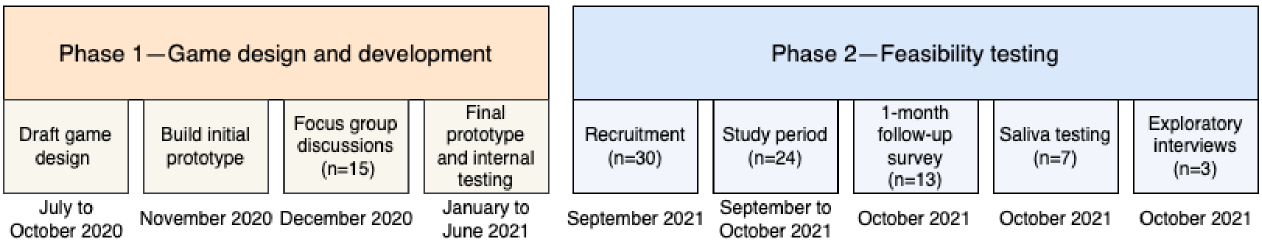
This feasibility trial is a precursor to a 2-arm pilot randomized controlled trial and part of a broad program that seeks to assess the effectiveness of gamifying an app for increasing smoking cessation. The pilot trial will evaluate the engagement, satisfaction, and early efficacy of gamifying the Smoke Free app compared with a standard version of Smoke Free to guide the design of a large trial. The aim of this study was to assess the feasibility and acceptability of adding the Inner Dragon gamification component to the existing Smoke Free smartphone app for smoking cessation.

Methods

Overview

The study was conducted in 2 phases. In the first phase, the study team designed and integrated the game into the Smoke Free app. In the second phase, the study team evaluated the feasibility and acceptability of the integrated game using a single-arm trial. An overview of the study approach is provided in Figure 2. Our approach follows the biphasic framework for gamification design by Marczewski [38], involving a first phase of planning and design based on iterative information collection and development and a second phase of measuring user activities and engagement [39].

Figure 2. Overview of study approach.



Phase 1—Game Design and Development

We followed a multistep usability testing procedure for the development of the Inner Dragon game: (1) we created a game design document and sketches of app screens for the game; (2) we conducted focus group discussions (FGDs) to gather feedback about sketches with Smoke Free users who are not participating in the feasibility trial; and (3) we finalized the game prototype, integrated it into Smoke Free, and performed internal app testing.

Game Development

As an initial step, we partnered with the game design studio, Workinman Interactive, LLC, to produce a game design document that described the significant features of the game. Workinman has a long history of developing games for apps and clients include Disney, Fisher-Price, and NBCUniversal. The investigative team provided an initial concept for the game. The game design document was refined based on a series of meetings and multiple rounds of revisions. Workinman also provided supporting art for wireframes, game flowcharts, and screen images. These materials were used by 23 Limited to build an initial prototype of the Inner Dragon game.

Design of Inner Design

In the Inner Dragon game, users care for a customizable pet dragon, whose growth reflects the user's own progress in quitting smoking. The game uses traditional virtual pet retention mechanics with some social features and many options for customization and personalization. Virtual pets have been popular with consumers because they can foster bonding and companionship [40]. The Inner Dragon concept is also broadly compatible with the genres of games most liked by adult smokers, namely action, role-playing, and action-adventure games [41].

Inner Dragon includes several game mechanics designed to increase user engagement and retention, with the primary goal of increasing exposure and adherence to the smoking cessation program, thereby improving the likelihood that the user quits smoking. Inner Dragon allows users to interact with a digital pet that is tied to their quit attempt as a means of progress toward continued abstinence, positive reinforcement for engagement with the smoking cessation program, and entertainment [40]. Game features were designed to accommodate any intensity of game play, whether heavy or sporadic, with no limitation on the amount of time or engagement. The key game mechanics were as follows. First, the user maintains a pet dragon that hatches on their quit day and evolves every 7 days to unlock new attributes and powers (Figure 3). The dragon acts as a virtual avatar that represents the user's progress. Second, the user earns experience points by engaging in selected in-app activities, including those in the game (eg, playing a minigame or feeding the dragon) and in the core Smoke Free app (eg, completing a mission or logging a diary entry). Rewards for engaging with core app features were designed to improve adherence to the smoking cessation program. The experience points unlock gifts and cosmetics, directly rewarding frequent and consistent use of the game. The user can customize their dragon (eg, wing shape or clothing accessories) over the course of the quit experience by steadily unlocking features. Third, the Inner Dragon home screen has "care meters" that users must work to keep from falling very low: calmness, nutrition, hygiene, and energy. Engaging with the dragon in various ways increases the meters. For example, petting the dragon increases calmness, and feeding the dragon increases nutrition. Caring for and interacting with a virtual pet through the care meters can foster a bond with the pet and motivate users to return to the game regularly [40]. Fourth, the game provides tools for the user to better cope with the challenges of withdrawal: a dragon-led breathing exercise to provide calmness and a memory minigame as a distraction. Fifth, a user can asynchronously interact with other users' dragons in a "dragon park" by (1) viewing their profile and progress and (2) sending and receiving motivational messages and emojis from a preset menu (Figure 4). These game mechanics are hypothesized to combine to increase the users' engagement with the app and, subsequently, their chance of quitting successfully.

The game design was informed by principles from the fields of psychology and behavioral economics. As noted in the following section, aspects of the game were motivated by several theories and theoretical constructs, such as self-determination theory, theory of present bias and hyperbolic discounting, theory of salience and limited attention, and variable reinforcement under operant conditioning. The avatar provides salient, visual feedback with endogenous value (tied closely to the user's motivation to quit) associated that may sustain and enhance motivation to quit. Self-determination theory predicts that this type of feedback is highly intrinsically motivating [42]. Furthermore, the user may identify with the digital pet as an avatar, and this may cultivate a digital therapeutic alliance with the game and app, for example, by creating a bond with the dragon and increasing the user's confidence to succeed [43,44]. The use of frequent, salient, in-game rewards was designed to counter the behavioral economic constructs of present bias and inattention to app use. The design further included evidence-based practices from contingency management, such as the use of escalating in-game rewards for abstinence, with a reset point for lapses and sustained abstinence (by harnessing regret and loss aversion) [45]. The use of surprise gifts provided a variable reward structure designed to boost engagement and novelty. The asynchronous interactions with other users in the dragon park provide opportunities for limited social support and social comparisons that may motivate the user to exert more effort in the quit attempt [46,47].

The various game mechanics and elements were designed to appeal to users with different motivations. For example, Yee [48] identified 3 main components of player motivation: *achievement* (advancement and competition), *social* (socializing and relationship), and *immersion* (discovery, customization, and escapism). The experience point system may appeal to achievers; the interaction with other players and a sense of connection with the dragon may appeal to socializers, and the rich opportunities for dragon customization and distraction game may appeal to players seeking immersion.

Figure 3. Dragon evolution. (A) Egg hatches into full dragon. (B) Evolves every 7d, gains new “abilities.”.

Figure 4. Dragon care. (A) Feeding dragon (fun). (B) Memory mini-game (distraction). (C) Breathing exercise (manage cravings). (D) Dragon park (social feedback and support).

FGD Procedures

Following the development of an initial game prototype, the investigative team conducted FGDs with existing users of the Smoke Free app to gather their feedback about the Inner Dragon game concept. The findings from the FGDs were used to refine Inner Dragon in preparation for the feasibility trial.

FGD participants were recruited using a recruitment message displayed to new Smoke Free users on an onboarding screen. The message included a hyperlink to a Qualtrics screening questionnaire. Eligibility criteria included the following: aged ≥18 years; had downloaded and opened the Smoke Free app; lived in the United States; spoke, wrote, and read English; smoked at least 1 cigarette every day; and was available during one of the scheduled FGDs.

The study team organized three 90-minute FGDs via Zoom (Zoom Video Communications). During each session, a facilitator guided the participants through several discussion topics: past smoking experience, preferences for methods of quitting, and feedback about the game prototype (Multimedia Appendix 1). For the latter topic, a facilitator provided the FGD participants with a description of the different elements of the initial prototype and accompanying screenshots. Participants received a payment of US $40 as a choice of a gift card or cash card provided through the Tremendous digital payment platform.

FGD sessions were transcribed. Overall, 2 independent coders identified key themes from the transcripts. Coders then input their findings into a series of "feedback capture grids," which organized the likes, criticisms, questions, and ideas of users for each discussion topic. Each gamification feature was evaluated with respect to its interest, ease of use, motivational potential, and overall satisfaction.

Phase 2—Feasibility Testing

Overview

This study included a single-arm, unblinded evaluation of the feasibility and acceptability of the Smoke Free app with integrated Inner Dragon game, in preparation for a planned randomized pilot trial. All participants in the feasibility study were given free access to the Smoke Free app with the integrated Inner Dragon game. Participants' use of the app was passively monitored for 28 days, and follow-up assessments occurred after 1 month.

Recruitment and Participants

Study participants were recruited from the population of general users of the Smoke Free app. Focus group participants were not included. New users of Smoke Free were invited to participate in a feasibility trial to quit smoking through an on-screen recruitment message presented on the initial onboarding screens within the app. The message asked the following: "Interested in a research study to test the latest version of Smoke Free? If you qualify you could earn up to US $100 and get some paid features for free!" The message included a hyperlink to a screening questionnaire and consent form in the Qualtrics web-based survey platform. Recruitment remained open until the prespecified sample size of 30 participants was met.

Inclusion criteria were the following: aged ≥18 years; downloaded and opened the Smoke Free app; lived in the United States; spoke, wrote, and read English; smoked at least 1 cigarette every day; planned to quit smoking within the next 7 days; and was willing to self-administer a salivary cotinine test remotely. At the end of the screening questionnaire, eligible respondents were asked to consent electronically to participate in the study. Respondents' eligibility data were automatically transmitted to Smoke Free's servers to designate each person as included in or excluded from the study. Following the completion of the remaining onboarding process in Smoke Free, eligible, consenting users were automatically given immediate access to Inner Dragon and certain core (ie, nongame) features of the app. Core features included all of those described previously, including the chatbot and daily missions, which are typically paid features.

Procedures

During onboarding, each participant in the feasibility trial selected their own planned quit date within 7 days of enrollment. Participants were invited to use the Smoke Free app in whatever way they liked for 28 days after their planned quit date. Therefore, all participants had the same amount of time with the app following their initial quit date. Use was self-directed and did not require any specific amount of time.

We collected self-administered questionnaire data from participants via Qualtrics at baseline and weekly on days 7, 14, 21, and 28 after the participant's planned quit date. After completing the screening questionnaire, meeting the inclusion criteria, and completing the informed consent in a web-based form, participants were automatically sent an email link to the baseline questionnaire. The 28-day ("1-month") follow-up assessment was the primary end point. Participants were sent 3 SMS text messages (1 invitation and 2 reminders) and 1 email reminder for the 1-month follow-up survey, using multiple modalities to try to increase response rates.

All participants who completed the 1-month questionnaire, regardless of smoking status, were invited to complete a salivary cotinine test to biochemically verify their smoking status. Within 2 business days of completing the 1-month follow-up questionnaire, participants were mailed a salivary cotinine test kit and test instructions by 2-day priority mail. We sent an email to participants with a link to a Qualtrics survey in which they were asked to upload a photo of the test results within 7 days of receiving the test kit.

Following the end of the saliva testing period, a randomly selected subset of participants was invited to participate in an exploratory 45-minute semistructured interview via Zoom to share their experiences with using the Smoke Free app.

Participants were eligible for up to US $95 in compensation. They received US $10 for completing the baseline questionnaire within 48 hours; US $5 for completing the weekly surveys on days 7, 14, and 21 within 48 hours; US $30 for completing the 28-day survey within 48 hours of being invited (or US $20 for completing it within 7 days); and US $40 for uploading a photo of their saliva test result within 48 hours of receiving the test kit (or US $30 for uploading a photo within 7 days). All study payments were delivered via email at the end of the study through Tango Card [49], a web-based gift card system that allowed participants to choose from a menu of Visa prepaid cards and hundreds of gift cards.

Outcomes

The study's outcome measures were selected principally to establish the feasibility and acceptability of the intervention and data collection methods for a planned pilot trial. The study had two primary outcome measures, both focused on user engagement: (1) the total number of unique app sessions from enrollment through 28 days after the user's initial quit date, measured as the number of times the app was opened, and (2) the mean duration of app sessions, in minutes, through day 28 after the quit date. Both outcomes were passively collected by the app. A new session was defined as opening the app after at least 30 minutes of inactivity.

Secondary outcomes focused on the feasibility and acceptability of the gamified app in the domains of (1) user engagement and retention and (2) user satisfaction. Secondary outcomes were the number of unique days with ≥1 app session; proportion entering Inner Dragon; and satisfaction with Smoke Free ("I liked using the Smoke Free app") and Inner Dragon ("I liked the dragon game"), reported on a 5-point Likert scale ranging from "Not at all" (score=1) to "Extremely" (score=5).

Tertiary outcomes included the following: (1) the proportion of participants who reported abstaining during the past 7 days at the 1-month follow-up assessment (self-reported 7-day point-prevalence abstinence); (2) biochemically verified 7-day point-prevalence abstinence at the 1-month follow-up assessment, obtained from uploaded results for a self-administered salivary cotinine test (Alere iScreen Oral Fluid Device); (3) program adherence, measured as the number of times of using selected core app features (reported a craving, recorded a diary entry, completed a mission, read a tip, and used the chatbot); (4) number of times of using selected game features (breathing exercise, cleaning the dragon, feeding the dragon, memory minigame, using the customization menu to change appearance, and reading the dragon instruction guide); (5) motivation to quit at the 1-month follow-up, reported on a 10-point scale ranging from not at all motivated (score=0) to very motivated (score=10); and (6) digital therapeutic alliance, measured from the bonding and confidence subscales of the Mobile Agnew Relationship Measure, reported on a 4-point measure and dichotomized at a threshold of "Agree" or higher [43,44].

Data Analysis

We started by calculating the descriptive statistics of demographic and smoking factors. For the primary aim, descriptive statistics were used to estimate user engagement with the app. A complete case analysis was conducted, including only those who opened the app after completing the screening questionnaire.

To explore the association between the total number of app sessions and the number of sessions with game use, we estimated an unadjusted linear regression of the relationship between the total number of app sessions and the number of sessions with game use. The total number of app sessions is equivalent to the total number of sessions with use of core features, because each session starts on the main dashboard screen that includes certain core features (eg, calculator of money saved by not smoking).

Smoking abstinence was assessed using both complete case analysis and assuming that nonrespondents were still smoking (ie, "missing = smoking"). Imputation methods were not used because of the small sample size.

As this was a feasibility study, the target sample size of 30 participants was based on budget and feasible accrual during the study timeline, rather than on a power analysis. Quantitative analyses were performed using Stata (versions 16.1 and 17.0; Stata Corporation).

Exploratory Qualitative Interviews

To assess the opinions about and use of the Smoke Free app with Inner Dragon, we invited the feasibility study participants to participate in a 45-minute semistructured interview via Zoom. The exploratory interviews occurred following the saliva testing period. Interview respondents received a US $50 gift card of their choice. The interview included topics about overall app experience, Inner Dragon game experience, and study and data collection processes (Multimedia Appendix 2). The qualitative interview data were compiled and summarized into key points.

Ethics Approval

The institutional review board of the University of California, San Francisco, approved study procedures for phase 1 and phase 2 (19-29335).

Results

Game Design and Development

In total, 3 FGDs were conducted via Zoom with 15 participants, each with 3 to 7 participants, between December 4, 2020, and December 11, 2020. Although participants had varied reactions to the prototyped concept, overall, the reaction was positive. Of the 15 FGD participants, 10 (67%) strongly agreed that they would like to use the gamified app frequently. Even when users expressed doubt or dislike, most (12/15, 80%) reported that the game, as presented, would likely encourage them to check the Smoke Free app more frequently, thus supporting the main study hypothesis.

FGD participants gave feedback about several aspects of the game. They tended to be the most enthusiastic about the "dragon park" and the ability to interact with other users and avatars. FGD participants wanted the game to hold them accountable, including by imposing a meaningful penalty for relapse. They preferred game features that facilitated distraction from and coping with cravings over pet care features, such as feeding the dragon, that were not directly connected to the quit attempt. FGD participants wanted the game to progress alongside the dragon's growth, for example, making leveling up more challenging as the game progresses. They tended to view the customization options as a means of distraction, rather than as motivation to continue engaging with Inner Dragon over time. Feedback from the FGDs and internal testing were incorporated into the final game design.

Feasibility Trial

Sample Characteristics

We screened 86 new Smoke Free app users over 3 days (September 8, 2021, to September 10, 2021) to reach our goal of enrolling 30 eligible, consenting participants for the feasibility trial (Figure 5). Of the 86 screened individuals, 56 (64%) were ineligible, of whom 9% (n=5) lived outside the United States, 11% (n=6) did not smoke daily, 93% (n=52) were not planning to quit within the next 7 days (including n=43, 77% who had quit already), and 14% (n=8) did not agree to complete a saliva test. Of the 30 enrolled participants, 24 (80%) opened Smoke Free after completing the screening questionnaire, thereby completing the onboarding process within Smoke Free. This is the denominator used for most of the analyses. There was 54% (13/24) response rate for the baseline questionnaire, 46% (11/24) response rate for the 1-month follow-up questionnaire, and 45% (5/11) response rate for the saliva test (only those completing the follow-up questionnaire were asked to complete the saliva test).

Table 1 shows the demographic and smoking-related characteristics of enrolled participants. Most (17/24, 71%) identified as female, and median age was 37 years. Most (21/24, 88%) were non-Hispanic White, and 8% (2/24) were non-Hispanic Black and 4% (1/24) was Hispanic. Among the 18 baseline survey respondents, median income was US $72,500, and there was a range of educational backgrounds, with 39% (5/13) having received a bachelor's or associate degree, 31% (4/13) having completed some college or technical school, and 15% (2/13) having received at most a high school diploma.

Participants who completed the baseline survey were asked questions about their smoking behavior (Table 1). Participants smoked a median of 15 cigarettes per day and had made a median of 5 past quit attempts. Participants had been smoking for a median of 18.5 years. Approximately 25% (3/12) of the participants reported using electronic nicotine delivery systems in the past 30 days, and 8% (1/12) reported using nicotine replacement therapy in the past 30 days. Most participants (18/24, 75%) set a quit date as within 1 day of enrollment.

Participants also reported about their past video game experience (Table 1). More than three-fourths (19/24, 79%) of the participants played video games at least monthly during the previous year, similar to the general population of smokers [20]. Moreover, 33% (8/24) of the participants played video games daily, and 33% (8/24) played at least weekly but not daily. Among participants who reported playing games monthly, mobile games were the most popular gaming platform (13/24, 54%), followed by web games (10/24, 42%).

Figure 5. Participant flow diagram. *Individuals may be ineligible because of >1 factor.

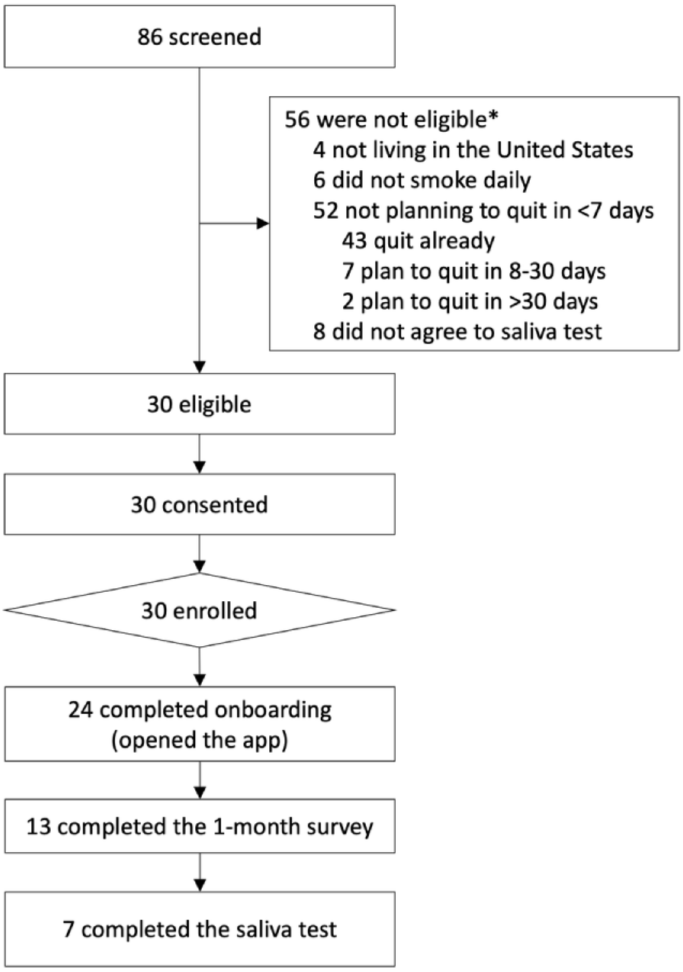


Table 1. Descriptive statistics of participants[a].

	Values
Demographics	
Gender (n=24), n (%)	
Female	17 (71)
Male	6 (25)
Nonbinary or transgender	1 (4)
Age group (years; n=24), median (IQR)	37 (26.5-43.5)
Household income (US $; n=13), median (IQR)	70,000 (30,000-87,000)
Education (n=13), n (%)	
High school diploma or less	2 (15)
Some college or technical school	4 (31)
Bachelor's or associate degree	5 (38)
Graduate degree	2 (15)
Racial and ethnic identity (n=24), n (%)	
Non-Hispanic Black or African American	2 (8)
Non-Hispanic White	21 (88)
Hispanic	1 (4)
Smoking-related characteristics	
Cigarettes per day (n=13), median (IQR)	15 (10-20)
Past quit attempts (n=13), median (IQR)	5 (3-10)
Years of smoking (n=13), median (IQR)	17 (11-29)
Used ENDS[b] in the past 30 days (n=12), n (%)	3 (25)
Used NRT[c] in the past 30 days (n=12), n (%)	1 (8)
Days to quit (n=24), median (IQR)	1 (0-1.5)
Video gaming experience (n=24), n (%)	
Frequency of playing video games in the past year	
Daily	8 (33)
At least weekly but not daily	8 (33)
At least monthly but not weekly	3 (13)
Less than once monthly	1 (4)
Not at all	4 (17)
Platform used at least monthly in the past year	
Mobile games	13 (54)
Web games	10 (42)
Console games	4 (17)
Other games	4 (17)

[a]Some values are missing for questions asked in the baseline questionnaire. Percentages may not add up to 100% because participants selected >1 race or ethnicity.

[b]ENDS: electronic nicotine delivery system.

[c]NRT: nicotine replacement therapy.

User Engagement

User engagement with the gamified Smoke Free app was generally high: a mean of 13.8 (SD 13.1; median 8; range 1-46) app sessions per user and an average of 5.8 (SD 10.6; median 1.1; range 0-81.1) minutes per session (Table 2). Overall, 75% (18/24) of the participants entered the Inner Dragon game at least once. The number of sessions decreased rapidly during the first week after the participant's quit date, for sessions overall and those involving the use of Inner Dragon (Figure 6A). The decline in sessions with game use was similar to the decline in sessions overall, based on the change over time in the share of sessions with game use. The high variability in the total number of sessions by user is shown in Figure 6B. The use of the Inner Dragon game was positively associated with the total number of app sessions (correlation 0.57), such that each additional session with the use of Inner Dragon was associated with 3.1 (SE 0.96) more total sessions (*P*=.003; Figure 7A). In addition, the average time a user spent per session decreased with the total number of sessions for that user (correlation −0.39), such that each additional session was associated with 1.25 (SE 0.63) fewer minutes per session on average (*P*=.06; Figure 7B).

We further characterized the variability in the use of different features of the game. Figure 8 shows the use of various pet care activities in the game. Only 44% (8/18) of the participants who tried Inner Dragon used these pet care activities with some frequency.

Table 2. App use during the intervention.

	Participants, n (%)	Values, mean (SD)	Values, median (range)
App sessions (n=24)			
Sessions per user[a]	24 (100)	13.8 (13.1)	8 (1-46)
Minutes per session per user[a]	24 (100)	5.8 (10.6)	1.1 (0-81.1)
Unique days with ≥1 session[b]	24 (100)	6.8 (5.9)	4 (1-19)
Any use of the Inner Dragon game[b]	18 (75)	—[c]	—
Sessions with any game use per user[d]	24 (100)	2.4 (2.4)	2 (0-10)
Pet care events[d,e]			
Breathing exercise	24 (100)	1.8 (2.1)	1 (0-6)
Cleaning the dragon	24 (100)	1.6 (1.9)	1 (0-6)
Feeding the dragon	24 (100)	3.3 (4.6)	0 (0-15)
Memory game	24 (100)	2.1 (2.8)	1 (0-10)
Dragon customizations[d]	24 (100)	7.2 (15.4)	0 (0-61)
Read the dragon guide[d]	24 (100)	4 (4.1)	1.5 (0-12)
Efficacy (7-day abstinence at 1 month)			
Self-reported, complete cases (n=11)[b]	5 (45)	—	—
Self-reported, missing cases (=smoking; n=24)[b]	5 (21)	—	—
Verified, complete cases (n=11)[d]	3 (27)	—	—
Verified, missing cases (=smoking; n=24)[d]	3 (13)	—	—
Motivation and satisfaction (n=24)			
Satisfaction—"I liked using the Smoke Free app"[b,f]	11 (46)	4.2 (0.6)	4 (3-5)
Satisfaction—"I liked the dragon game"[b,f]	3 (13)	2.0 (1.0)	2 (1-3)
Motivation to quit (0-10)[d]	11 (46)	8.8 (1.7)	10 (5-10)

[a]Primary outcome.

[b]Secondary outcome.

[c]Not applicable.

[d]Tertiary outcome.

[e]Participants who did not use the pet care events, including those who did not use Inner Dragon at all, were coded as 0.

[f]Questions were rated on a 5-point Likert scale: extremely (score=5), very (score=4), somewhat (score=3), slightly (score=2), and not at all (score=1).

Figure 6. Total number of sessions. (A) Percentage of users with a session by day. (B) Number of sessions by users.

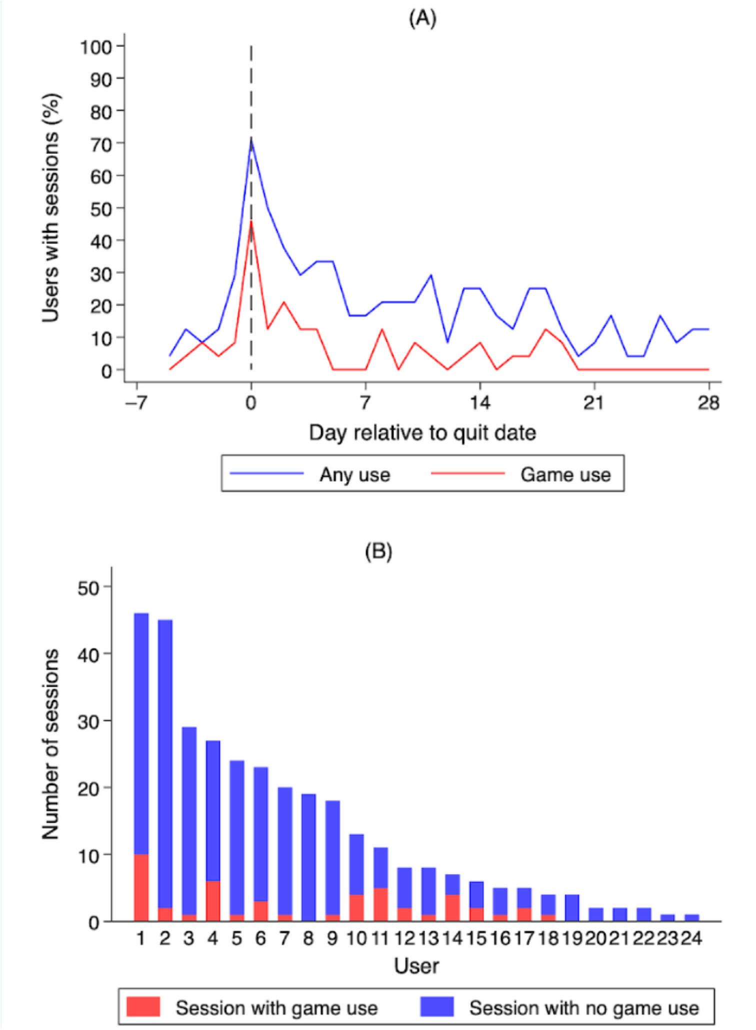


Figure 7. Association between number of sessions with and those without the use of Inner Dragon. (A) Number of sessions with game use. (B) Average minutes per session versus number of sessions.

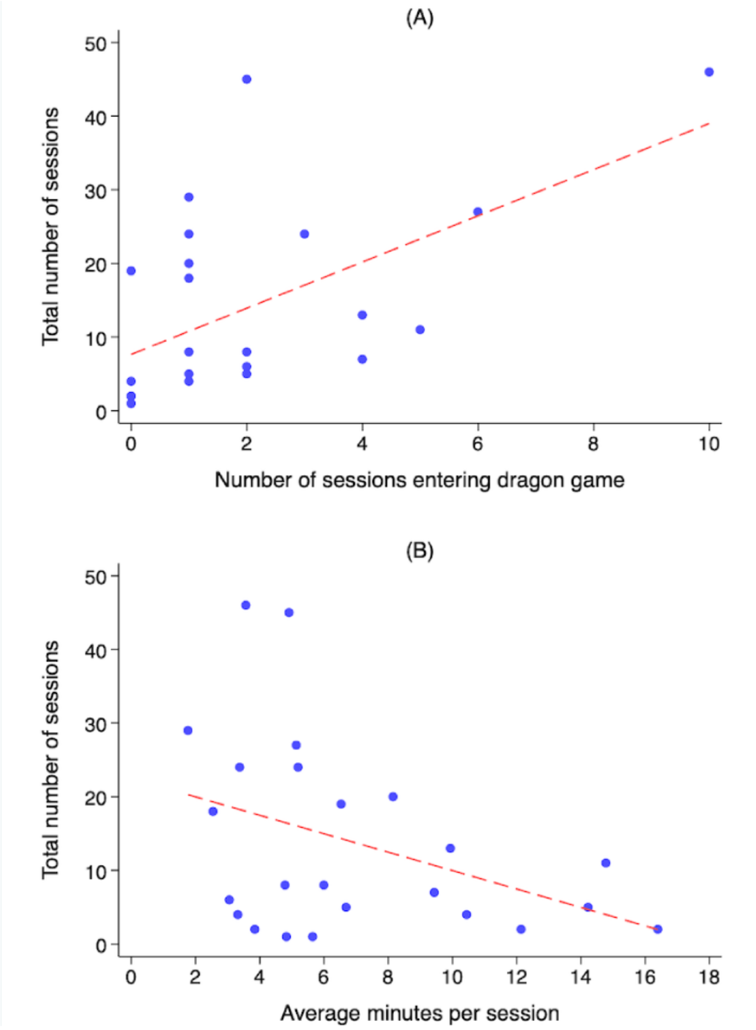
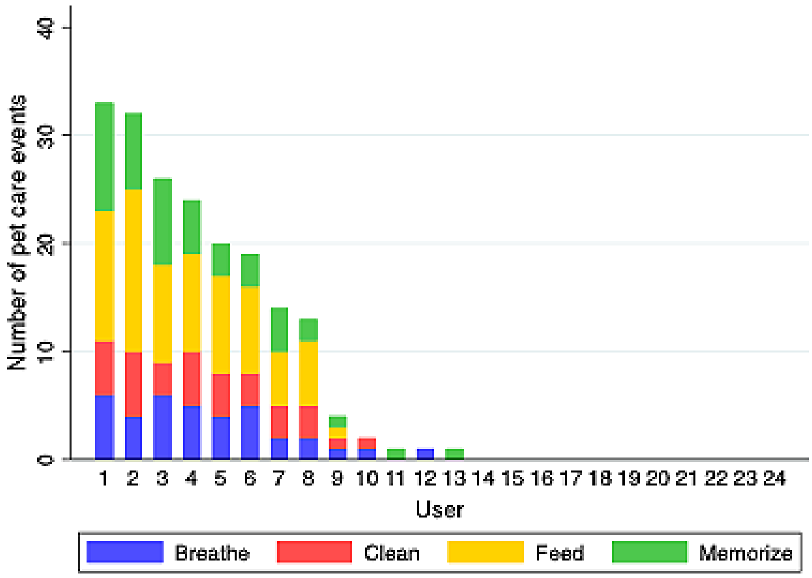


Figure 8. Pet care events by user.



Efficacy of the Intervention

The percentage of self-reported 7-day point-prevalence abstinence at 1 month was 45% (5/11) among complete cases and 21% (5/24) when assuming that nonrespondents were still smoking. Biochemically verified 7-day point-prevalence abstinence was 27% (3/11) among complete cases who were mailed a saliva test kit and 13% (3/24) when assuming that nonrespondents were still smoking. Only 1 self-reported abstainer reported having used e-cigarettes in the past 30 days, but they did not complete the saliva test. None of the participants reported having used nicotine replacement therapy in the past 30 days.

The total number of sessions was positively associated with self-reported abstinence in a simple regression analysis. An additional session was associated with increase in abstinence of 1.3 percentage points when assuming that nonrespondents were still smoking (P=.04) and of 2.7% points with complete cases only (P=.01). However, the number of sessions with Inner Dragon use and the ratio of game sessions to total sessions were not associated with either measure of abstinence.

Satisfaction and Motivation

Among the 12 participants who completed the follow-up questionnaire, participants were very satisfied with the gamified Smoke Free app at the 1-month end point (mean score 4.1, SD 0.8 on a 5-point Likert scale). Satisfaction ratings were slightly higher among those who had used Inner Dragon (mean 4.2, SD 0.2; 9/12, 75%) compared with those who had not (mean 3.7, SD 0.3; 3/12, 25%); however, this difference was not statistically significant according to the Wilcoxon rank-sum test (P=.21). Only 25% (3/12) of the participants who had used Inner Dragon provided a satisfaction rating for Inner Dragon, because the question was not mandatory; their ratings were substantially lower (mean 2, SD 0.1) than that for Smoke Free overall.

Exploratory Qualitative Interviews

Qualitative interviews were conducted with 14% (3/22) of the participants who were invited and agreed to participate in the interview. Overall, 67% (2/3) of the interviewed participants had used the Inner Dragon game. In general, the participants liked the design of the app and had no major complaints. Participants found the progress indicators of health improvements as one of the most popular features, and 67% (2/3) of the participants commented about the helpfulness of the chatbot.

However, the participants reported that they had difficulty in understanding the purpose of the game and how to navigate the game. Participants also reported overlooking certain features of the game, such as the memory minigame. They recommended adding a notification to the dashboard that would link the users directly to the game and providing additional tutorials to explain the purpose of the game.

Adverse Events and Operational Issues

There were no adverse events reported during the trial. However, the study implementation faced technical challenges. In particular, we discovered that the dragon park had not been operational during the feasibility trial. Therefore, users were not able to use this key game feature, and user satisfaction may have been influenced accordingly. We had also planned to include a once-daily pop-up to assess daily smoking status; however, this also was not operational.

Discussion

Principal Findings

Drawing on multiple behavioral theories, we designed a unique, multifaceted digital pet game to promote user engagement and retention in a leading smartphone app for smoking cessation. Participants, who were given access to the gamified app, averaged 13.8 app sessions and 5.8 minutes per session throughout the 28-day trial. User satisfaction with the app was high; users reported an average score of 4.2 on a 5-point scale when asked if they "liked the Smoke Free app." Regarding smoking abstinence, 46% (5/11) of the participants reported having abstained from smoking during the previous 7 days, and 27% (3/11) of the participants were biochemically verified to have abstained.

The development process demonstrated the feasibility of integrating the Inner Dragon game within the Smoke Free app. The single-arm trial demonstrated the feasibility of performing planned procedures for a pilot randomized controlled trial and provided proof of concept that the Inner Dragon game might be able to increase the engagement of Smoke Free users. The evaluation found that user engagement with the gamified Smoke Free app was generally high, with considerable variability across participants. Short-term data about app use suggested that users who used the game more frequently were also more likely to use core app features more frequently. A randomized controlled trial could reveal whether this is a causal relationship. Participants in the feasibility evaluation liked the gamified app overall; however, we did not collect sufficient data to gauge their satisfaction with the Inner Dragon game.

Our study makes 2 key contributions to the literature about serious games and gamification for smoking cessation. First, although several existing games such as Tobbstop and Quittr use similar frameworks and game features to promote engagement and smoking cessation, our use of a digital pet is novel for smoking cessation apps. Second, we use the game in a unique context in which it is integrated into an app with 6 million downloads so far and available at a scale that is rarely achieved by serious games.

Comparison With Previous Studies

Our study of Inner Dragon contributes to the developing literature about the feasibility, engagement, and effectiveness of gamified smoking cessation apps. A small number of such apps have been developed and evaluated, including Crush the Crave [23,24], QuitIT [26,27], Quittr [28,29], and Tobbstop [30,31]. Overall, the literature highlights low user engagement for gamified smoking cessation apps. Crush the Crave participants reported an average rating of 2.4 out of 5 for their frequency of using the game [23]. QuitIT users also had low user engagement, with only 40% of participants reporting that they played the game [27]. User engagement was high among the Quittr users with access to the Tappy Town game (mean of 58.4 min of using the app over a 28-day trial) [29] and the Tobbstop app in which 65.9% of participants successfully used the app [31]. In comparison, 75% (18/24) of our study's participants used the Inner Dragon game in the Smoke Free app at least once throughout the 28-day trial, resulting in relatively high user engagement compared with other apps.

A small number of randomized trials have been conducted to evaluate the efficacy of gamified apps to improve smoking cessation. Although participants have generally reported high satisfaction with the gamified app, most of the apps have not demonstrated improved smoking abstinence rates [23,27,29,31]. Our feasibility trial found a point-prevalence abstinence that exceeded those reported for most other gamified smoking cessation apps (eg, 4% for Quittr, 14% for Crush the Crave, and 39% for Tobbstop); however, the gamified Smoke Free app will need to be tested in a randomized trial with a control group.

Future Directions

The feasibility evaluation produced several important findings with implications for the planned pilot randomized controlled trial and for future studies more generally. Several lessons relate to the game design. First, users reported overlooking the game entirely or not remembering to open it. To increase the visibility of the game, we subsequently included a message at the top of the main dashboard that linked to the game. A message linking to the game was also added under the *support* tab, where many other resources, such as the chatbot, were available. Second, to address participants' misunderstandings regarding the purpose of the game and the availability of game features, we created and embedded a promotional video that plays when the user opens the Inner Dragon screen for the first time. The video describes the purpose of the game and its relationship with the user's quit attempt and highlights the key features of the game, such as the breathing exercise. We also added and expanded on tutorials to clarify the availability and purpose of certain features. Third, we provided tight integration between Inner Dragon and the core features of Smoke Free through the use of more salient messaging outside the game and navigation buttons to the game. In particular, we added messages on nongame screens to inform participants when they earned experience points for completing core activities. For example, upon logging a diary entry, a message popped up to inform the user that they had won experience points that can be claimed in Inner Dragon, along with a button to navigate directly to Inner Dragon.

The feasibility trial also provided lessons for improving the study design of the planned pilot trial. The low response rates pointed toward a need to send reminder messages regarding questionnaires via SMS text message rather than via email. There was also a need to devise procedures for monitoring which app features were active.

Study Limitations

The study has important limitations. First, the small sample size limited the precision of estimates for main outcomes. Second, and relatedly, low response rates and the potential for selection bias made it difficult to assess certain outcomes, such as user satisfaction. However, our experience allowed us to formulate new procedures to improve participant retention. In response, we have planned a large pilot trial with 500 participants to mitigate this small sample size limitation. Finally, the follow-up period was short, and a long follow-up was implemented in the next phase of the project. Several game features, such as the dragon evolutions, converting experience points into gifts, and social interactions in the dragon park, provide the basis for promoting long-term engagement with the app, and this will require further design and development.

Conclusions

In summary, this trial showed that it is feasible to integrate a gamification component into an existing smartphone app for smoking cessation. Moreover, we developed a set of study procedures that could feasibly be used to evaluate the game intervention. Digital gamification is a promising strategy that merits further attention from smoking cessation researchers.

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Data Availability

The survey data sets generated and analyzed during this study are not publicly available but are available from the corresponding author upon reasonable request. The app use data generated and analyzed during this study are not publicly available owing to a third-party agreement between the University of California, San Francisco, and 23 Limited (the developer of Smoke Free) that prohibits data sharing.

Conflicts of Interest

DC is the Founder and chief executive officer at 23 Limited, the software development company that owns and operates Smoke Free. EW is the chief technical officer at 23 Limited. CL was a Visiting Researcher at Google during the publication of this study. LA receives royalties for the sale of Text2Quit, a quit smoking program. JT reports membership on the scientific advisory board of MindCotine, Inc, which offers a smoking cessation program. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflicts of interest policies. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Focus group discussion guide.
[PDF File (Adobe PDF File), 93 KB - games_v11i1e46602_app1.pdf]

Multimedia Appendix 2
Exploratory interview guide.
[PDF File (Adobe PDF File), 88 KB - games_v11i1e46602_app2.pdf]

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Abbreviations

FGD: focus group discussion
mHealth: mobile health

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Original Paper

A Serious Game to Self-Regulate Heart Rate Variability as a Technique to Manage Arousal Level Through Cardiorespiratory Biofeedback: Development and Pilot Evaluation Study

Tony Estrella[1,2], MSc; Carla Alfonso[1,2], MSc; Juan Ramos-Castro[3], PhD; Aitor Alsina[4], PhD; Lluis Capdevila[1,2], PhD

[1]Laboratory of Sport Psychology, Department of Basic Psychology, Universitat Autónoma de Barcelona, Barcelona, Spain

[2]Sport Research Institute, Universitat Autònoma de Barcelona, Barcelona, Spain

[3]Group of Biomedical and Electronic Instrumentation, Department of Electronic Engineering, Universitat Politècnica de Catalunya (UPC), Barcelona, Spain

[4]Department of Information and Communications Engineering, Universitat Autònoma de Barcelona, Barcelona, Spain

Corresponding Author:
Lluis Capdevila, PhD
Sport Research Institute
Universitat Autònoma de Barcelona
Edifici N, Planta 1
Barcelona, 08193
Spain
Phone: 34 93 581 3329
Email: lluis.capdevila@uab.cat

Abstract

Background: Heart rate variability biofeedback (HRVB) is an established intervention for increasing heart rate variability (HRV) in the clinical context. Using this technique, participants become aware of their HRV through real-time feedback and can self-regulate it.

Objective: The aim of this study was 2-fold: first, to develop a serious game that applies the HRVB technique to teach participants to self-regulate HRV and, second, to test the app with participants in a pilot study.

Methods: An HRVB app called the FitLab Game was developed for this study. To play the game, users must move the main character up and down the screen, avoiding collisions with obstacles. The wavelength that users must follow to avoid these obstacles is based on the user's basal heart rate and changes in instantaneous heart rate. To test the FitLab Game, a total of 16 participants (mean age 23, SD 0.69 years) were divided into a control group (n=8) and an experimental group (n=8). A 2 × 2 factorial design was used in each session. Participants in the experimental condition were trained in breathing techniques.

Results: Changes in the frequency and time domain parameters of HRV and the game's performance features were evaluated. Significant changes in the average RR intervals and root mean square of differences between adjacent RR intervals (RMSSD) were found between the groups (*P*=.02 and *P*=.04, respectively). Regarding performance, both groups showed a tendency to increase the evaluated outcomes from baseline to the test condition.

Conclusions: The results may indicate that playing different levels leads to an improvement in the game's final score by repeated training. The tendency of changes in HRV may reflect a higher activation of the mental system of attention and control in the experimental group versus the control group. In this context, learning simple, voluntary strategies through a serious game can aid the improvement of self-control and arousal management. The FitLab Game appears to be a promising serious game owing to its ease of use, high engagement, and enjoyability provided by the instantaneous feedback.

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KEYWORDS

serious game; heart rate variability; biofeedback; mobile health; mHealth; app; mobile phone

Introduction

Background

Heart rate variability (HRV) represents the temporal variation between successive heartbeats (RR interval), and it is measured in milliseconds [1]. HRV is a biomarker of cardiovascular [2] and mental [3] health, reflecting the balance between the parasympathetic and sympathetic branches of the autonomic nervous system (ANS) [4]. HRV has been considered as an objective and noninvasive health indicator, with higher resting HRV being associated with lower cardiovascular risk [5], reduction of negative emotions through acute stress [6], flexible and adaptive response to environmental demands [7], and improved fitness [8]. This reflects the numerous applications of HRV in various fields.

HRV biofeedback (HRVB) is an established intervention that increases HRV in the clinical context and has proven to be effective as a treatment for anxiety and depression [9,10]. With this technique, participants become aware of their HRV through real-time feedback and can self-regulate it, restoring its homeostasis [11]. HRVB is based on the physiological phenomenon of respiratory sinus arrhythmia, which is defined as the variation in heart rate (HR) caused by respiration [12]. The analysis of respiratory sinus arrhythmia shows that the instantaneous HR (iHR) increases during inhalation and decreases during exhalation. Thus, the original HRVB procedure proposed by its promoters emphasizes the importance of breathing training to maximize HRV and achieve the maximum benefits of this technique [12]. In a recent systematic review [13], a series of methodological guidelines were proposed to improve the effectiveness of HRVB interventions. This review highlighted the importance of the breathing protocol as the core of the HRVB interventions, concluding that concrete aspects such as the inhalation, holding, or exhalation ratio should be explained in detail to the participants who apply the technique. Furthermore, HRVB can help establish a connection between the mind and body through voluntarily controlled physiological behaviors, such as breathing, facilitating the learning process and self-control.

HRVB is becoming more widely used owing to its ease of application and high cost-benefit potential, particularly because of the current accessibility of health technologies through mobile health devices [14,15]. The growth of mobile health technology has allowed the development of game-based mobile apps, which are known to increase the transfer of learning and motivation toward practice [16]. The use of games either in health or educational interventions allows the participants to immerse themselves in the activity that is required by the game, promoting a flow state [17,18]. Similarly, other studies have shown that when playing serious games, the student's role changes from a passive receiver of information to an active entity interacting with the game, facilitating the learning process [19,20]. Serious games, rather than being geared toward entertainment, are aimed at educating, training, and informing the player about a specific topic [21]. They are being used in various health domains [22-24]. For instance, in the field of HRVB, they can be a way to teach participants to control HRV through breathing techniques in an interactive environment.

Objectives

With the information provided in the *Background* section, the aim of this study was 2-fold: first, to develop a serious game that applies the HRVB technique to teach participants to self-regulate HRV and, second, to test the app with participants in a pilot study.

Methods

This study has two phases: (1) the development of a serious game biofeedback app called the FitLab Game and (2) the testing of the app with participants in a pilot study.

Phase 1: App Development

Visual Environment and Game Explanation

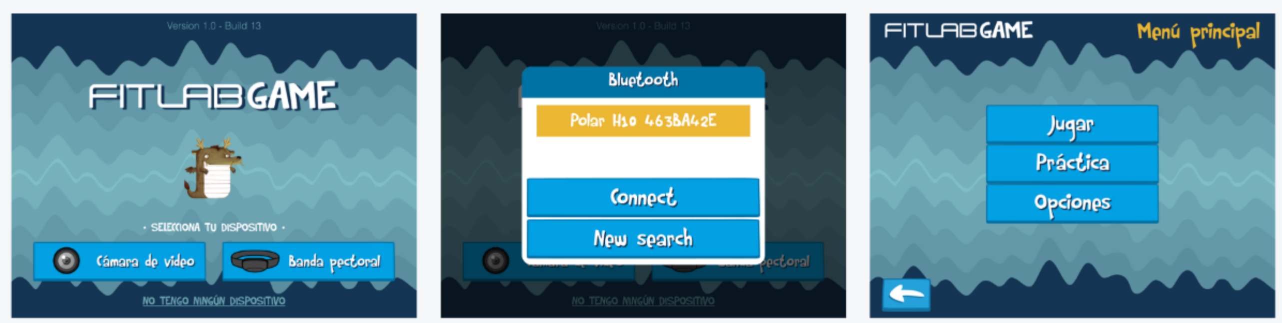
General Design

In accordance with definition of serious games by Djaouti et al [25], the FitLab Game is meant for physical and mental training in the health care sector and intended for the general public. The overall goal of the game is to help the user self-regulate their HRV by providing biofeedback in an attempt to follow or mimic a preset iHR waveform. The architecture and design of the game allows the incorporation of new real iHR curves (RR) to imitate and can be adapted to different levels of complexity in the different existing scenarios (levels). These real recordings can be chosen by the player or a professional accompanying the player. Depending on the level and the preset iHR waveform chosen, the game will lead to a state of relaxation (increasing cardiac variability) or a state of activation in the participant (decreasing cardiac variability), according to the needs demanded by each particular situation. Different gamification techniques were used in its design to increase the players' engagement with the tasks. More general techniques include having a goal to aim toward, a set of rules to follow, a challenge to complete, and *real-time* feedback to tell the player how he is doing and how close he is to completing the goal. More specific gamification techniques were added to further engage the player, including Bonus points, increasing challenge, and performance graphs.

Menus

The game's menus were designed in landscape mode and presented in Spanish. The first screen that appears when opening the app is the main screen, which allows users to choose the sensor used to input data: either the device's camera ("Cámara de vídeo") or a HR band ("Banda Pectoral"). The latter was used in this study. Once connected to the sensor, the app allows access to the game's mode, where the player can select between the option "Jugar" ("Play"), in which the user overcomes different levels in an orderly manner so that the difficulty of the game gradually increases, or the option "Práctica" ("Practice"), in which the user can activate an independent session. The tab "Opciones" ("Options") refers to the game's settings (Figure 1).

Figure 1. Screenshots of the game's menus. Game's transition from the main screen to the screen that appears when you select "Banda pectoral" ("Chest Band") and which allows to connect a heart rate sensor to the game. On the right, the third menu shows where the player can select "Jugar" ("Play") to play.



Screens

The FitLab Game has 9 levels distributed in 3 visually different worlds (Figure 2). Each world has 3 scenarios or levels of difficulty that the user must overcome in a set order to be able to access the next one when in "Jugar" ("Play") mode. To overcome a scenario, the user must move the main character up and down the screen to avoid colliding with obstacles that keep appearing. Touching an obstacle results in the loss of a life, and losing all lives means the game is over and needs to be restarted. The movement of the main character reflects cardiac variability and can be controlled by different voluntary strategies such as breathing.

The upper and lower limits and the obstacles in each scenario of the game are not placed randomly. They follow a specific waveform determined by previously recorded RR intervals, corresponding to a real recording. Each scenario represents a real RR series transformed and visualized as iHR, with different difficulty to imitate depending on the particular and distinct RR series (represented as a curve of iHR values) on which each scenario is based. Before starting the game, the data were calibrated to establish an initial HR range for the user (based on iHR from RR intervals). An algorithm was created specifically for the game, which takes this initial HR and displays it on a "grid" (invisible to the user) where each box is 1 second wide per 1 second high. With this algorithm, the screen is configured to place the character in the central area vertically, and the width of the screen is adjusted such that it is proportional to the range of variability presented by the user. In addition, the upper and lower limits and the obstacles, based on the previously recorded RR series, are placed above and below the defined waveform, leaving a space for the character to pass in between (Figure 3).

As a result of the initial calibration, all users start the game under similar conditions, while also having the level of difficulty of each scenario of the game adjusted to their own HR values. Overall, the configuration of each game is a dynamic and individual process, setting it apart from "one-size-fits-all" games. The individually tailored nature of the FitLab Game was designed to increase motivation and the learning process [26].

The left side of Figure 3 illustrates the algorithm that defines the ideal pathway of the character. The blue line represents the waveform defined by the prerecorded iHR curve (from a specific RR series), and the dark gray boxes represent the upper and lower limits of this curve, where the obstacles would be positioned. The right side of Figure 3 shows an example of how this algorithm would be seen in the game (see a dynamic example in Multimedia Appendix 1). Once the obstacles are placed, the objects and landscape of the scene are selected. For each world, there is a bank of images that can be used (mountains, animals, houses, etc) and placed by distributing them according to their size. Larger objects form the background plane, such as the mountains. Medium objects, such as houses, gradually fill the spaces that the first type of images could not fill because of their size, and small objects, such as birds, trees, or other details, are placed in the spaces that are missing to be filled in, which in Figure 3 are the dark gray boxes. Notably, the placement of obstacles is not exhaustive, meaning that it is not intended to fill all the space reserved for obstacles; otherwise, the screen will be saturated with objects. The goal is to place objects in the most harmonious way possible but clearly marking the path that the main character should follow. When the user reaches the end of the level or loses a life owing to touching obstacles, a final page appears. On this screen (Figure 4), a "Level Completed" message is shown, together with the total points collected, and the average stress index and average HR of the player and of all participants who have played the game is also shown.

Figure 2. Screenshots of worlds and scenarios of the game: "Campo" ("Rural area"), "Mar" ("Sea"), and "Espacio" ("Space").

Figure 3. Example of wave based on an instantaneous heart rate curve from a particular RR interval series.

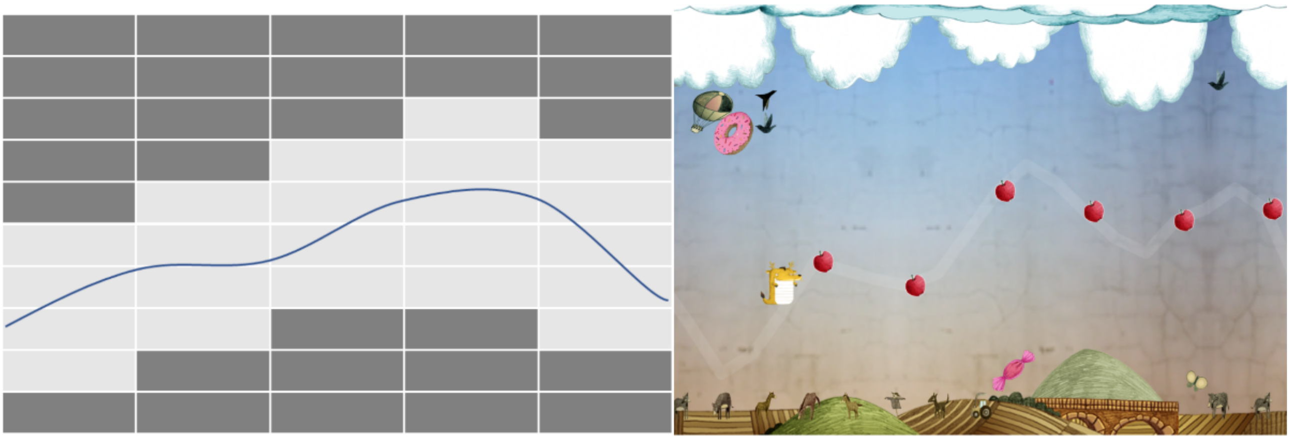
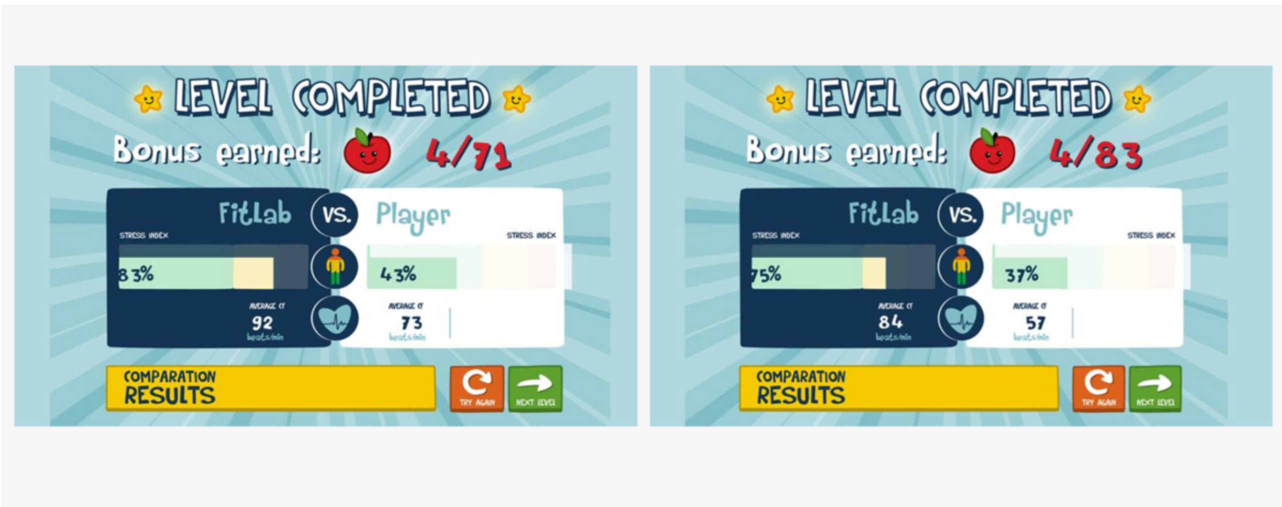


Figure 4. Example of the final page, appearing after a word of the FitLab Game is played.



App Architecture

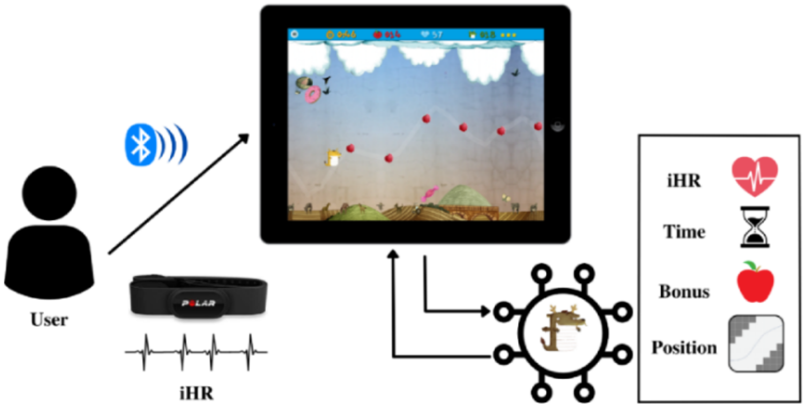
Programing Language and Functionalities

The architecture of the app consists of two parts: (1) the base of the game and (2) the container of the app and the communication with another device. The base of the game refers to the visual part, the game's engine, screen management, menus, and navigation. This entire part has been implemented with HTML (WHATWG) assisted by CSS (World Wide Web Consortium) and JavaScript (Oracle Corporation) technologies, so that it can be run in any web browser, whether hosting the application on a web server or running it directly on a local computer or mobile device. Note that opening the game in a web browser will not allow the use of the sensors and hardware; therefore, on a web browser, the game can only run in the test mode. Nonetheless, in the test mode, it is still fully functional using the cursor on a computer keyboard or by tapping on the screen of a mobile device, which allows testers to move the character up and down the screen manually.

The container refers to what allows the game to be installed as a mobile app on an Android or iOS operating system. In addition, it provides the necessary functionality to access the camera of the device and process the images as well as to establish Bluetooth connections with HR sensors and process the collected data. In this case, data processing is used in the game as input commands, replacing the usual input methods, including the keyboard or touch screen (for testing purposes). That is, it is with iHR data (from real-time RR intervals) that the user can move the main character up and down the screen using the variation of each iHR beat with respect to the previous one. This app container was implemented using a cross-platform environment for writing applications for Android and iOS operating systems called Titanium SDK (TiDev, Inc).

The game engine is written in JavaScript and is based on a constant loop where, at each step, the current position of the character is evaluated with respect to its environment (screen boundaries, obstacles, and prizes) and the input of the user (iHR data; Figure 5). The game engine, menu screens, and navigation are written in web languages compatible with any browser. Finally, both operating systems (Android and iOS) allow the introduction of web components within the app to reproduce web code (ie, HTML+CSS+JavaScript) as if it were part of the same app. The current app takes advantage of this feature to separate the game from the app's container, which allows communication via Bluetooth with other devices. When the container receives a command via Bluetooth, the app container code sends the corresponding interpretation of this command to the game part. For example, when instantaneous HR data are received over Bluetooth, the app container unpacks the received frame, obtains specific iHR data, and sends it to the game, which interprets it and moves the character. Figure 5 shows a game flow representation, where the user wearing a chest band sends iHR signals via Bluetooth and the game algorithm evaluates iHR, time playing, Bonus achieved, and position on a constant loop.

Figure 5. Game flow representation. iHR: instantaneous heart rate.



Data Collection and Bluetooth Connection

Before communication occurs between the sensor (HR sensor) and the FitLab Game, a connection must be established between the entities. Such a connection is established via Bluetooth and is known as pairing. In this type of connection, one of the devices acts as a host or receiver of data and the other acts as a client or sender. The device acting as a receiver can establish connections with multiple sending devices, but a sending device can only connect to a single receiver. Currently, the present app allows only 1 sender to be connected to the device because each game is calibrated to a user's iHR.

It should be noted that the iHR reading device used for the FitLab Game could be any, but it must offer a Bluetooth low energy connection so that the app can obtain the data. This version of Bluetooth can define specific data formats using standard attribute profiles (Generic Attribute Profile). This allows, for example, Bluetooth communication in the Heart Rate Profile mode to be established between the data sensor (the sender) and the app (the receiver). In this way, the receiver can interpret the data in whichever format it is packaged and can obtain the iHR information regardless of the manufacturer and model of the sending device, as long as it uses Bluetooth low energy with the Heart Rate Profile mode.

At present, when the app is opened, the user is asked to select the data entry method. When Bluetooth is selected, a screen with detected nearby Bluetooth devices is displayed. The list of displayed devices is filtered to show only those in the Heart Rate Profile mode. The user can select a device from the list of available devices and establish a connection. This process may take 1 or 2 seconds, and the user receives a confirmation if the connection has been successfully established or if an error has occurred. Once the connection is established, the application takes the user to the game's playing menu.

Data Processing

For each game carried out in the app, iHR data are collected together with other metadata, including the start and end times of the game, a user's identifier code, an ID assigned to the session, the level of the game played, the Bonus achieved, and the iHR calibration. All these data are packaged, saved in the container of the app, and can later be exported for analysis. Multiple user sessions can be stored locally, that is, in the application, but an internet connection is required to export the data to a server. Note that the game does not need an internet connection to work, and a wireless Bluetooth connection between the sender and the receiver in proximity is sufficient. For research purposes, the sessions that are temporarily saved on the device are accessible from a configuration menu by an application manager. To export data, the manager needs to select the desired sessions and indicate an email address to which the anonymized data will be sent, that is, identified by user codes and never by names or other identifying data.

Phase 2: Pilot Study

Study Sample

A total of 16 participants (9 men and 7 women; mean age 23, 0.69 years) were divided into 2 groups: a control group (4 men and 4 women; mean age 23.25, SD 0.99 years) and an experimental group (5 men and 3 women; mean age 22.75, SD 1.01 years). All participants were aged >18 years and did not present any cardiovascular disorder or take any medication that could affect HRV. The descriptive statistics of the participants are presented in Table 1. All participants, selected via a convenience sample of university students, were volunteers, and all participants provided written informed consent.

Table 1. Descriptive data of the participants (N=16).

Variable	Control group (n=8)	Intervention group (n=8)	All participants (N=16)	*P* value
Gender (woman), n (%)	4 (50)	3 (38)	7 (44)	.61
Age (years), mean (SD)	23.25 (2.82)	22.75 (2.87)	23 (2.76)	.73
Height (cm), mean (SD)	170 (10.53)	173.88 (8.34)	171.94 (9.39)	.43
Weight (kg), mean (SD)	66.5 (13.86)	66 (9.41)	66.25 (11.45)	.93
BMI (kg/m^2), mean (SD)	22.84 (3.38)	21.78 (2.50)	22.31 (2.92)	.49

Material and Instruments

Control Measures Self-Report

Before attending the session, participants were recommended, by email, to avoid taking nonessential drugs (up to 24 hours before the session) as well as caffeine, smoking, or any other psychostimulant (up to 2 hours before); alcohol (10 hours before); heavy meals (3 hours before); or eating in general (1 hour before). They were also asked to avoid high-intensity physical activity or any unusual exercise (20 hours before), to sleep for at least 6 hours, and to wear comfortable clothes to the laboratory. A brief questionnaire was administered immediately before the laboratory sessions to record these conditions. The participants were also asked to report their weight and height. In addition, the BMI was computed based on the participants' reported height and weight. This measure was used as a control variable between the groups because of its possible influence on HR [27].

Polar Band H10

An H10 cardiac chest band (Polar Electro) was used to record the RR interval signal (transformed to iHR), as validated previously [28]. The signal was sent and collected to the FitLab Game App (iOS version 1.0, build 1; Health&SportLab SL), which was active on an iPad Air 2 (version 12.1.4).

Questionnaire of Satisfaction With FitLab Game

An ad hoc satisfaction questionnaire based on the proposals of different works [29-31] was tailored to our research purpose. The questionnaire was created to collect participants' information about the following factors (see *item number* in brackets): (1) usefulness, (2) ease, (3) enjoyment of the game, (4) personal ability, (5) intention to use, (6) clarity of the goal of the game, (7) controllability of the game, (8) strategic approach, (9, 10, and 11) flow, (12) feedback, (13) educational aspect, (14 and 15) motivation, and (16) design aspects. Each factor was represented by a single item, except for flow and motivation, which consisted of 3 and 2, respectively. The participants responded to the questionnaire using a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Mean scores >3 can be considered as positive, 3 as neutral, and <3 as negative. Items related to the techniques used to modulate HR were not included in the control group. The average total score was computed based on participants' responses, providing a general satisfaction score.

Procedure

The study consisted of 1 individual session per participant, which lasted for approximately 35 minutes and took place in the Basic Psychology Laboratory of the Universitat Autònoma de Barcelona. The day before this session, each participant was provided a list of recommendations, based on the *Control Measures Self-report*, to record variables that may affect HRV, including physical activity and intake of caffeine, psychostimulants, alcohol, drugs, and food. At the beginning of the session, the H10 cardiac band was placed on the participant's chest so that they could become familiarized with the sensation of the band. A few drops of conductive gel were applied to the band to facilitate good contact with the skin. Once the band was placed, the participant answered the *Control*

Measures Self-report questionnaire. The participants were then introduced to the FitLab Game for the first time. Play time was divided into 3 parts, with the first and third parts being recorded for the study (Figure 6). In part 1, the baseline phase, each participant played 2 levels of the game to familiarize themselves with the functioning of the app, without time constraints. In part 2, the practice phase, participants practiced on a different level for 6 minutes, or a maximum of 3 levels. Finally, in part 3, the test phase, each participant played the same 2 levels as in part 1.

Figure 6. Example of screens of the game that participants played. Testing consisted of 3 parts (part 1: baseline phase, part 2: practice phase, and part 3: test phase).

A few techniques to consciously control iHR (and thus manage HRV) were explained to the participants in the experimental group but not to those in the control group. To increase HRV (and reduce iHR), it was recommended to either breathe at a pace where the exhalation was longer than the inhalation [32-34] or to hold one's breath [35]. To reduce HRV (and increase iHR), participants were instructed to slightly hyperventilate [36], to perform muscle movements [37], or to swallow saliva voluntarily all at once [38].

For each level and session that the participants played, the FitLab Game calibrated a baseline iHR, which allowed the game's character to be placed in the center of the screen, in such a way that the starting point and the difficulty of the iHR series were equal for all participants. Then, participants had to follow the same pre-established route corresponding to each level and session, collecting apples (Bonus), which marked the correct route, and avoiding other elements such as unhealthy foods, tobacco, or the upper and lower limits marked by the floor and ceiling of the screen. To follow the route (or avoid certain elements), the main character had to move up or down the screen, which was controlled by changes in iHR. Participants in the control group were given no instructions on how to do so, whereas participants in the experimental group were explained the techniques mentioned in the paragraph above. All participants started the game with 20 lives, and the game ended when they ran out of lives or when they reached the end of the level without losing all these lives.

Data Analysis

Descriptive statistics are reported as means and SDs. A 2 × 2 multivariate analysis of variance following a general linear model was used to analyze the differences between the baseline and test situations. The baseline values were calculated as the average of the 2 games played in part 1, and the test values were calculated as the average of the 2 games played in part 3 (Figure 6). This statistical analysis was carried out to analyze the baseline versus test data obtained from HRV parameters, as well as time and Bonus, all separately. Statistical analysis was performed using SPSS (version 28.0; IBM Corp).

The raw RR interval values recorded by the Polar H10 cardiac chest band were processed to remove artifacts owing to false positive or false negative detections; afterward, the RR intervals were filtered, and the corresponding iHR values were shown in real time on the screen when the participant was playing. The same processed RR interval values were saved and analyzed to calculate the HRV parameters. A time domain HRV analysis was performed to calculate average RR intervals (RR mean), SD of RR intervals, root mean square of differences between adjacent RR intervals (RMSSD), and percentage of consecutive RR intervals that differ by >50 ms between them. A frequency domain analysis was used to calculate the low-frequency band (low frequency [LF]; 0.04-015 Hz) and high-frequency band (high frequency [HF]; 0.15-0.4 Hz). HRV analysis followed the guidelines recommended by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology (1996). HRV analysis was performed using MATLAB (R2021 update 3 for 64 bits Windows; MathWorks).

Ethics Approval

This study was conducted according to the local ethics committee for human experimentation (protocol code CEEAH-5745).

Results

Change in Gaming Performance (Pilot Study)

To analyze the participants' performance in the game, the change in the number of apples collected (Bonus) and the total time played in seconds (Time) were considered, as presented in Table 2. No significant changes were found in the baseline versus test situation when comparing the experimental and control groups. However, there was a tendency for both groups to have increased Bonus and Time from the baseline to the test condition.

Table 2. Game outcomes in baseline and test phases in the control and experimental groups.

Variables	Baseline, mean (SD)	Test, mean (SD)
Bonus		
Control	16.75 (10.91)	18.06 (9.54)
Experimental	15.75 (5.34)	20 (10.15)
Time		
Control	91.08 (26.79)	109.05 (58.17)
Experimental	91.07 (26.79)	116.67 (52.31)

Participants' Satisfaction

The satisfaction questionnaire was completed by 13 (81%) of the 16 participants. Overall, participants expressed high satisfaction with the FitLab Game, reporting positive experiences, with a total score of 3.87 (SD 0.42) for the control group and a total score of 4.30 (SD 0.50) for the intervention group. The intervention group answered 16 questions, with 4 specific questions related to the techniques used during the game. Table 3 provides an extended description of the items and their scores for each group.

Table 3. Items and scores of the ad hoc game's satisfaction questionnaire for the control group (n=5) and intervention group (n=8)[a].

	Items	Control group, mean (SD)	Intervention group, mean (SD)
1	"I can learn self-control techniques better and faster with games like this."	N/A[b]	4 (0.53)
2	"Using games like this would be easy for me."	4.2 (0.45)	4 (1.07)
3	"Playing to learn techniques is more fun than following a pacer."	4.6 (0.55)	4.87 (0.35)
4	"I would be able to play this game even if nobody was there to teach me."	N/A	3 (0.76)
5	"In the future, I would play if I wanted to learn how to control my heart rate."	4.2 (0.84)	4 (0.76)
6	"The aim of the game was clear the whole time I was playing."	4 (1.22)	5 (0)
7	"The instructions for functionality were clear."	N/A	5 (0)
8	"While playing, I understood how to achieve points and how to end the game successfully."	4.2 (1.30)	4.6 (0.52)
9	"While playing, I was only thinking about the game."	3.6 (1.14)	4.75 (0.46)
10	"While playing, I forgot everything else around me."	4 (1)	4.5 (0.53)
11	"While playing, I didn't realise how much time was passing."	3.2 (0.84)	4.13 (0.83)
12	"When I did something in the game, I knew if it was right or wrong."	3.4 (1.82)	4.25 (1.04)
13	"By playing I learned how the techniques affect my heart rate, and how I can modify it."	N/A	4.13 (0.64)
14	"The game format increased my motivation to continue playing and achieve more bonus points."	3.4 (0.89)	4.63 (0.52)
15	"A game that applied different breathing techniques would increase my interest in this topic."	4 (0.71)	4.63 (0.52)
16	"The levels are fun and esthetically pleasing."	4.2 (0.45)	4.38 (0.74)

[a]Total score: control group—mean 3.87 (SD 0.42); intervention group—mean 4.30 (SD 0.50).

[b]N/A: not applicable.

Change in HRV Parameters

When analyzing the changes in HRV before and after the game, the results showed some differences between the experimental and control groups (Table 4). In particular, the experimental group showed a decrease in RR mean from baseline to test, which was different from the increase observed in the control group (*P*=.02; Figure 7). In contrast, the experimental group showed a decline in RMSSD from baseline to test, which was more pronounced than that in the control group (*P*=.04). No other HRV parameters presented a significant or tendential change.

Table 4. Multivariate analysis of variance of heart rate variability variables in baseline and test conditions in the control and experimental groups.

Variables	Baseline, mean (SD)	Test, mean (SD)	*P* value
RR mean[a]			.02
Control	800.33 (109.02)	816.89 (106.59)	
Experimental	1004.52 (148.41)	930.90 (132.45)	
SDRR[b]			.56
Control	62.55 (24.12)	65.64 (20.16)	
Experimental	111.35 (33.97)	109.81 (32.44)	
RMSSD[c]			.04
Control	43.10 (19.96)	41.60 (20.16)	
Experimental	93.80 (40.71)	80.07 (31.73)	
pNN50[d]			.36
Control	23.83 (17.53)	20.77 (17.25)	
Experimental	42.90 (18.63)	34.64 (17.52)	
LF[e]			.39
Control	3063.58 (2789.61)	2595.49 (2190.80)	
Experimental	6612.13 (3438.65)	6972.52 (3760.22)	
HF[f]			.10
Control	661.70 (458.82)	739.14 (547.80)	
Experimental	2985.17 (2311.75)	2046.96 (1594.17)	

[a]RR mean: average RR intervals.

[b]SDRR: SD of RR intervals.

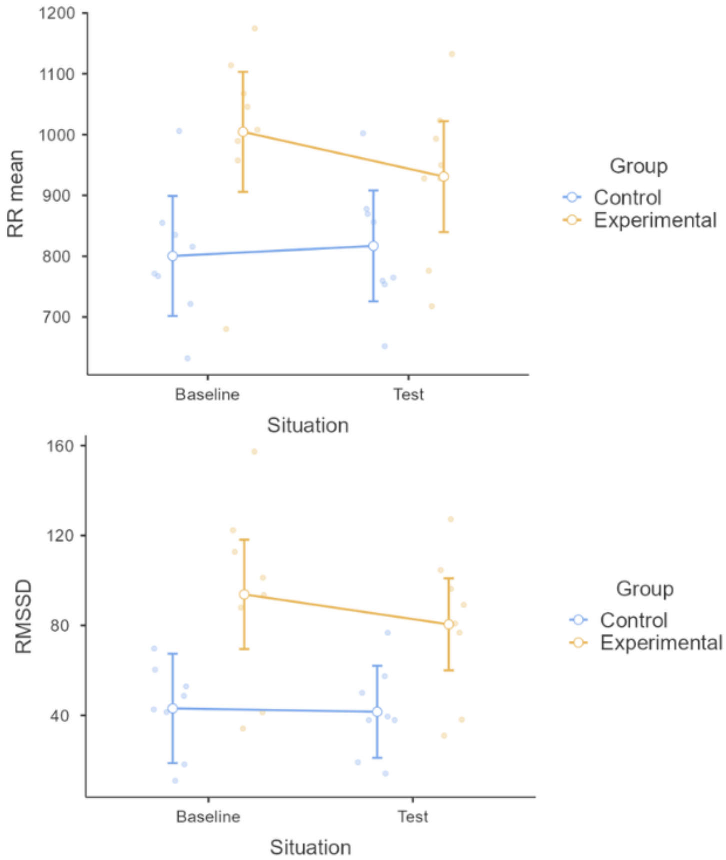
[c]RMSSD: root mean square of differences between adjacent RR intervals.

[d]pNN50: percentage of consecutive RR intervals that differ by >50 ms between them.

[e]LF: low frequency.

[f]HF: high frequency.

Figure 7. Mean, 95% CI, and distribution of average RR intervals (RR mean) and root mean square of differences between adjacent RR intervals (RMSSD), when comparing baseline and test situations in the experimental and control groups.



Discussion

Overview

The aim of this study was 2-fold: to develop a serious game that teaches the user to self-regulate iHR using HRVB and to carry out a pilot study to test the game with participants. A total of 16 participants took part in the pilot study and were divided into a control group and an experimental group. The results were analyzed in 2 parts: one focused on changes in the performance of the game and the other on fluctuations on HRV parameters. The results related to the usefulness of the game are discussed in the *Game and App Performance* section.

Game and App Performance

Analyzed globally, the gaming performance of all participants was in line with the results of another gaming study [39], in which the participants played a biofeedback game 6 times and both the control group that received simulated feedback and the experimental group that received physiological feedback improved their gaming performance. These results indicate that playing a given game, in itself, leads to improvement in its final score through repeated training or habituation. That is, both groups got to experiment and learn how to move the game's character. Regarding the differences in performance between groups, the results showed that the experimental group had a greater improvement in all indicators compared with the control group, even though the differences were not significant. The experimental group showed a greater improvement in Bonus score (increase of 4.25 Bonus points in the test with respect to the baseline), compared with the control group (increase of 1.31 Bonus points in the test; Table 2). The same trend was observed in the total playing time, where the experimental group kept playing 7.6 seconds longer than the control group, but these results were not statistically significant (Table 2). All these results are consistent with the idea that the application of specific strategies in the experimental group could have improved the self-regulation of heart variability, more than simply practicing the game (as shown with the control group). However, these results should be interpreted with caution because of the small sample size and the high values of SDs shown in Table 2.

In our study, a few gamification techniques were introduced to increase players' desire to engage with the tasks. General techniques include having a goal to aim toward, a set of rules to follow, a challenge to complete, and *real-time* feedback to tell the player how he is doing and how close he is to completing the goal. More specific gamification techniques included Bonus points, increasing challenges, and performance graphs. Reynard et al [40], in a systematic review and meta-analysis of digital interventions for emotion regulation, found that digital game interventions consistently provided stronger evidence compared with other types of digital interventions. In this review, 64% of digital game studies provided feasibility for engagement, implementation, adherence, expectations, and transference to real life. However, they did not explain which elements of the specific game design were responsible for this feasibility. For their part, Maher et al [41] concluded that gamified apps were used substantially longer than nongamified apps. Other studies highlight specific game elements that impact health behavior and achieve adherence, similar to digital rewards, such as points, badges, or rewards that we used in our game [42]. Similarly, in the design of our game, we complied with five gamification principles relating to the motivation of the user [43,44]: (1) meaningful purpose, as the goal of the users participating in the study was to learn a technique to improve their health; (2) meaningful choice, as users could control how they achieved their goal of eating the apples on the screen; (3) supporting player archetypes, as in our game, the initial iHR level is individualized based on the user characteristics; (4) feedback, as the user's actions to control the movement on the screen based on their own cardiac variability affect progress, and it is clearly communicated; and (5) visibility, as the amount of progress made in each level (apples, points, and Bonuses achieved) is visible at all times. Most of these principles are reaffirmed by the users' responses to the subsequent questionnaire, as discussed in *Participants' Satisfaction* section. Thus, the different techniques applied in the present serious game could contribute to behavioral changes, such as increasing players' engagement with the tasks and adhering to the use of the game. For example, the instant feedback provided by the game may have helped produce high engagement and enjoyability for the participants, as noted by Siriaraya et al [45]. At the same time, the fact that the levels of the game are adapted to each participant's cardiac recording means that each person plays in a personalized environment, which is thought to increase motivation toward the game [46]. Finally, regarding the app's functionality, we highlight the possibility of using either Bluetooth devices or photoplethysmography sensors [47], allowing participants to play in different contexts and with different resources.

The serious game created for this study can be used in multiple situations (in the long term). The game provides flexibility to play in new scenarios, depending on the specific training or situation goals set by the player. Furthermore, there is a menu for practice in which the players can play to test different techniques. Therefore, this game supports repetitive practice as an effective training method. In addition, the game uses the Bonus and time measurements to self-track the learning progression. As the players enhance their level of expertise, the Bonus points and time increase accordingly. This mechanism ensures that as the player improves, they are rewarded with higher Bonuses and more time in the level, motivating them.

Participants' Satisfaction

Participants expressed an overall positive satisfaction with the FitLab Game, with a greater total score in the intervention group (4.30 out of 5) than in the control group (3.87 out of 5). As Table 3 shows, this higher satisfaction in the intervention group is also supported by the fact that all the items that both groups had in common showed a higher score of 4 (out of 5) only for the intervention group. Both groups considered the game to be easy and fun (punctuations >4 for both groups). The goal and strategic approach to achieve Bonuses and continue playing were clear for both groups, with scores >4. Furthermore, both groups expressed positive intention (score >4) to continue playing the FitLab Game and learn how to control their HR in the future. The participants in the intervention group rated the feedback provided by the game more positively (score >4) compared with the control group (score >3). Regarding the experience of flow during the game, although both groups scored >3, the intervention group scored >4 across the 3 items. Similarly, in terms of motivation, the intervention group scored >4 and the control group scored >3. Finally, both groups found the screens visually appealing and balanced in terms of colors, with scores >4.

As shown in Table 3, the techniques provided to the intervention group were found to be useful in establishing control over iHR and were considered important for playing successfully. Thus, the neutral score in the personal ability factor indicates that the instructions based on different techniques for controlling iHR should be considered necessary for success in the game. The gameplay was understood by both the groups, and the game was generally perceived as easy and enjoyable. With regard to flow and motivation, the intervention group reported a more favorable experience with the game. This can be explained by the use of techniques that enable participants to exert voluntary control over the characters, thereby enhancing the game experience through the interactive component of the game. These findings are in line with those of previous studies, indicating that a gamified visualization component results in higher intrinsic motivation [48]. It is worth noting that the participants expressed a strong interest in continuing to play the FitLab Game in the future, reflecting their engagement and willingness to play to learn about cardiac variability control.

On the basis of the results presented, we propose an extensive use of the game with the main goal of helping individuals learn how to self-regulate their cardiac variability to achieve emotional self-control. This could be applied in different contexts, including clinical (eg, in anxiety or stress disorders) and nonclinical populations. This is in line with the results of a systematic review where consistent evidence was found for reduced negative emotional experience provided by digital games [40]. Ideally, these games should be used under the supervision of health professionals to facilitate learning-specific techniques for controlling cardiac variability. This is reaffirmed because the only response <4 in the specific items for the intervention group is for the item: "4 I would be able to play this game even if nobody was there to teach me" (rating of 3 out of 5). Nonetheless, as shown in Table 3, participants reported that the game was easy to understand and play (item 2), indicating that both the control and experimental groups understood the game well.

HRV Analysis and Biofeedback

Regarding HRV, the results of the pilot study showed some differences in the cardiac behavior of the experimental and control groups (Table 4; Figure 7). This suggests that the strategies used by the experimental group to compete in the game improved their control of cardiac variability, which in turn may have enhanced their performance. Owing to its pilot nature and limited number of participants, the precise reasons underlying the relationship between control of cardiac variability and performance cannot be conclusively determined. Nonetheless, it is possible that the results reflect the activation and the control of attention mechanisms in the experimental group. If we consider that the game requires a certain level of concentration and attention to play, especially if the participants are remembering and applying the techniques that were just learnt, some arousal level is needed, reflected in a reduction in the activity of the parasympathetic nervous system, as shown by a reduction, although not significant, in the experimental group (HF parameter) compared with a slight increase in the control group. This result is consistent with the increase, but not significant, in the LF values in the experimental group compared with the decrease in the control group. There is evidence that higher LF values are related to a greater activation of the sympathetic nervous system [49]. At the same time, a significant reduction in cardiac variability was observed in the experimental group, as shown by the RR mean and RMSSD parameters. The set of previous results could explain the improvement in the control of arousal or activation in the experimental group. In line with this idea, Fuentes-García et al [50] found that in chess games, the player's level and the difficulty of the game determined the activity of the ANS of the individuals, with higher demands in attentional focus resulting in lower HRV. Thus, in this study, the experimental group may have shown reduced vagal activity and cardiac variability because they were given techniques to control their HRV, requiring greater attention when playing [51]. In that sense, HRV is an indicator that the experimental group was active and applying what had been taught.

An array of scientific papers highlights the potential of incorporating biofeedback into different types of digital game interventions, including virtual and augmented reality, internet therapy, biofeedback and neurofeedback, digital games, and web-based programs. In a systematic review by Reynard et al [40], 39 interventions were identified, 10% of which were based on biofeedback. The effectiveness and impact of incorporating biofeedback into digital games have been tested in a range of topics, from stress reduction to physical rehabilitation [52]. For instance, Knox et al [53] and Wenck et al [54] studied biofeedback-driven digital game interventions for stress levels before the emergence of smartphones and concluded that symptoms of anxiety and depression were significantly alleviated in children. Similarly, Jerčić and Sundstedt [55] showed that visual and gameplay biofeedback in serious games supported emotional regulation skills. Moreover, aside from the impact on the psychophysiology of individuals, digital interventions appear to be accessible and attractive compared with one-to-one clinical therapies [40], particularly for the younger population [56]. Lüddecke and Felnhofer [57] demonstrated that biofeedback interventions increased the motivation and long-term participation of users in health-related interventions. Finally, games that incorporate biofeedback, compared with other digital interventions, seem to provide the most evidence for emotional skills transference to real life [40]. In conclusion, there is a growing body of research that emphasizes the utility of incorporating biofeedback into digital game interventions for its attractiveness and potential to enhance emotional regulation, among other benefits.

Returning to our study, our results seem to contradict most studies using the HRVB technique, which conclude that this technique helps improve HRV [58,59] with the general aim of achieving relaxation. However, this was not the case. These articles used set breathing paces, usually between 4.5 and 6.5 times per minute, as HRVB to induce relaxation [60,61]. For example, on the topic of gaming, Al Osman et al [62] used game-based biofeedback to control the activity of the ANS and showed that HRV increased following a controlled breathing rate. In contrast, the goal of this study was not to increase, maintain, or decrease HRV but to teach participants to control its rises and falls through various techniques, including breathing control, but not at a set pace. Thus, our study is not comparable with most other studies, given that we did not focus on breathing paces but rather on an array of techniques to teach the participants how to increase or decrease their HRV. These techniques include the voluntary production of apneas to suddenly increase cardiac variability [35], the performance of muscle movements to achieve a reduction in HRV (in line with Guidi et al [37]), or voluntary swallowing. This last strategy can produce changes in some HRV parameters in healthy people, such as SD of RR intervals, LF, and HF power [63], and effortful swallowing increases LF power and the LF/HF ratio [64]. On a practical level, in our case, these strategies allowed the player to move the character up and down the game screen because they provide rapid changes in cardiac variability.

Limitations and Future Directions

This study had 3 main limitations. The first limitation is the sample size of the pilot study. Even if the results show significance in the mean iHR (proportional to the RR mean) and RMSSD, they should still be considered preliminary. The second limitation is that participants were not monitored before and after the game but only during it. This means that the HRV indicators were collected as the game was being played, thus in an active state and not in a resting situation. Our interest was to test whether there were changes in the HRV parameters and game performance at all, as a pilot study, but in future studies, it would be interesting to observe the influence of our intervention on basal HRV.

Finally, most previous studies using techniques such as HRVB included a sample of clinical patients, unlike this study, which was conducted in healthy university students. For instance, Siepman et al [65] compared the effects of HRVB in both healthy people and individuals classified as depressed, showing that the latter experienced a significantly greater improvement in HRV, compared with healthy volunteers. Similarly, Pyne et al [66] reported that HRVB training reduces symptoms of posttraumatic stress in older people only. These studies highlight that HRV parameters seem to be difficult to alter with HRVB in healthy and younger people than in older or clinical populations, potentially explaining the results of this study, with few to no significant changes in some HRV parameters. In the future, a larger sample size of healthy university students or testing the FitLab Game in a clinical population could provide more consistent results. Finally, it would also be interesting to provide new strategies for the voluntary control of HRV, perhaps further refining the ones we have already developed in this study. It would also be necessary to deepen the swallowing strategy, as Yildiz and Doma [38] and Yıldız [67] concluded that spontaneous saliva swallowing can change some short-term HRV parameters significantly even in healthy people.

Conclusions

This study developed a serious game, called the FitLab Game, that teaches the user to self-regulate the iHR using cardiac variability biofeedback. The game was also tested with the participants in a pilot study. Overall, the FitLab Game appears to be a promising serious game because of its ease of use, high engagement, and enjoyability provided by the instantaneous feedback. The strategies learned by the experimental group to compete in the game, which included the voluntary production of apneas, muscle movements, and voluntary swallowing, improved the self-control of cardiac variability and, in turn, may have enhanced performance. A significant reduction in cardiac variability observed in the experimental group, based on the RR mean and RMSSD parameters, could explain the improvement in the management of arousal or activation compared with the control group. Thus, the application of specific strategies in the experimental group may have improved the self-regulation of HRV more than simply practicing the game.

The usefulness of HRV as a health indicator is well known, and HRV biofeedback is considered an established intervention in the clinical context. Thus, learning simple and voluntary strategies through the developed game can help improve self-control and arousal management. Ultimately, with sufficient training, the game can become a relaxation technique for the general population or clinical populations, or, for example, an activation technique for athletes in certain situations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Gameplay of the FitLab Game.
[MP4 File (MP4 Video), 20497 KB - games_v11i1e46351_app1.mp4]

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Abbreviations

ANS: autonomic nervous system
HF: high frequency
HR: heart rate
HRV: heart rate variability
HRVB: heart rate variability biofeedback
iHR: instantaneous heart rate
LF: low frequency
RMSSD: root mean square of differences between adjacent RR intervals
RR mean: average RR intervals

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Original Paper

Parents' Perceptions of a Serious Game for Educating Families on Prescription Opioid Safety: Qualitative Pilot Study of MedSMARxT: Adventures in PharmaCity

Olufunmilola Abraham[1], BPharm, MSc, PhD; Grace Ann Nixon[1], PharmD; Laura Louise Seitz[1], BSc

Social and Administrative Sciences Division, School of Pharmacy, University of Wisconsin-Madison, Madison, WI, United States

Corresponding Author:
Olufunmilola Abraham, BPharm, MSc, PhD
Social and Administrative Sciences Division
School of Pharmacy
University of Wisconsin-Madison
Room 2515 Rennebohm Hall
777 Highland Avenue
Madison, WI, 53705
United States
Phone: 1 6082634498
Fax: 1 6082625262
Email: olufunmilola.abraham@wisc.edu

Abstract

Background: Opioid misuse is a pervasive, worsening problem that affects the health of people throughout the United States, including adolescents. There are few adolescent-focused interventions designed to educate them about opioid medication safety. The MedSMARxT: Adventures in PharmaCity, is a serious educational video game that teaches parents and their youths about safe opioid practices.

Objective: This study aimed to elucidate parent's perceptions of MedSMARxT: Adventures in PharmaCity and its potential use by parents and their adolescents.

Methods: Parents of adolescents aged 12 to 18 years who live in the United States were recruited from April to October 2021 via Qualtrics research panels, social media, email listserves, and snowball sampling. The study participants played MedSMARxT: Adventures in PharmaCity for 30 minutes and then participated in a 30-minute postgame interview via WebEx (Cisco). Questions were developed and piloted to examine adults' perceptions of the game. Participants were asked three sets of open-ended questions: (1) questions about the game and elements of the game, (2) what they learned from the game, and (3) questions about their experience with games. Audio recordings were transcribed verbatim. Interview transcripts were coded using content and thematic analysis by study team members to identify major themes and subthemes from the data.

Results: Parent participants (N=67) played MedSMARxT: Adventures in PharmaCity and completed a postgame interview. Analysis extrapolated four primary themes from the data: (1) participant gaming experience, (2) perception of game features, (3) educational purpose of the game, and (4) future use of the game. Most participants (n=56, 84%), had at least some experience with video games. More than half of the participants (n=35, 52%) participants, had positive reactions to the game characters and scenes depicted in MedSMARxT: Adventures in PharmaCity and stated they were realistic for adolescents. Most participants (n=39, 58%), would recommend the game to others. Significant difficulties with gameplay navigation were reported by 38 (57%) participants, as well as a slow game pace. All participants were able to accurately identify the overarching goal of the game: opioid or medication safety. The game reinforced existing knowledge for participants, though many (n=15, 22%), reported a new awareness of the need to store opioid medications in a locked area and the availability of medication disposal drop boxes at pharmacies. Participants stated that they would recommend the game for future use by families and youths in various health care and non–health care settings.

Conclusions: The use of a tailored serious game is a novel, engaging tool to educate adolescents on opioid safety. MedSMARxT: Adventures in PharmaCity can be used as a tool for parents and adolescents to facilitate meaningful dialogue about safe and appropriate opioid use.

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KEYWORDS

opioids; opioid; parents; adolescents; medication safety; family health; serious games; parent; adolescent; youths; gaming; game; games; teenager; teenagers; acceptance; perception; perceptions; patient education; pharmacy; pharmaceutic; pharmaceutics; pharmaceutical; drug; safety

Introduction

Background

The opioid crisis has palpable impacts throughout the United States across all demographics. Seldom can one go a significant amount of time without hearing about the epidemic's dire impacts on health and well-being. Death rates from opioid misuse have nearly tripled since 1999, and opioids were involved in an estimated 80,816 deaths in the United States in 2021 alone [1,2]. Curbing opioid misuse has been a long-standing focus of policy and governmental efforts, with the White House declaring the opioid epidemic a public health emergency in 2017 [3].

Youths are just as vulnerable to the growing opioid crisis as adults. In a survey collected by the Centers for Disease Control and Prevention in 2019, approximately 14% of high school students reported misuse of prescription opioids during their lifetime [4]. Opioid misuse encompasses taking opioids outside of their prescribed regimen, such as taking more than prescribed, using them in the absence of pain, or taking them after expiration. Among adolescents, misuse often begins at home, where leftover opioid medications enable misuse [5,6]. Adolescents tend to model the behaviors of their parents regarding their opioid prescription usage [7]. Research shows that the proportion of adolescents and young adults with opioid-related health problems has increased over time despite a decrease in the total number of adolescent and young adult personal opioid prescriptions during the same period [8]. Out of all the adolescents and young adults who experienced an opioid-related problem, 40% had received a personal prescription for opioids in the past year while 48% had a family member prescribed an opioid in the past year. Even adolescents who are prescribed opioids and take them appropriately are 33% more likely to develop problems such as opioid dependence or lifelong patterns of misuse [1].

However, research has shown that educating parents can improve their behavioral intentions and reduce the likelihood that they will store unused opioid medications in the home [9-11]. Alongside rising rates of adolescent opioid misuse, youths have reported misconceptions about safe opioid use practices, including inaccurate identification of medications that are opioids, improper storage and disposal techniques, and inappropriate sharing of prescribed opioids with others [12]. Due to the vulnerability of adolescents and their limited knowledge about opioid medication safety, it is essential to create tailored, educational interventions that teach youths and families about the importance of safe prescription opioid use.

Currently, there is a lack of interventions tailored to adolescent education on opioid medication safety [13-16]. Previous literature suggests that parents and youths are receptive to game- and web-based opioid misuse prevention programs, citing a belief that gamified educational methods would improve adolescent engagement [17,18]. These studies have also shown that serious educational games may enhance the retention of information, accelerate learning, and increase accessibility to educational material. Other health-focused games have shown effectiveness in improving key behavioral intentions and improving education for youths [18-21]. Novel approaches to engaging youths can be effective and are paramount in combating the opioid crisis [22,23]. One such approach is the use of a serious game. Serious games are video games designed to impart knowledge or improve social-behavioral outcomes for players wherein the primary objective is not entertainment [24].

MedSMARxT: Adventures in PharmaCity

Overview

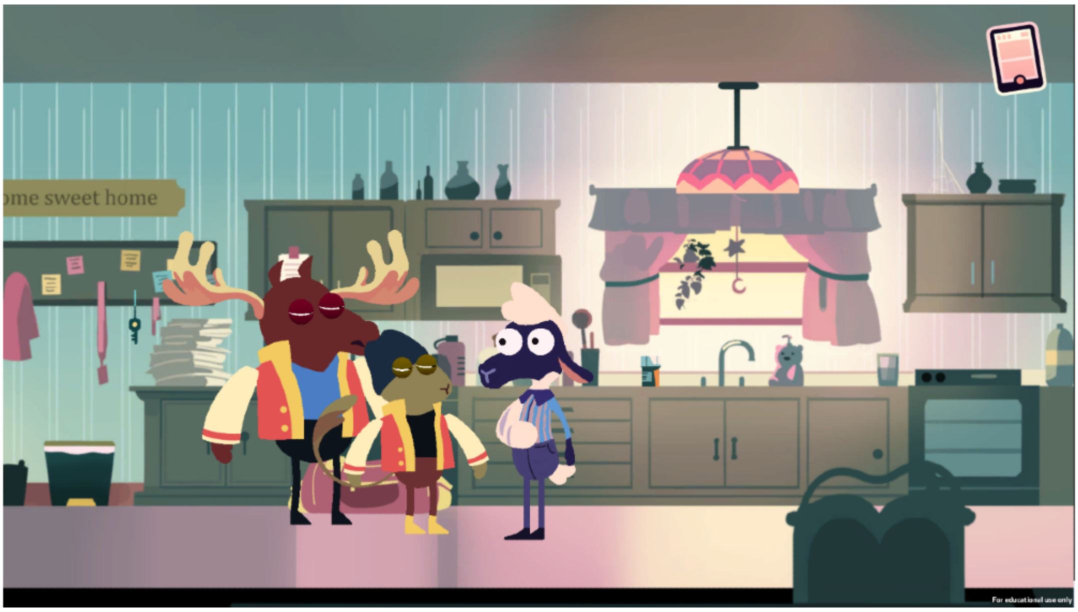
MedSMARxT: Adventures in PharmaCity is a theory-driven, adolescent-focused serious game developed to educate adolescents and their families on how to safely manage complex, real-life situations involving prescription opioid medications [25,26]. By playing the game, youths and their family members (such as parents) are able to identify best practices for the safe and responsible management of opioid medications with a focus on appropriate disposal, proper storage, and preventing medication sharing. The game scenarios were created with the interdisciplinary study team comprised of game designers and developers, health services researchers, pharmacists, an adolescent health physician, and an addiction medicine physician. The scenarios were further assessed by adolescents and young adults who overall found the scenarios to be realistic and relevant. The game content, game design, and scenarios were informed by several extensive studies previously conducted by the study team to understand opioid safety knowledge games of adolescents and their preferences for game-based education [9,14-16,25,26]. Findings from these studies showed that adolescents significantly lacked information on safe opioid storage and disposal; hence, a critical knowledge gap that needed to be addressed via game-based learning. Parent involvement in medication-related behaviors (such as medication storage and disposal) remains an important protective factor against adolescent prescription medication misuse [27]. Therefore, the inclusion of parents in the feedback and development was key to creating an intervention that would facilitate adolescent education and promote family medication safety.

The game's format was a responsive narrative wherein players make choices that affect the game's outcomes, such as choosing their own adventure. Players play as an anthropomorphized sheep, Shan, who recently broke their arm. Players must use critical thinking and decision-making to select the correct (safest) choices regarding opioid use through 5 levels simulating real life. If players make a decision that is unsafe, they are presented with an opportunity to replay the level. The game is played using an internet-enabled computer via a web browser.

Level 1

A Quiet Sunday Afternoon focuses on teaching the player about the safe storage of opioids and requires the player to appropriately store opioids in a locked cabinet before Shan's friends gain access to the medications and overdose (Figure 1).

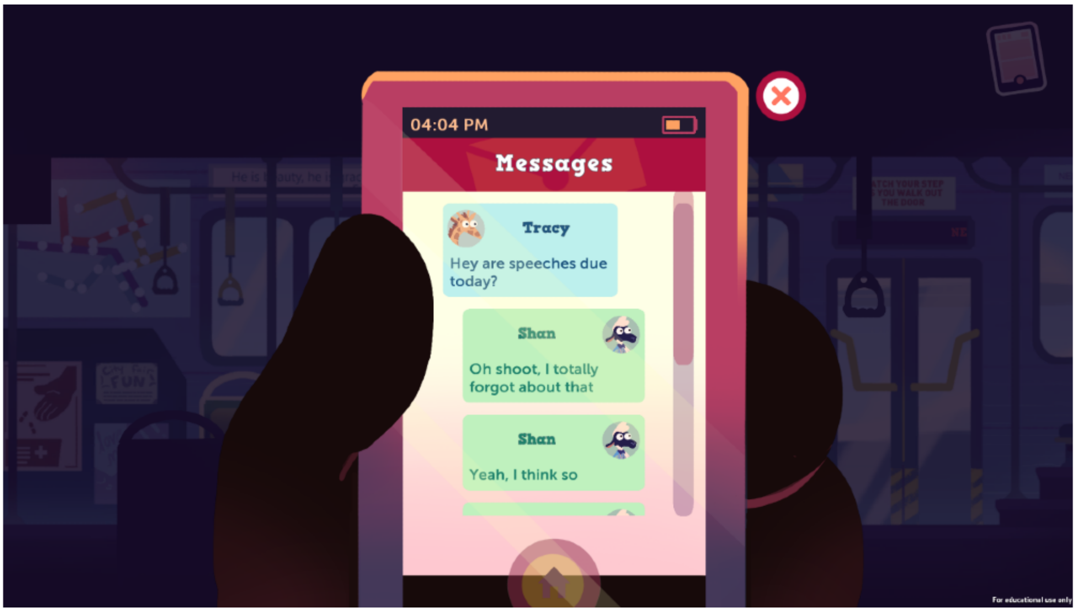
Figure 1. Game level 1.



Level 2

Monday Morning Bus Ride, in this scene, the player is in pain and forgets there was an important assignment due that day (Figure 2).

Figure 2. Game level 2.



Level 3

A Persuasive Speech at School teaches the player not to take others' pain medications through peer pressure from a friend and discusses the negative consequences of taking someone else's prescription medication (Figure 3).

Figure 3. Game level 3.

Level 4

Bus Ride Home teaches the player not to share their medication with others and reinforces the risks of sharing medications. This game level also introduces the use of Narcan through an encounter with a stranger on the bus who acts as if they are in pain and needs relief (Figure 4).

Figure 4. Game level 4.

Level 5

Last Minute Chore shows the player the correct approach to dispose of opioid medication and that medication disposal drop boxes are available at local pharmacies (Figure 5).

Figure 5. Game level 5.

Study Objectives

The purpose of this study was to examine parents' perceptions of the MedSMARxT: Adventures in PharmaCity game. Specifically, the study assesses parents' perceptions of the game features, what participants learned from the game, and their gaming experience.

Methods

Ethics Approval

This study was approved by the University of Wisconsin-Madison's institutional review board (2020-1638) on January 5, 2021.

Sampling and Recruitment

From April to October 2021, a national sample of parents was recruited via Qualtrics research panels, social media, email listserves, and snowball sampling. The study team partnered with Qualtrics to identify and recruit from preexisting research panels. Social media sites included Facebook (Meta Platforms), Instagram (Meta Platforms), Reddit, and Twitter. Listserves came from the University's mass email system and the study team's own list of youths and parents. Eligible participants were parents of adolescents aged 12 to 18 years who live in the United States, could read, speak, and understand English, and had access to a computer with a working webcam. After screening for eligibility, parents were asked to provide consent and their contact information for scheduling purposes. Parents were then contacted to partake in the study and screened for eligibility by the research staff.

Data Collection

Study sessions were held via WebEx. Parents were told that the study was being conducted by a team of researchers interested in adolescent opioid misuse prevention and that they were looking for data to help refine their game. Parents were asked to play the MedSMARxT: Adventures in PharmaCity game for 30 minutes (or until they completed all 5 levels, whichever happened first), and answer follow-up interview questions. Data were collected through 30 minutes of gameplay and a 30-minute semistructured interview. Only participants and a member of the research staff were present during the data collection. The research team created interview questions to examine parent players' feedback on the game. Participants were asked three sets of open-ended questions: (1) about the game and elements of the game, (2) what they learned from the game, and (3) about their experience with games. Interview questions were developed for the purpose of understanding parents' perceptions of the game, confirming the salience of educational content, and characterizing the gaming experience of parents of adolescents. The study team used interview questions that had previously been pilot-tested and proved to be effective for examining adults' use of the game. The interview ended with, "Is there anything else you'd like to add?" to allow the participant to share any other thoughts or details that were not previously captured. Parents were compensated US $30 via an Amazon gift card for their participation in the study. Interviews were professionally transcribed verbatim using audio recordings collected through WebEx. The interview guide is shown in Multimedia Appendix 1.

Data Analysis

Two research team members (GAN and LLS) independently analyzed each interview transcript using NVivo (Lumivero) [28]. The main themes from participant responses were coded using content analysis followed by a thematic approach [29]. The coding members of the study team first familiarized themselves with the data by reading through each transcript in detail and then independently extrapolated codes. The research team members met regularly to discuss coding differences and develop a master codebook. The codes were then exported to Excel (Microsoft Corp) for further thematic analysis using an inductive and deductive approach to identify salient themes [30]. The primary investigator (OA) met with the coders to address any coding discrepancies and prevalent themes identified. Each coder identified themes and subthemes from the data based on code prevalence, and then the research team met to compare and finalize the results reported below.

Results

Participant Demographics

Feedback was elicited from 67 parent participants who played MedSMARxT: Adventures in PharmaCity. Participant characteristics are described in Table 1. Notably, 92.5% (n=62) of them identified as female, 77.6% (n=52) of them identified as White, and the mean age was 46.03 (SD 5.75) years.

As depicted in Textbox 1 below, four major themes were identified: (1) participant gaming experience, (2) perception of game features, (3) educational purpose of the game, and (4) future use of the game. A detailed description of the themes and prevalent subthemes that emerged from the data analyses is described below.

Table 1. Participant demographics (N=67).

Characteristics	Values
Level of education, n (%)	
High school	3 (5)
Associates or trade school	8 (12)
Bachelor's degree	26 (39)
Master's or PhD	30 (45)
Age (years), mean (SD)	46.03 (6)
Sex[a], n (%)	
Female	62 (93)
Male	5 (8)
Race or ethnicity[b], n (%)	
White	52 (78)
Black or African American	7 (10)
Hispanic or Latinx	3 (5)
Asian	2 (3)
More than one selected	3 (5)
Other please specify	0 (0)
Income (US $), n (%)	
Under $25,000	2 (3)
$25,001-$50,000	8 (12)
$50,001-$100,000	23 (34)
$100,001-$250,000	32 (48)
$250,001-$500,000	2 (3)
Employment status, n (%)	
Part-time, unemployed, retired, and other	34 (51)
Full-time	33 (49)
Regions[c], n (%)	
Atlantic	16 (24)
Central	28 (42)
Southern	16 (24)
Western Pacific	7 (10)

[a]Three options were presented to the participants to select for their sex assigned at birth: “male,” “female,” and “other: please specify.”
[b]If participants only selected 1 category, that was their defined race; all other combinations of selections were defined as “More than once selected.”
[c]Regions are generated from participant zip codes according to the United States Postal Service data.

Textbox 1. Summary of themes and subthemes.

Participant gaming experience

- Experience with board and card games
- Experience with video games
- Experience with educational games

Perception of game features

- Levels
- Characters
- Graphics
- Navigation
- Pace

Educational purpose of the game

- Perceived main idea of the game
- Reading level
- Target audience
- Participant learning experiences

Future use of game

- Suggested improvements
- Applications

Theme 1: Participant Gaming Experience

Overview

Parents had a wide range of experience with games. Overall, participants preferred games that required strategy and discrete tasks to accomplish. Study participants enjoyed games that foster family or social interaction. Most parents reported at least some experience with video games and favorable impressions of educational games.

Experience With Board and Card Games

Many participants (n=32, 48%), reported playing board games, and overall, participants listed 70 different board games that they had played in the past. Social interaction with family and friends was a frequent motivator for participants to play board games. A smaller number of participants (n=13, 19%), discussed playing card games.

> *I play them with my family so it's something fun to do with my family or with my friends. […] So, it's more of a social thing for me, it's not a sit on my phone or computer and do something by myself.* [Parent 152]

> *I'm not a competitive person, but I like having something to do while you're sitting around and talking with someone else.* [Parent 184]

Experience With Video Games

Most participants (n=56, 84%), stated they had at least some video gaming experience. A few participants (n=3, 4%), considered themselves frequent players, and nearly half of the participants (n=30, 45%), considered themselves infrequent players. Of some participants (n=11, 16%), reported minimal to no experience with video games. Participants had used a variety of gaming platforms and systems, but mobile gaming was most frequently reported. Participants listed a total of 132 unique video games played. Common types of video games played include word, puzzle, and matching games.

Motivations for playing video games included a desire to pass time when relaxing or bored, to have a mental challenge, and to socialize with others, especially participants' own children. Lack of time, preferences for other forms of entertainment, and avoidance of violent themes were the 3 most frequent reasons for not playing video games. Some participants (n=18, 27%), stated nothing could be changed about video games to entice them to play more. Furthermore, a few participants (n=5, 7%), reported easier navigation would increase appeal and 5 (7%) participants mentioned that including goals would motivate them to play.

> *Yes, I have experience playing. I mean, I'm not sitting there every day playing, but I do play with the kids here and there. I like to mostly use my phone for games, but we do have consoles like the Xbox 1.* [Parent 194]

> *I'm really busy and I like to do other things with my time. I spend a lot of time on the computer at work and so when I come home, it's like, the last thing I want to do is spend more time on the computer.* [Parent 144]

Experience With Educational Games

Most participants (n=44, 66%), reported previous experience playing an educational game. Some of these participants (n=11, 16%), reported playing an educational game with their child in the past, and other parents (n=11, 16%), stated that educational games were a part of their career. Participants listed 36 unique educational games that they had previously played, which commonly included math games, crossword puzzles, early learning games, and trivia games.

Most parents (n=43, 64%), had a positive perception of educational games. Study participants perceived game-based learning as an appealing modality that is more engaging than traditional learning methods. Features such as the ability to learn from mistakes within the game and entertainment features were important to parents. A few participants (n=7, 10%), stated that educational games would be more beneficial for youths than adults.

> *I think it's really good. I mean, obviously, depending on what you're being educated on. But I think is a great way to learn and also kind of keep your interest as opposed to just reading it on the Internet or reading a book about it. It's a way to, a different way to learn to kind of keep it a little spicy, I guess.* [Parent 163]

> *I feel like your kids and adults enjoy playing them and have fun with them without realizing that it's a learning process because sometimes if you're like, "hey, we're going to teach you something," or "this is going to be educational," people automatically go to like, "this is going to be really boring." Um, so the good educational games kind of distract you from the fact that you're learning something by making it mostly fun. For younger kids, that's especially good.* [Parent 161]

Theme 2: Perception of Game Features

Levels

The most frequent positive descriptors of game levels included "cute" and "engaging." Participants appreciated the variety of game levels, which they reported represented real life. Parents appreciated the responsive narrative format which allowed the player to choose from multiple available actions, learn the consequences of wrong (unsafe) actions, and replay scenes to discover the appropriate actions.

A total of 35 (52%) participants reported that game levels were realistic. Some participants (n=10, 15%), specifically stated that the levels were applicable to the lives of adolescents. Only 3 (4%) participants reported that game scenes were not realistic due to the severity of the consequences portrayed. Some parents expressed uncertainty about whether adolescents encountered opioid misuse frequently. A small number of 3 (4%) participants noted that in the game a child's character performs actions they would not have their own child perform, such as medication disposal.

In level 1, some participants reported uncertainty around the correct actions to take, though many benefited from the educational content of this level. Level 3 was well-received by participants due to its depiction of an opioid misuse scenario with peer pressure which they felt adolescents may encounter. Level 4 was sometimes viewed as being unlikely, as participants felt that a stranger would not ask for pain medication from another person.

> *We don't necessarily know what kids are thinking. […] The conversation between Stan and Tracy was very interesting because you would never think […] that another teenager would offer their friend opioids, trying to help them out, nothing nefarious about it. But it's very dangerous. I mean, I could see how it could happen.* [Parent 199]

> *I think there were good choices, especially with the things at home and then the potential at school with somebody else having other medications. I liked that they were more of like, situations that kids might find themselves in, not trying to so, like, not actually having that seeking behavior, or, like, trying to purchase them from somewhere, but just happening, especially like, with the friend offering.* [Parent 172]

> *I think it's kind of realistic, but I haven't experienced or heard like from my kids or my family and my friends, I never heard this sharing the high-dose painkiller opioid in some, this kind of things. So, I will be neutral. I don't say it's realistic or not realistic.* [Parent 188]

Characters

Parents responded positively to the game's characters. Parents' positive impressions of the characters were mentioned 166 times, whereas negative impressions of characters were noted only 38 times. Characters were described as cute, realistic, and sincere in their interactions. Some participants mentioned that the use of cartoon characters or animation-style graphics may be better suited for younger adolescents rather than older teenagers. Fifteen (22%) participants noted a preference for animal characters, while 4 (6%) participants preferred human characters. Participants appreciated that characters were gender-inclusive with neutral names and presentation. According to parents, animal characters contributed to this inclusivity.

> *And so, I think that it was, it was a good, you know, they had the things that the kids could find in common with them, you know. Common things in terms of like, for instance, being anxious about things at school, you know, and things like that, it was, it was a good thing. I liked the characters.* [Parent 150]

Graphics

Parents stated that the graphics were cute and interesting but may have been designed for younger children. Only 4 (6%) participants stated that the game graphics were outdated. Participants also stated that the graphics may be basic for adolescents who often play games with advanced graphics.

> *In comparison to games and apps that kids use right now. They're pretty, it was pretty basic. And the, the*

> *animals were- if you're looking for teenagers or adolescents- a bit juvenile.* [Parent 165]

Navigation

Some parents (n=38, 57%), had difficulties with navigation, especially in level 1. Eleven (16%) participants sought more in-game directions for navigation while playing and suggested that keyboard controls (W, A, S, D keys) were difficult to use. For most parents, the game navigation became easier as the participants continued to play the game. Some participants (n=10, 15%), suggested gameplay may be more intuitive for a child rather than a parent.

> *Like, I wasn't sure I was supposed to walk around and look for things, or if it was going to read me something, or if I was just waiting for things. So, I think at least at a time in the beginning, like, figuring that part out. And then when it had me redo a level a couple of times because I did something wrong. So, I knew I was looking for a key in the beginning, but I couldn't walk around the room and look for it.* [Parent 183]

> *It was a little hard to know how to use it at the very beginning because there weren't a lot of instructions, I wasn't sure exactly what I was supposed to do when it started. But I caught on after the end of the, by the end of the 1st scene.* [Parent 118]

Pace

Participants mentioned that the game had a slow pace with opportunities to repeat the game scene when the wrong action was selected. Time burden was reported due to the amount of dialogue the participant had to read throughout the game.

> *There was just too much to read. Instead of like, little blurbs, it was like, big passages to read. I mean, as far as getting people's attention, unfortunately, I felt like it was more like, I was reading it, but if I wasn't doing a survey for it, I'd just be clicking, clicking, like, waiting for it to ask me a question. That way I can answer it and move on to the next subject.* [Parent 155]

Theme 3: Educational Purpose of Game

Overview

Many participants expressed positive opinions about using a video game to educate their children on opioid medication safety. The parents reported that game-based learning would help their children remain engaged with the content. They also noted that the game would be a beneficial way for children to share what they learned with friends.

Perceived Main Idea of Game

When asked what they perceived to be the main educational point of the game, 23 (34%) participants reported the promotion of safe use of opioids and 13 (19%) stated prescription medications in general. Additional perceived goals of the game included education on proper opioid medication storage, which was reported by 9 (13%) participants while 22 (33%) participants reported that the overall goal of the game was medication storage in general. Encouragement to avoid sharing prescription medications was cited by 33 (49%) participants, and discussion of proper medication disposal techniques for opioids was suggested by 10 (15%) participants or medications overall was stated by 10 (15%). A portion of 17 (25%) participants further stated that the game accomplished the goals that they perceived.

> *The main goal of the game was to me, it was educating the public and, and people about, uh, using prescription medicine faithfully. And to me, the, the game did meet that goal. Especially like in that first part getting it, you know, securing it, locking it up. And not taking things that are, that do not have your name on it, that are not for, you. Um, and not offering it to people because you think it may help them. I think the game did- for what I played of the game- I think that did drive that point home.* [Parent 147]

Reading Level

Parents believed that the game's reading level was more appropriate for older adolescents than elementary-aged children.

> *And so, it seemed like it was designed for much younger than the characters in it, which was fine, but some of the things they were saying, I don't think the younger kids would be able to read.* [Parent 131]

Target Audience

Participants reported that children of elementary or middle school age would be the primary target audience. Participants thought children 5 to 15 years of age would benefit most from the game but mentioned that the educational points are important for all ages. Dialogue and game scenes were perceived as more appropriate for older teenagers than younger children. Parents stated that their older teens may think the game less engaging due to its slow pace. However, parents reported that their children would learn from the game and gain confidence in safe prescription opioid behaviors.

> *I think that it can be valuable and not just the game itself, but […] perhaps the kid and parents could play it together, or the parent could watch the child playing it and it could help fill in any missing pieces or answer questions that the kid might have. I think it's a nice way to introduce the topic for a family discussion in a way that could be more engaging and that could hold the kid's interest a bit more than just straight laying it out there.* [Parent 137]

> *I definitely would recommend it to others because it obviously is extremely important and needs to be, it needs to be brought up to anyone who will listen. But I would recommend it to a younger crowd, I think.* [Parent 143]

Participant Learning Experiences

Some (n=27, 40%), participants reported that the game confirmed their existing knowledge, while 22 (33%) others reported that the game did not provide novel educational points. Two frequently reported educational outcomes included medication storage recommendations and awareness of medication disposal options. Specifically, participants realized that they do not typically store medications in a locked area and do not have a locked area available in their homes. A substantial number of participants (n=15, 22%), were not aware of available pharmacy medication disposal drop boxes until playing the game. The game also emphasized the importance of parent-to-child medication safety education wherein participants discussed improved awareness of medication safety scenarios, such as when friends of their children visit the home. Parents were also motivated to increase communication about medication safety with their children after playing the game.

> *That opioids should be locked up. That's that got most to me because when, because my children were a little older when I was prescribe[d] codeine and, you know, you just assume they're not going to touch it. And the childproof caps, I didn't lock mine up. But now seeing that I probably should have, because you don't know who else is in your house and can get to your medication.* [Parent 199]

> *I had no idea that there were drop boxes for medicine or that you were supposed to take it back to the pharmacy.* [Parent 169]

Theme 4: Future Use of Game

Overview

Over half of participants (n=39, 58%), stated they would recommend MedSMARxT: Adventures in PharmaCity, and 17 (25%) other participants would provide a conditional recommendation. A small number of 5 (7%) participants mentioned that they would not recommend the game, 1 (1%) participant would conditionally not recommend it, 1 (1%) participant was indifferent, and 2 (3%) participants had mixed recommendations. Two (3%) participants did not provide a recommendation for or against the game.

Suggested Improvements

Improved navigation was cited as a future improvement 39 times. Participants recommended a tutorial, in the beginning, to explain navigation, pop-ups throughout the game to encourage exploring the scene, or adding a hint button. They also endorsed the use of keyboard arrow keys, a computer mouse, or touchscreens over current W, A, S, D keyboard controls.

> *I would have benefited from like, a little simple, like, practice round at the beginning, just a simple like, this is, I mean, this is how you move and how you jump and how you do these things.* [Parent 183]

To increase the pace of the game, participants desired an option to skip over dialogue especially if repeating a game scene. Participants would prefer less text dialogue and more direct questions to prompt user action. Participants recommended the incorporation of social media, live video clips, and customizable characters to increase engagement for older teens.

Participants sought additional educational content, including a scene in the beginning of the game where the main character discusses information and instructions about their medication with a physician or a parent. Participants suggested this scene could include exposure to the medication package insert, a display of warning labels found on the medication bottle, or background information on the character's injury. More education regarding the recognition and treatment of opioid overdose was requested. Participants emphasized the importance of all users being able to see the consequences of wrong actions, even if they choose the correct actions in the game.

> *I would say to ensure that all the scenarios, so, even if you didn't, you know, end up in a particular sort of side quest you still got that information. Um, so maybe creating additional scenarios that so you didn't miss certain information if you answered in a particular way, and you just didn't end up on that diversion.* [Parent 142]

Applications

Specific settings thought to be right for future use include health care settings (physician offices, pharmacies, and dental offices), particularly in waiting rooms and school settings (health classes, drug awareness programs, and use with sports injuries). Participants stated that the game would be effective as a kiosk within a pharmacy or as a mobile game linked via a QR code in a health care setting.

> *I can see this being a game for again, in the clinic, or a doctor's office, meant to be educational or in school. I'm not sure if anyone would, like, download this game to play it just to just to play a game about learning about opioids or, you know, how to use them correctly and stuff like that, but I could definitely see this being a way to educate kids where it doesn't seem like it's a chore for them where they can use it to have fun and play a game and learn something at the same time.* [Parent 167]

Discussion

Principal Findings

Parental feedback demonstrates the acceptability and appropriateness of MedSMARxT: Adventures in PharmaCity as evaluated through parent perceptions of game design, navigation, educational purpose, and future game applications. The study findings indicate that most parents support the use of educational games to teach adolescents about opioid medication safety, emphasizing that this approach is more appealing and engaging for youths as compared to traditional learning methods. Moreover, many parents stated that they would recommend the game to others, showing its appropriateness in engaging parents and garnering their support in using the game to educate their children. Despite being a serious game directed toward use by youths, MedSMARxT: Adventures in PharmaCity also taught parents of adolescents important opioid medication safety practices, including safe storage and disposal.

Comparison to Prior Work

Video games, specifically serious games, demonstrate the potential to improve key behavioral intentions and knowledge related to positive outcomes in various health conditions [31-33]. MedSMARxT is the first serious game to address opioid safety in adolescents [14]. As such, it is critical that the game be evaluated with relevant stakeholders to ensure key quality criteria [34-36]. Prior research has elucidated some key quality criteria in the development of serious games including the salience of the overarching goal of the game, appropriateness of the game content, enjoyment, and acceptable media presentation [37]. In order to best tailor the game to the target players, the study team has rigorously evaluated the game among groups of stakeholders. For example, the study team has conducted research with pharmacists to validate the educational content and their perceptions of using the game in pharmacies when opioid medications are dispensed. Pharmacists reported that the information presented in the MedSMARxT is accurate and age-appropriate while potentially useful for populations aside from adolescents such as parents or older adults [38].

Previous work by the study team has focused on the development of MedSMARxT wherein community-based participatory research was used to elucidate adolescent knowledge gaps and preferences for education on medication safety [39]. Adolescents most frequently reported web searches, parents, health care providers, and web-based videos as resources for medication safety information, which highlights the integral position of parents and health care professionals such as pharmacists in ensuring appropriate and correct education for adolescents [39]. In prior studies on adolescent receptiveness to using educational games to improve medication knowledge, nearly 80% of adolescent participants indicated they would be receptive to using an educational game [40]. Concordantly, this study demonstrates that parents are also receptive to the use of an educational game to educate their adolescents on opioid safety. Moreover, parents of adolescents in this study reported experience with video games at elevated levels (84%). In conjunction with previous studies, this study indicates sufficient receptiveness toward MedSMARxT for families with adolescents.

Existing research also indicates that serious games contain realistic scenarios that engage and motivate participants more than traditional learning approaches [41]. Parents in our study offered positive feedback on the game features including the media presentation (graphics) as well as the characters and individual gameplay levels. Coupled with the correct identification of the game's overarching goal, these findings describe the potential balance of serious and game elements in the MedSMARxT game.

Although the original, intended audience is adolescents, parents likewise reported new learnings. Parents most often reported newfound knowledge about proper disposal and storage. Research has demonstrated the importance of educating patients on safe disposal. When patients are taught the proper method of disposal, they are more likely to dispose of their medications in a safe manner [42,43]. Beyond the use of a serious game to provide education to adolescents, parental involvement in adolescent medication use practices has been a protective factor against prescription drug misuse [27]. Parents can act as useful resources for information about opioid safety and important models of proper opioid use when they themselves have the requisite education. Recognizing the vital role that the family plays in the development of medication use behaviors, the National Institutes of Health [44] recommends family-based prevention programs as an effective means to reduce rates of opioid misuse among youths. Parental exposure to topics their children are learning about can promote discussions foundational to future safe medication use behaviors. Parent responses suggest that this intervention could foster family conversations around opioid and prescription medication safety by providing parents with an educational resource for both them and their children.

This study of MedSMARxT: Adventures in PharmaCity showed a perceived educational benefit for adolescents and a reported gain in parental exposure to opioid medication safety topics. Parents were able to explore realistic scenarios that their child may experience. For example, through playing level 1, parents realized that proper opioid storage in the home is not only important for their child but also for their children's friends who may visit the home.

Future Directions

While overall perceptions of the MedSMARxT game were positive, findings from this study suggest further improvements including a navigation tutorial, an option to skip through dialogue when repeating scenes, and explicit hints or objectives. While iterative improvement of the game itself is vital to future uptake, implementation effectiveness studies are integral to determining the best location and means for implementing this novel educational technology. Future studies will work to evaluate the effectiveness of MedSMARxT in different health care and non-health care settings to determine fit and implementation.

Strengths and Limitations

Strengths of this study include sampling a significant parent population from across the United States, which provided a representation of many parenting opinions and styles. Second, the use of open-ended questions during the interview provided participants ample opportunity to discuss all aspects of MedSMARxT: Adventures in PharmaCity that they perceived were important. Third, analysis was carried out by 2 research team members for triangulation (GAN and LLS), guided by the principal investigator for reflexivity (OA), and validated through peer debriefing and an audit trail to support trustworthiness in terms of credibility, transferability, dependability, and confirmability.

There are limitations to this study. The first is that of self-selection bias in this sample. While this study uses a considerably large sample size for a qualitative study, parents' self-selected participation could be present in terms of those who favor the use of educational games being more likely to participate. Second, there are limitations surrounding demographic homogeneity in this sample. The format of study activities would exclude families without access to high-quality internet or those without a computer in the home. Therefore, our study sample, while a national sample, is homogenous in terms of socioeconomic status and education level. Hence, findings of acceptability may be less generalizable to those in more difficult socioeconomic situations and those who discontinued education after high school. Recruitment was carried out across multiple streams (Qualtrics panels, social media, listserves, snowball) across a few months in order to create a sample that was as robust as possible. The study team used practices such as investigator triangulation, peer debriefing, and reflexivity to improve the trustworthiness of the data collected.

Third, social desirability bias could play a role in the positive perceptions of the parents. It is possible that when asked about their perceptions, parents were more likely to offer a positive response than a negative response. To account for this potential, the interview guide was designed and piloted to ensure neutrality in questions and prompts. Future work could use anonymous surveys to remove the researcher from data collection and decrease social desirability. The findings of this study are trustworthy given that questions were tailored to touch on multiple parts of the intervention and questions regarding potentially threatening topics were not used.

Conclusions

The creation and use of serious educational games to teach adolescents about opioid medication safety could be an effective approach to improving youths' knowledge of opioid prescription safety. This study investigated parent perceptions of MedSMARxT: Adventures in PharmaCity and found that parents believe this game would be beneficial for youths. MedSMARxT: Adventures in PharmaCity could be used in various non-health care and health care settings in the future to educate adolescents and inspire meaningful parent-adolescent conversations about safe opioid use.

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Data Availability

Data collected for this study are not publicly available as it may contain private health information. Those looking to gain access to the data should contact the corresponding author.

Authors' Contributions

OA contributed to the conceptualization, funding acquisition, investigation, methodology, resources, supervision, formal analysis, project administration, writing-review, and editing. GAN contributed to the formal analysis, writing-original draft, writing-review, and editing. LLS contributed to the formal analysis, writing-original draft, writing-review, and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 13 KB - games_v11i1e49382_app1.docx]

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Original Paper

Translating and Testing a Digital Game Promoting Vegetable Consumption in Young Children: Usability Study

Sophie Bucher Della Torre[1], PhD; Marlene Lages[2], RD; Sara S Dias[2,3], PhD; Maria P Guarino[2,3], PhD; Cátia Braga-Pontes[2,3], PhD

[1]Geneva School of Health Sciences, HES-SO University of Applied Sciences and Arts Western Switzerland, Carouge, Switzerland
[2]ciTechCare- Center for Innovative Care and Health Technology, Polytechnic of Leiria, Leiria, Portugal
[3]School of Health Sciences, Polytechnic of Leiria, Leiria, Portugal

Corresponding Author:
Sophie Bucher Della Torre, PhD
Geneva School of Health Sciences
HES-SO University of Applied Sciences and Arts Western Switzerland
Rue des Caroubiers 25
Carouge, 1227
Switzerland
Phone: 41 225586604
Email: sophie.bucher@hesge.ch

Abstract

Background: Promoting healthy eating in children is key to preventing chronic diseases, and vegetable consumption is notably lower than recommended in this population. Among the interventions tested, gamification has shown promise in promoting familiarization, increasing knowledge, and potentially increasing vegetable intake.

Objective: This pilot study aimed first to translate the digital game “Veggies4myHeart” into French and to assess its influence on young children’s preferences and willingness to taste vegetables when combined with repeated tasting and education. We also aimed to investigate the acceptability and applicability of the game in 2 classrooms.

Methods: During 5 consecutive weekly sessions, children from 2 elementary classes played the digital game consisting of 5 mini games on different vegetables (lettuce, carrot, red cabbage, cucumber, and tomato) in pairs for 10-15 minutes. In addition, they discussed one of the vegetables and tasted the 5 vegetables in each session. Pretest and posttest food preferences and willingness to taste the vegetables were compared. Teachers participated in a semistructured interview.

Results: A total of 45 children aged 5 to 6 years tested the French version of the digital game. The children’s declared food preferences were already high for carrot, cucumber, and tomato, with scores higher than 4 out of a maximum of 5. The scores did not change significantly after the intervention, except for red cabbage (pretest: mean 2.52, SD 1.49; posttest: mean 3.29, SD 1.67; *P*=.006) and a composite score (pretest: mean 3.76, SD 1.06; posttest: mean 4.05, SD 1.03; *P*=.001). Before the intervention, 18 (44%), 30 (73%), 16 (39%), 29 (71%), and 26 (63%) children out of 41 were willing to taste lettuce, carrot, red cabbage, cucumber, and tomato, respectively. After the intervention, no significant statistical differences were observed, with 23 (51%), 36 (80%), 24 (53%), 33 (73%), and 29 (64%) children out of 45 willing to taste lettuce, carrot, red cabbage, cucumber, and tomato, respectively. Teachers supported this tool combined with repeated tasting and education and highlighted facilitators and barriers that should be anticipated to improve implementation in schools.

Conclusions: In this study, we translated an existing digital game applicable and acceptable to both children and teachers. A larger study is warranted to confirm the effectiveness of interventions using the digital game to promote vegetable preference, willingness to taste, and intake.

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KEYWORDS

vegetable; food preference; serious games; video game; children; child; pediatric; obesity prevention; pilot study; gaming; educational game; nutrition; diet; healthy eating; food consumption; food intake

Introduction

Vegetable Consumption in Children

Healthy eating is recognized as a cornerstone of health promotion [1], yet there is a persistent gap that exists between dietary recommendations and actual intake [2]. This is particularly true for children, and especially with regard to fruit and vegetable consumption [3-5]. Establishing healthy eating habits during infancy and childhood is a widely shared public health goal [6], and the promotion of fruits and vegetables is often at the heart of such programs [7]. In fact, fruit and vegetable consumption is a protective factor for many health conditions [8]; however, children often begin to reject these foods during the developmental phase of neophobia [9]. Food neophobia is defined as the fear of eating new foods and appears around the age of 2 years, with a paroxysm between the ages of 2 and 6 years [10]. During this time, children tend to reject any new food or food presented in a novel way; this is especially true for vegetables, which is often explained by their low energy density and strong taste [10]. Evidence shows that the effects of food neophobia can be limited by increasing familiarity with the food and promoting exposure, associative learning, and tasting [11,12].

Serious Games to Promote Vegetable Intake

Gamification is an interesting new approach to engage children with vegetables in an attractive way. Moreover, this tool may be particularly suitable for highly neophobic children, as it works through visual exposure [13]. Some traditional games, such as memory or board games, have been shown to have a positive influence on eating behaviors [14,15], and the ability of digital games to improve health and food habits has also been tested, taking advantage of their ability to promote interactivity, provide fun, and attract attention [16]. The "Veggies4myHeart" digital game was developed in Portugal and consists of 5 mini games, each featuring a vegetable superhero. It was successfully tested with children aged 3-6 years and, when combined with exposure through vegetable tasting, led to an increase in vegetable consumption [17].

Challenges in Developing and Using Serious Games

Developing digital games is time-consuming and resource-intensive [16]. Using existing games is a solution to save resources; however, whether cultural specificities exist should be clarified before translating and using such games on a large scale. The question of how to use digital games more effectively also remains open. A digital game can be used as a stand-alone tool or integrated into a larger program and combined with other features.

Objectives

The aim of this pilot study was to translate the digital game Veggies4myHeart into French and to assess its influence on the preferences and willingness to taste vegetables of young Swiss children in combination with repeated tasting and education. As a second objective, we investigated teachers' opinions about the game and its acceptability and applicability in two classrooms.

Methods

Participants

This pilot study involved 45 children from two classes of an elementary school in the French-speaking part of Switzerland and their teachers. The children were between 5 and 6 years old and included 19 boys and 26 girls. The children from the two classes received the same intervention. The two teachers volunteered to participate in the study.

Ethical Considerations

Parents were informed about the intervention and could request that their child not participate in the study. No personal data were collected, so this pilot study did not fall under the Swiss Federal Human Research Act. However, it was submitted to and approved by the Service of Research in Education in Geneva, Switzerland (research number 584).

Veggies4myHeart Digital Game and Translation

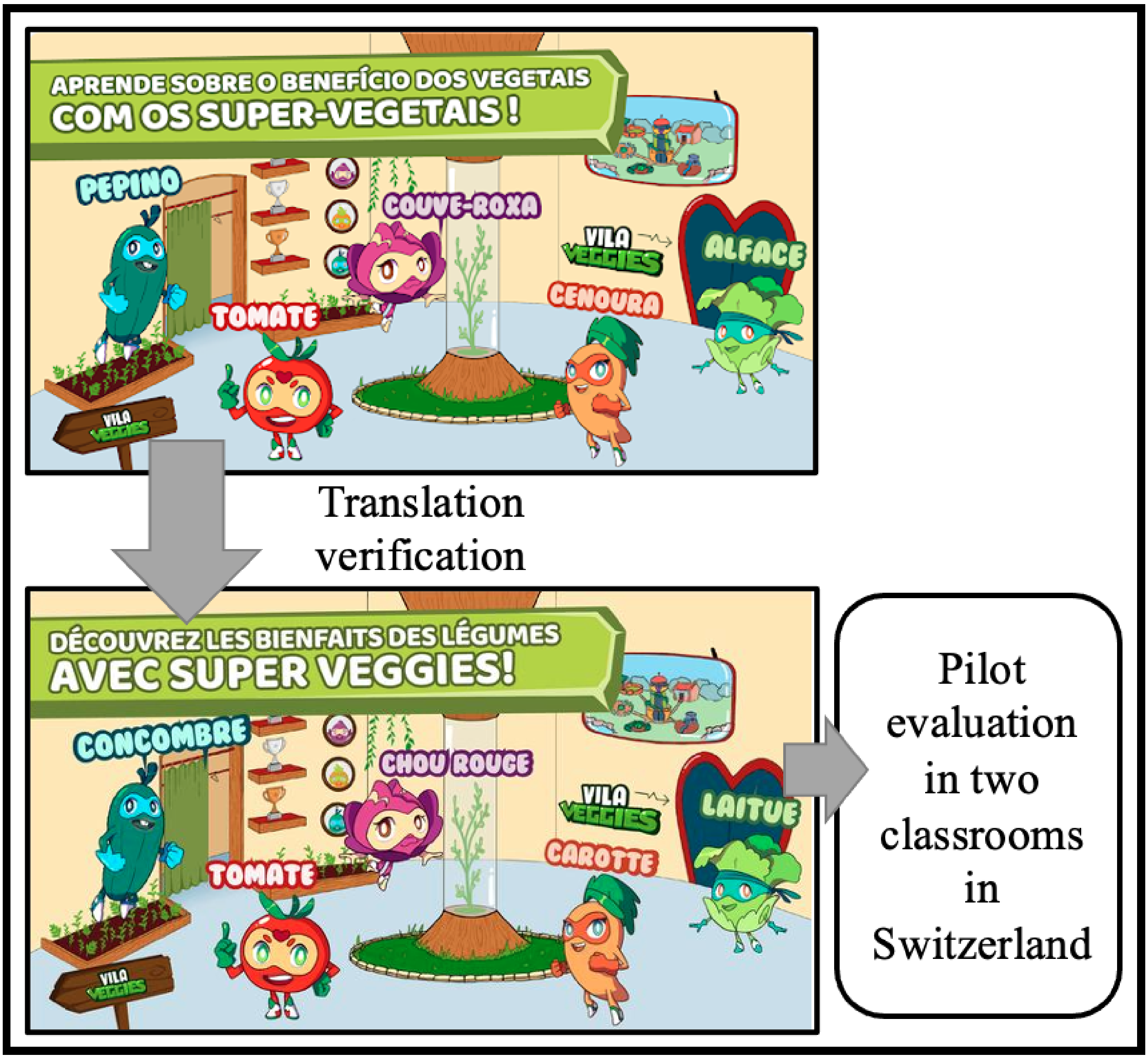
The Veggies4myHeart digital game was developed by a team of researchers at the Polytechnic of Leiria in Portugal [17]. The digital game was designed for preschool children aged 3-6 years and consists of 5 mini games, each related to one of the following vegetables: carrot, tomato, lettuce, cucumber, and red cabbage. For each vegetable, an introduction presents the vegetable, its characteristics, and health benefits and explains the goal of the task in the game.

The game setting is a farm. Children, through the vegetable superheroes, are involved in watering the fields, protecting the vegetables from pests, or picking the vegetables. In each mini game, children must race against the clock to collect as many points as possible, winning medallions at each step. Children can also customize their superheroes.

The Veggies4myHeart video game was developed to support the personal factors of motivation and knowledge that are necessary to improve the targeted behavior. Indeed, in a model based on social cognitive theory, Reynolds et al [18] show how environmental factors (availability, modeling, and nutrition education) and personal factors of motivation and knowledge can improve the specific behavior of fruit and vegetable consumption in young children. Specifically, the game enhances the following important determinants of vegetable consumption: (1) perceived self-efficacy through positive experiences with vegetables, persuasion, and by convincing the children of their ability to eat vegetables in different situations; (2) outcome expectations through age-appropriate persuasive communication and game stories that emphasize the positive effects of eating vegetables; and (3) food preferences by increasing familiarity with the vegetables. Knowledge about vegetables is also increased through the various messages delivered throughout the game. In addition, several known mechanisms involved in learning to eat vegetables underlie our intervention [19]. For example, the digital game allows nontaste exposure to vegetables. Previous studies have shown that it is possible to increase familiarity in the absence of real food through picture books, storybooks, and digital media [13,20]. Associating images of vegetables with a narrative or a character enhances the playful element of the learning experience and encourages a willingness to taste by enabling a positive affective experience during exposure [19]. Rewards, ranging from social praise to small nonfood gifts such as stickers, are another well-known strategy to increase learning and have been used to facilitate children's intake of fruits and vegetables and promote liking [21]. In digital games such as Veggies4myHeart, rewards are used differently: as participants progress through the game, they earn achievements, prizes, or rewards that encourage learning and increase extrinsic motivation to play the game [22,23].

The digital game was originally developed in Portuguese. A Portuguese French teacher translated the scripts into French, a Swiss researcher verified the French script, and two children recorded the texts in French, as illustrated in Figure 1.

Figure 1. Steps to translate Veggies4myHeart from Portuguese into French and to test it in Switzerland.



Procedures of the 5 Sessions

The research team visited each class for the intervention once a week for 5 consecutive weeks. Each session focused on one vegetable: carrot, red cabbage, lettuce, tomato, and then cucumber. The study took place in May and June 2021.

At the beginning of each session, the dietitian introduced the vegetable of the day and asked the children if they knew how to prepare or cook it. The characteristics and benefits of the vegetable were discussed. This short educational session was designed to complement the digital game.

The children then got into pairs and played the Veggies4myHeart digital game described below on an iPad-type tablet. Each child played the mini game related to the vegetable of the day for 10-15 minutes.

During each session, children were invited to taste the 5 vegetables presented raw and plain in small pieces and the investigator recorded the types of vegetables tasted. Repeated exposure was included in the intervention because it is a very simple yet powerful strategy to promote vegetable intake, as shown in a meta-analysis published in 2018 [24]. The authors found that intake was positively associated with the amount of taste exposure and was greater for unfamiliar vegetables and when they were presented in plain form [24]. Repeated exposure allows children to increase their familiarity with unknown vegetables and to learn about their safety, resulting in increased acceptance and liking [19].

At the end of the intervention, children received a booklet with recipes using the 5 vegetables in the game and information for parents on how to download the game for free if they wished. Throughout the whole process, the children were unaware of the objectives of the study.

Pre-Evaluation and Postevaluation of Preferences and Willingness to Taste

Two identical standardized assessment sessions were conducted by a team of dietitians. These sessions took place 1 week before the first session and 1 week after the last session. The assessment included an evaluation of the preferences of 10 food items, including 8 fruits and vegetables, and an assessment of the willingness to taste the 5 vegetables in the game as a way of evaluating behavioral neophobia [25].

To evaluate preferences, each child was asked to indicate his or her preference for each of the 10 photographed foods using a visual rating scale of 5 smileys (5: like it a lot; 4: rather like it; 3: neither like or dislike it; 2: rather dislike it; 1: dislike it a lot). The document used for this evaluation is provided in Multimedia Appendix 1. To assess the willingness to taste, each child was invited to taste the 5 vegetables from the digital game (ie, carrot, tomato, lettuce, cucumber, and red cabbage). The 5 vegetables were cut into small pieces and presented simultaneously on a table in front of the child, with a similar level of accessibility. The number of different vegetables tasted was counted.

Throughout the assessment, the children were assessed individually, and the dietitian remained neutral throughout the assessment (no help, praise, or encouragement). With the help of the teachers, a code corresponding to the child's number on the class list was used to identify the children. Thus, the investigators did not collect any personal data on the children.

Assessment of Acceptability and Applicability

To answer our second objective, the investigators observed and took notes on the process of each session. After the 5 sessions, they collected the teachers' opinions on the usefulness and acceptability of the digital game, potential adaptations, and the facilitators and barriers to its use in schools. Both teachers participated in a common semistructured interview based on open-ended questions (Multimedia Appendix 2). The interview was recorded and the teachers signed a consent form.

Data Analysis

Descriptive statistics are reported as means and SD, medians and IQR, frequencies, and percentages. Pre-post comparisons were performed using the Wilcoxon test for paired samples due to a lack of normal distribution. $P<.05$ was considered statistically significant. All analyses were performed using SPSS Statistics 27 (IBM Corp).

Regarding the teacher interviews, one researcher analyzed the data using a qualitative descriptive approach based on notes and recordings. The researcher identified dominant and relevant themes associated with the data and highlighted conceptual similarities and differences between the two teachers. Two other researchers reviewed the analysis and checked the themes for reliability. Themes were then synthesized, classified, and analyzed based on the interview grid and predefined research questions.

Results

Translation and Implementation

The Veggies4myHeart digital game, originally developed and accessible in Portuguese, was successfully translated into French. The narrative of the game and the messages about the 5 vegetables did not need to be changed, and no cultural adaptation was required. The main adaptation in game use related to the seasons in which the 5 vegetables are grown locally in Switzerland. Children and teachers did not report any problem with comprehension. The intervention was implemented as planned; however, a 45-minute period was necessary when taking into account the time needed for the children to settle into the classroom, wash their hands, and socialize with the dietitian.

Pre-Evaluation and Postevaluation of Preferences and Willingness to Taste

The pretest evaluation highlighted that some vegetables in the game already scored high in the children's food preferences, especially carrots. On a scale of 1-5 (5 being "I like it a lot"), the mean rating was >4 for carrots, cucumber, and tomato, as well as for apple, which was not part of the video game. The liking of carrots further improved by another 7%, but the greatest increase in preference was for red cabbage, which increased significantly by 31% to a mean score of 3.29 (SD 1.67; $P=.006$), as shown in Table 1. When combining the scores of the 5 vegetables in the game into a composite score, the children's liking improved post intervention. The preference for fruits and vegetables not present in the game did not change significantly in pre-post comparisons. Before the intervention, the mean score was 3.88 (SD 1.54) for apricots, 2.12 (SD 1.48) for fennel, and 4.31 (SD 1.35) for apples, and after the intervention, the mean scores were 4.09 (SD 1.31), 2.11 (SD 1.56), and 4.51 (SD 1.12), respectively.

A similar progression was seen in the willingness to taste task, with 24 (53%) children willing to taste red cabbage after the intervention compared to 16 (39%) before. However, none of the differences in willingness to taste were statistically significant (Table 2).

Table 1. Preintervention and postintervention mean score of preference of the five vegetables in the video game.[a]

	Pretest (n=42), mean (SD)	Posttest (n=45), mean (SD)	*P* value[b]
Lettuce	3.90 (1.46)	4.02 (1.47)	.37
Carrot	4.19 (1.40)	4.49 (0.99)	.16
Red cabbage	2.52 (1.49)	3.29 (1.67)	.006
Cucumber	4.10 (1.54)	4.31 (1.40)	.12
Tomato	4.07 (1.50)	4.13 (1.50)	.12
Composite score	3.76 (1.06)	4.05 (1.03)	.001

[a]Maximum score=5.

[b]Wilcoxon test for paired samples.

Table 2. Number and proportion of children who tasted each vegetable before and after the intervention.

	Pretest (n=41), n (%)	Posttest (n=45), n (%)	*P* value[a]
Lettuce	18 (44)	23 (51)	.25
Carrot	30 (73)	36 (80)	.23
Red cabbage	16 (39)	24 (53)	.09
Cucumber	29 (71)	33 (73)	.39
Tomato	26 (63)	29 (64)	.46

[a]Wilcoxon test for paired samples.

Teachers' Opinion on Acceptability and Applicability

Two teachers commented on the usefulness and acceptability of the digital game, the potential adaptations needed, and the facilitators and barriers to its use in schools.

Both teachers rated the game very positively and found it appropriate for children aged 4-6 years. They observed that the children were very interested and engaged in the activity. The teachers appreciated the progressive nature of the game, which allowed the children to start with easy levels and then move on to more complex games. In the teachers' view, the game helped to develop knowledge of the names of vegetables and familiarity with them. By remembering what they had to do in the game, the children were able to remember some functions of the vegetables (eg, watering the garden as an illustration of hydration).

The teachers appreciated that the children played in pairs, as this favored interesting interactions between the children. The initial 15 minutes of play was felt to be too long; 10 minutes per child was sufficient for the final sessions. In addition to the game, the teachers felt it was important to offer a tasting and a discussion about the different ways of consuming the vegetable in each session to give a concrete aspect to the activity.

To promote and facilitate the integration of the information, the teachers recommended systematically repeating the messages of the game during the conclusion of the activity following the game sequence. They also suggested developing visual material, such as pictograms for each vegetable or a laminated map of the game to facilitate navigation in the game.

Regarding the implementation of the activity in the classroom, the teachers stated that they could manage the sequence on their own, but this would require having tablets readily available.

Discussion

Principal Findings

In this study, a Portuguese digital game consisting of 5 mini games about vegetables was successfully translated into French and tested in two classrooms with children aged 5-6 years. No cultural adaptation was necessary, and the children played the digital game without any difficulties. The teachers confirmed their interest and the feasibility of integrating such a game into their teaching. In addition to the game, the children received information about the vegetables in the game and had the opportunity to taste them repeatedly. However, although the pre-post comparison of preferences and willingness to taste vegetables showed some promising trends, few differences were statistically significant.

Comparison With Prior Work

In the literature, eHealth interventions to promote fruit and vegetable intake consistently produce small but significant improvements. In a meta-analysis that included 19 studies (only 4 of which were in children), all showed a small effect size favoring eHealth interventions [26]. Tailored interventions and those using at least 7 behavior change techniques were the most effective [26]. Given the many factors that influence vegetable consumption, it is expected that no single tool or strategy will work for all children. Multicomponent interventions, on the other hand, combine several techniques, increasing the likelihood that all children will benefit from one strategy or another [19]. Interestingly, brief digital interventions can already be effective, although repeated exposure strengthens the effects [27]. The first study to test the Veggies4myHeart video game was conducted in Portugal. In a preschool, the video game combined with repeated tasting was compared with the use of a storybook and repeated tasting with or without sticker rewards and a control group [17]. After the intervention and at a 6-month follow-up, children in all groups, including the control group, had increased their vegetable consumption. In another study conducted in Taiwan with children aged 5-6 years, a 4-week intervention based on a computer game called "Healthy Rat King" resulted in increased nutritional knowledge among participants, but no differences in junk food consumption were observed compared to the control group [28]. Using a mobile app based on repeated visual exposure, modeling, and rewards, Farrow et al [29] showed an increase in the consumption and liking of vegetables displayed in the app compared to control group. Digital games raise a lot of interest and expectations to promote healthy eating in children, but studies evaluating them, including ours, often lack sufficient sample sizes and appropriate designs to demonstrate their effectiveness and to describe the mechanisms involved [30]. In addition, developing a digital game is expensive and requires a multidisciplinary team of experienced and skilled members [16]; therefore, to conserve resources, translating existing games is a rational and attractive option. In a previous study, an American digital game designed to reduce the risk of obesity and type 2 diabetes was translated and culturally adapted for Hong Kong Chinese children. As in our study, their evaluation, based on a survey and individual interviews, confirmed the acceptability and applicability of the game in the new context [31,32].

Digital Games as Prevention Tools

Serious games expand the range of learning tools available to promote balanced nutrition. We know that, in addition to experiential learning, playful activities enhance children's learning. Digital games appear to be an attractive complementary tool to promote vegetable intake while maintaining a balance between education and play and enjoyment, as an overemphasis on education risks reducing learning [16,19]. Indeed, both enjoyment and user experience have been shown to be positively correlated with learning, as measured by increased knowledge in children [33].

In addition to the game itself, implementation is a critical consideration for effective health promotion interventions. In this study, dietitians implemented the intervention. To scale up and sustain this type of intervention, teachers should be able to implement it by themselves. Following our experience, the two teachers confirmed that they thought the digital game could be used as an additional learning tool, as long as they had support for the logistical aspects, for example, from the school administration. In this respect, our game is easily accessible as a free application on common platforms. To further support teachers, some additional material would be useful, such as a teacher's guide with background information on the overall benefits of vegetables and the specifics of each vegetable, prompts and visuals for class discussions on each vegetable, and recipes. Because the Veggies4myHeart game is freely available, children can continue to play the game at home, potentially maintaining or increasing the impact of the intervention.

Strengths and Limitations

Despite the encouraging results, this pilot study has several limitations. First, the sample size was small and the study lacked a control group to isolate the effects of the intervention. Second, the design did not allow us to analyze the effect of the digital game separately from the effects of the discussions and tastings that were conducted concurrently, nor to identify which game elements were the more effective. Third, we did not measure the children's eating traits, such as fussiness. These factors should be taken into consideration in future analyses. However, based on a quantitative and qualitative evaluation, this study provides useful information for the development and implementation of future interventions that include a digital game to promote vegetable consumption in young children.

Future Directions

Future studies should include a larger sample size and a control group, ideally designed with multiple arms to allow a comparison between elements of combined interventions. Moreover, future samples should include children who do not especially like the vegetables to avoid or limit the ceiling effects observed in our study. Could digital games support food literacy through the development of functional and relational skills? This would be interesting to assess, as a digital game may promote basic nutrition knowledge and a healthy and positive relationship with food and encourage the experience of new and different foods, which are all important elements of food literacy [34]. More generally, larger studies including greater sample sizes are needed to assess the actual impact of digital games and to reach statistical significance.

Conclusions

Digital games are a useful and engaging tool for promoting vegetables to young children. In this study, an existing video game was translated into French and paired with repeated tasting and education to combine multiple strategies and increase the chance of reaching every child. Our experience shows that the digital game was easy for teachers to use in younger grades, but the logistical aspects should be very well prepared. Pre-post comparisons of preferences and willingness to taste vegetables showed some promising trends; however, confirmation with larger samples is warranted.

Using existing games and collaborating to translate them is a promising way to maximize development investments and increase the use and reach of such games. Future games should focus on unfamiliar vegetables and include in-game progression.

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

CB-P conceptualized the study; CB-P, ML, and SBDT developed the methodology; CB-P and SBDT administered the project; SBDT curated the data; SBDT, SSD, ML, and CB-P performed the analyses; SBDT wrote the original draft of the manuscript; and ML, SSD, MPG, and CB-P reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire used to assess children’s food preferences.
[PDF File (Adobe PDF File), 318 KB - games_v11i1e43843_app1.pdf]

Multimedia Appendix 2
English translation of the questions asked to the teachers regarding their opinion on the video game and the possibilities to use it in the classroom.
[PDF File (Adobe PDF File), 87 KB - games_v11i1e43843_app2.pdf]

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Review

The Application of Fully Immersive Virtual Reality on Reminiscence Interventions for Older Adults: Scoping Review

Zhipeng Lu[1], PhD; Wenjin Wang[1], MDes; Wei Yan[1], PhD; Chung Lin Kew[2], PhD; Jinsil Hwaryoung Seo[3], PhD; Marcia Ory[2], PhD

[1]Department of Architecture, Texas A&M University, College Station, TX, United States

[2]School of Public Health, Texas A&M University, College Station, TX, United States

[3]School of Performance, Visualization & Fine Arts, Texas A&M University, College Station, TX, United States

Corresponding Author:
Zhipeng Lu, PhD
Department of Architecture, Texas A&M University
3137 TAMU
College Station, TX, 77845
United States
Phone: 1 9798456183
Email: luzhipeng@live.com

Abstract

Background: The increasing number of older adults with mental, behavioral, and memory challenges presents significant public health concerns. Reminiscence is one type of nonpharmacological intervention that can effectively evoke memories, stimulate mental activities, and improve psychological well-being in older adults through a series of discussions on previous experiences. Fully immersive virtual reality (FIVR) may be a useful tool for reminiscence interventions because it uses realistic virtual environments connected to a person's significant past stories.

Objective: This review aims to examine empirical evidence regarding the application of FIVR in reminiscence interventions, its usability and acceptability, and its effectiveness in assisting the intervention to achieve optimal outcomes.

Methods: We followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) approach for scoping reviews. The PubMed, PsycINFO, Embase, CINAHL, Web of Science, ACM, and IEEE Xplore electronic databases were used for the search. We included peer-reviewed studies that used FIVR as an assistive tool for reminiscence interventions; were published between January 1, 2000, and August 1, 2022; reported empirical research; involved older adults as participants; and addressed health- and behavior-related outcomes or the feasibility and usability of FIVR. We used Endnote X9 to organize the search results and Microsoft Excel for data extraction and synthesis.

Results: Of the 806 articles collected from the databases and other resources, 11 were identified. Most of the studies involved participants aged between 70 and 90 years. Only 1 study did not involve those with cognitive impairments, whereas 3 specifically targeted people living with dementia. The results indicated that FIVR reminiscence interventions enhanced engagement and reduced fatigue. Although some studies have observed positive effects on anxiety, apathy, depression, cognitive functions, and caregiver burden reduction, these findings were inconsistent across other research. In addition, FIVR showed overall usability and acceptability with manageable side effects among older adults across various health conditions during reminiscence sessions. However, 1 study reported adverse feelings among participants, triggered by unpleasant memories evoked by the virtual reality content.

Conclusions: The role of FIVR in reminiscence interventions remains nascent, with limited studies evaluating its impacts on older adults. Many of the reviewed studies had notable limitations: small sample sizes, absence of rigorous research design, limited assessment of long-term effects, lack of measures for health and behavior outcomes, and quality of life. Beyond these limitations, this review identified a list of future research directions in 6 categories. On the basis of the review findings, we provide practical recommendations to enhance FIVR reminiscence interventions, covering topics such as virtual reality content, device choice, intervention types, and the role and responsibility of facilitators.

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KEYWORDS

older adults; fully immersive virtual reality; reminiscence; Alzheimer; cognitive function; mental health; psychological well-being; memory care; dementia; scoping review

Introduction

Background

In recent years, there has been a surge in groundbreaking technologies and their applications in transforming care, therapies, treatments, and health prevention for older adults. Fully immersive virtual reality (FIVR) is one among these rapidly evolving technologies applied in diverse interventions, including poststroke rehabilitation [1], cognitive training for people with neurodegenerative diseases [2], mobility and balance training [3], and the reduction of depression [4]. This paper examines the application of FIVR in reminiscence interventions through a scoping literature review, with a particular focus on people living with dementia or mild cognitive impairments.

Reminiscence Interventions

Reminiscence intervention is a type of nonpharmacological therapy [5] that was developed in the 1960s and has gained popularity since the 1980s [6]. Reminiscence is an act of recalling or retelling past experiences or facts [7]. As an early advocate of this technique, Butler [8] argued that reminiscence was an older person's natural adaptive response to late-life developmental crises, with thoughts related to their approaching death. Used in life review therapy, reminiscence helps an older person reorganize past experiences, settle unresolved issues, bring new meaning to the present life, and better prepare for death [8]. Molinari [9] expanded on the notion proposed by Butler [8] and purported that reminiscence activities could take many forms, including storytelling, autobiography, music, reunions, and scrapbooks. He suggested that reminiscence could be conducted in community or clinical settings, with a person or group of people, by laypersons, or by trained professionals; with structured or unstructured methods; or in a formal or casual format [9]. However, many states in the United States, such as Texas, require counseling therapy to be delivered by licensed professionals [10]; interventions done by family members, friends, and noncertified personnel may be referred to as informal exercises or activities.

Pinquart and Forstmeier [11] and Woods et al [12] identified three main types of reminiscence interventions: (1) simple reminiscence, which involved the recall and sharing of positive memories and stories to increase positive feelings; (2) life review, which was conducted in a structured way with the whole-life story, seeking to integrate both negative and positive memories; and (3) life review therapy, which typically aimed at the reevaluation of negative memories, promoting a more positive view of life.

According to Molinari [9], reminiscence interventions help reshape a person's views of life experiences and stories toward positive and coherent outcomes, focusing on strength, success, and lessons learned. Therefore, reminiscence interventions have been used in diverse settings for various purposes: in dementia and Alzheimer care to lessen behavioral and psychological symptoms and enhance cognitive function, social interaction, self-esteem, and quality of life [12,13]; in end-of-life care, such as hospices and palliative care, to enhance life satisfaction and reduce feelings of regret [14]; in patients with cancer to lower anxiety and depression scales and increase hope, dignity, and quality of life [15]; and in rehabilitation to motivate patients to actively participate in the rehabilitation process, fostering a sense of identity and continuity in their life story [16]. Moreover, a literature review conducted by Shin et al [17] revealed that a reminiscence intervention was effective in improving the quality of life and life satisfaction among community-dwelling older adults with no dementia symptoms.

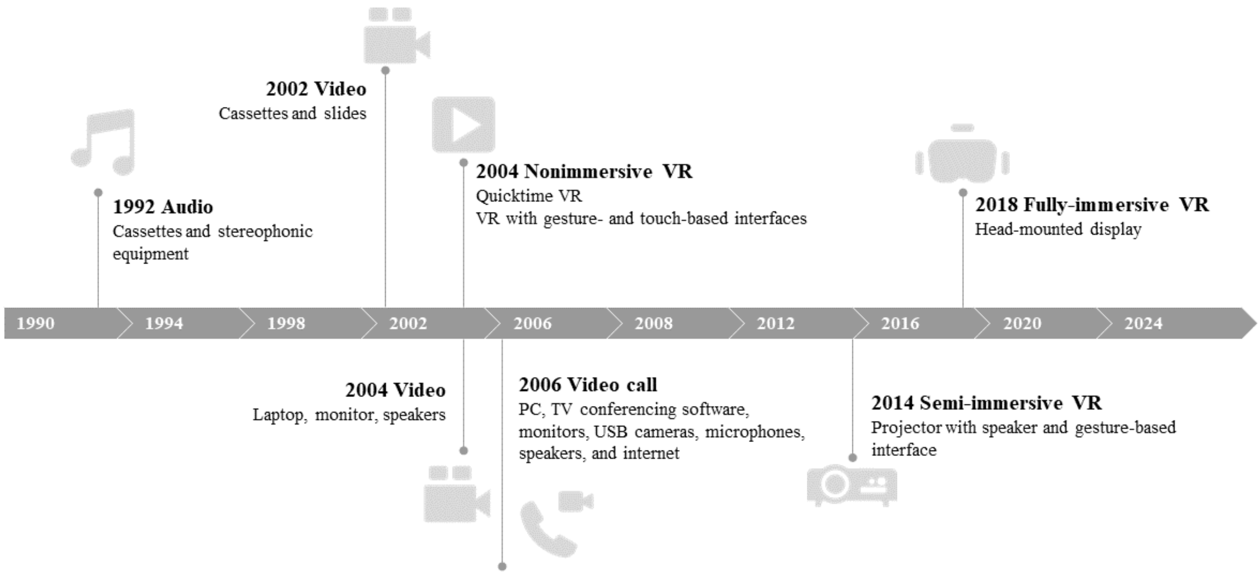
Cues for Reminiscence Interventions

Similar to other psychotherapeutic interventions, a reminiscence session is primarily carried out through conversations, with a provider guiding the person to recall past events, discuss their meanings and impacts, resolve past conflicts, and pave the way for more positive views of the present life. Various media or artifacts that provide visual or audio cues have been applied to stimulate memory and prompt conversations, especially for those with memory problems.

In a literature review, Lazar et al [18] reported that common media for reminiscence interventions included text, videos, photographs, images, music, audio, and personal objects and artifacts such as toys, which were closely related to the person's past experience. The authors also revealed that the technologies to present these media ranged from slide projectors and tape recorders from the 1990s to touchscreen tablets in the early 2010s [19-21]. Moreover, digital technologies have since created more innovative alternatives to aid reminiscence [22-25]. For example, personalized digital memory books and multisensory mobile multimedia environments delivered more content or multiple stimuli in convenient ways [26].

Figure 1 [19-25,27] shows the timeline of different technologies used in reminiscence interventions since 1992. It is worth noting that therapists may have used technologies to aid reminiscence activities in earlier years, but this was not documented in peer-reviewed publications.

Figure 1. Timeline of the technologies applied to reminiscence interventions documented in peer-reviewed publications. VR: virtual reality.



Virtual Reality as an Aid to Reminiscence

Virtual reality (VR) uses computer simulation to provide realistic visual and tactile experiences in a 3D virtual world. VR appears in many forms: (1) nonimmersive, in which a computer or television screen is used to display the content; (2) semi-immersive, in which multiple screens or a Cave Automatic Virtual Environment display present the virtual environment surrounding the participant [28]; and (3) fully immersive, in which the participant wears the VR head-mounted display or haptic devices to be fully immersed in the virtual world. According to Logan [29], VR possesses three main characteristics: (1) interactivity, whereby the user can interact with the virtual world through commands; (2) immersion, whereby the user should have similar authentic feelings, through different sensors, such as those in real environments; and (3) imagination, whereby the user should be able to imagine beyond the virtual world, finding new perspectives or new ways to solve problems.

VR has been applied in a variety of interventions for older adults. D'Cunha et al [30] conducted a literature review on the application of VR and augmented reality in nonpharmacological interventions, examining their effectiveness in promoting psychological health and users' experience. Three types of interventions were tested in the reviewed studies: (1) cognitive or memory training; (2) reminiscence; and (3) therapeutic activities, including physical exercises. The results showed that VR and augmented reality were preferred and well accepted by people living with dementia or mild cognitive impairment and that these technologies helped improve mood, apathy, and cognitive functions. However, some side effects raised concerns about negative feelings after the reminiscence sessions that triggered participants' unpleasant memories. Although immersive VR was used in some studies selected by the authors, most of them were semi-immersive but did not use a head-mounted display that would provide a fully immersive experience.

Although the first head-mounted VR display with 3D graphics and head tracking was invented in the 1960s [31], it was not until the last decade, marked by the introduction of the first consumer-grade VR headset (Oculus Rift) in 2011, that FIVR became more affordable, more technically accessible, and easier to use [32]. FIVR has been popular in a variety of fields such as gaming, education, professional training, medical practice, therapies, and research [33-37]. With its capability to promote interactivity, immersion, and imagination, FIVR may be an excellent aid for reminiscence interventions by stimulating or reactivating the past memories of older adults, especially those living with mild cognitive impairment or dementia.

Reminiscence Interventions for People Living With Dementia or Mild Cognitive Impairments

Population aging has brought about a rapid increase in the number of older adults with cognitive and behavioral problems. Rajan et al [38] estimated that 12.23 million Americans aged ≥65 years experienced mild cognitive impairments in 2020 and that this number would rise to 21.55 million in 2060. The Alzheimer's Association reported that 10% to 15% of people with mild cognitive impairment transitioned to dementia each year [39]. Furthermore, approximately 1 in 9 older adults (10.7%) in the United States had Alzheimer disease, accounting for 60% to 80% of people living with dementia. Cognitive impairment affecting memory, language, orientation, attention, and judgment leads to behavioral and psychological disturbances, dysfunction in activities of daily living, and instrumental activities of daily living [40-42]. Such functional disabilities and behavioral problems have added to caregivers' and family members' burdens and strained health care resources [43].

According to the Alzheimer's Association, pharmacological and nonpharmacological options may be available to treat cognitive impairments, depending on their causes [39]. However, pharmacological treatment options are limited, with only 6 drugs—specifically for Alzheimer disease—currently approved by the US Food and Drug Administration [39]. In addition, there is evidence that pharmacological treatments for behavioral and psychological symptoms of people living with dementia often come with adverse side effects, including an increased risk of falls and fractures, stroke, and even mortality and limited efficacy in symptom management [44]. Nonpharmacological therapies are safer options with manageable side effects for people with cognitive impairments than pharmacological treatments. These therapies can help reduce anxiety, depression, apathy, irritation, and other negative emotions and possibly decrease the need for pain and psychoactive medications by not inducing biological changes [45]. After reviewing the literature, Cammisuli et al [5] categorized nonpharmacological interventions into four main categories: (1) holistic techniques, including reality orientation that helps people living with dementia be aware of who and where they are and what time it is; cognitive stimulation therapy that uses a series of objects, themes, or activities, such as physical games, sounds, food, current affairs, scenes, word association, using money, and number games to stimulate cognitive functioning; and reminiscence; (2) brief psychotherapies, a type of psychodynamic therapy that emphasizes the identity of people living with dementia through a conversation about past experience, with the aim of reducing emotional distress and other behavioral problems; (3) cognitive methods, such as the space retrieval technique, which trains people living with dementia to regain the ability to associate names with human faces or with objects; and (4) alternative strategies, such as music therapy and bright light therapy [5].

As previously noted, Cammisuli et al [5] categorized reminiscence interventions as a holistic technique of nonpharmacological therapy. Evidence has shown that appropriate reminiscence interventions for older adults with cognitive impairment can effectively evoke memories, alleviate anxiety and depression, reduce stress, manage cognitive decline, increase self-esteem, and improve quality of life [11,46,47]. Importantly, these interventions may potentially lower caregivers' burden and stress due to the improvement in their care recipients' psychological, mental, and behavioral health [48], which is significant as the world is experiencing a serious shortage in the nursing workforce.

Research Aims

We found little collective knowledge on how FIVR works in reminiscence interventions. Therefore, this scoping review aimed to assess and synthesize existing evidence regarding the influence and effectiveness of FIVR as an aid in reminiscence interventions. We expected the findings to elucidate potential directions for future research, offer recommendations for practice, and address the critical needs of caring for frail older adults, particularly those living with dementia and mild cognitive impairments.

Methods

Overview

We adopted PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews) to map the evidence for FIVR-based reminiscence interventions. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) is a minimum set of evidence-based items for reporting in systematic reviews and meta-analyses [49]. The PRISMA-ScR—with 20 essential reporting items and 2 optional items—was created to synthesize evidence and assess the scope of the literature on a topic [50]. The detailed descriptions of the 22 items are reported in Multimedia Appendix 1. Compared with systematic reviews, scoping reviews address a broader research question [51]. They allow researchers to identify the scope of the literature in a certain area, provide a clear indication of the available literature and an overview of its focus, and examine emerging evidence that informs field practice [51]. We adopted the scoping review approach because it perfectly aligns with our study's aims.

Search, Screening, and Selection

We applied the following inclusion and exclusion criteria for article selection: (1) the use of FIVR as an aid for reminiscence interventions; (2) the inclusion of adults aged ≥65 years; (3) reporting on empirical studies; (4) reporting on outcomes related to health and well-being and the feasibility or usability of FIVR; (5) publication in English; and (6) publication in peer-reviewed journals or peer-reviewed conference proceedings between January 1, 2000, and August 1, 2022. Electronic databases—PubMed, PsycINFO, Embase, CINAHL, Web of Science, ACM, and IEEE Xplore—were used for the literature search. The search terms included all possible synonyms and combinations of "Reminiscence Interventions and/or Therapies" (reminiscence, life story, reminisc* therapy*, and memory simulation) and "Virtual Reality" (VR, imagined 3D environment, and simulat* environment).

First, a researcher used a consistent set of keywords to search each database between March and August 2022. The search results were imported and organized using Endnote X9 (Clarivate), a computer reference management program. Second, 2 researchers scanned the titles and subsequently the abstracts of the retrieved articles. They then independently reviewed the full texts, collating all eligible articles. References from these articles were also scrutinized to capture any potentially overlooked information in the initial database search. Subsequently, the researchers deliberated each article in detail, deciding on its inclusion based on predetermined criteria and the study objectives. In case of any disagreements between the 2 researchers, a third researcher was ready to intervene with a final decision. However, this contingency was not triggered.

Data Extraction and Analysis

We continued to use Endnote X9 to manage the selected articles and Microsoft Excel spreadsheets for data extraction. The categories of the data included title, author, year of publication,

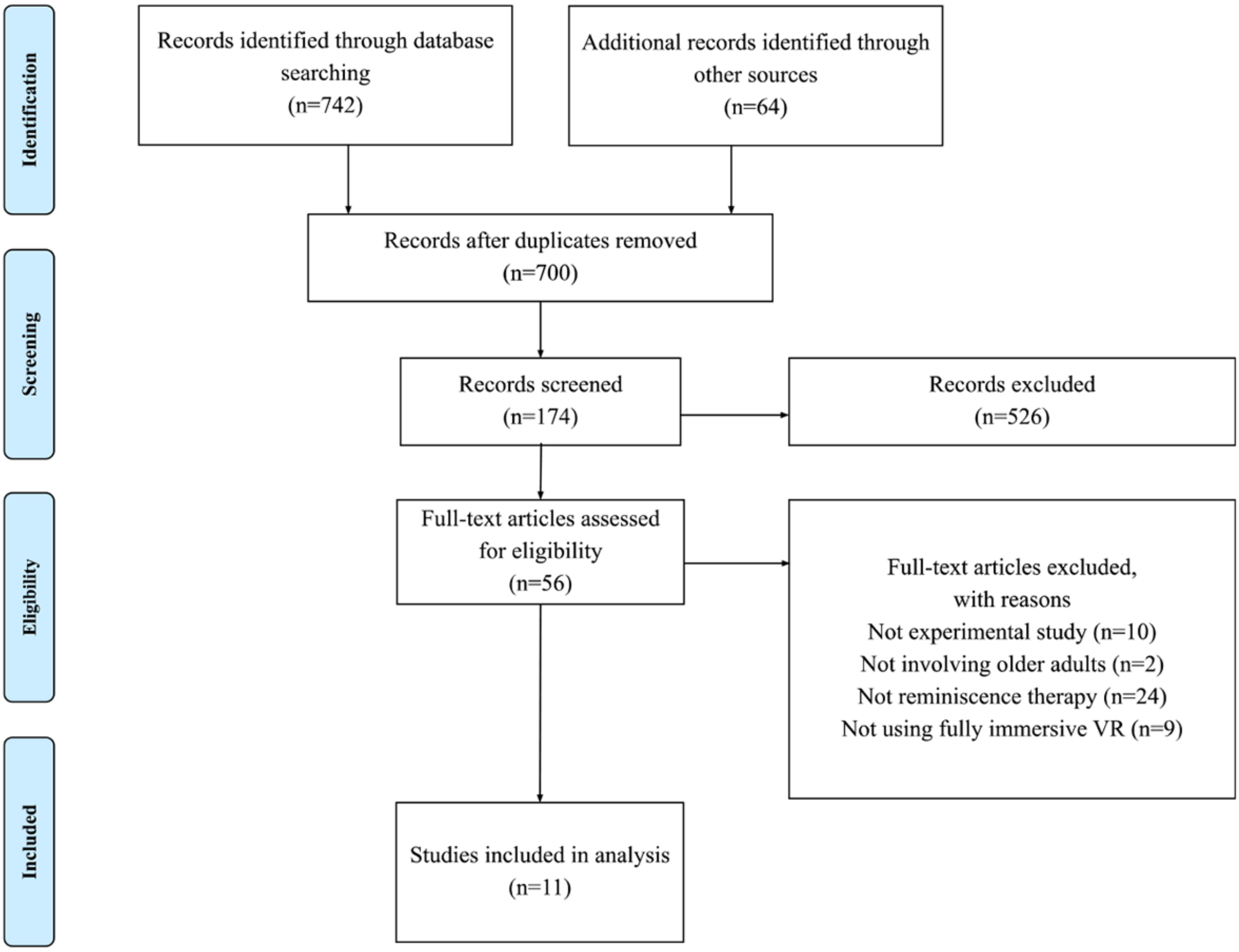
publication type such as journal or conference paper, research design, research questions, intervention information including reminiscence types, VR contents, VR types, and devices, and participant information, measurements, results, study limitations, and future research questions. One researcher charted the data into a spreadsheet, whereas another oversaw the process, critically assessed the extraction, and made necessary adjustments based on joint discussions when a disagreement arose. The charted data were further summarized and analyzed by both researchers.

Results

Search Results

The screening and selection process for eligible articles is shown in Figure 2. Additional details can be found in Multimedia Appendix 2. The first search resulted in 742 articles from the databases and 64 others from further sources such as references of selected articles. After removing the duplicates, 700 articles were retained. After the authors screened each article's title and abstract, 174 articles remained in the pool. We quickly scanned the full text and retained 56 articles for additional evaluation. Through the detailed full-text reviews, 45 studies were excluded according to the inclusion criteria, with specific reasons documented in Figure 2. Finally, 11 studies were identified for this scoping review [25,40,52-60].

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the literature search and screening process. VR: virtual reality.



Characteristics of the Selected Studies

Table 1 summarizes the general information of the selected studies, including basic article information such as authors, year of publication, and research design.

Nine articles were published in peer-reviewed journals and 2 in peer-reviewed conference proceedings. There were 4 studies that were conducted in Australia [53,56-58], 4 in Asia (China, Taiwan, and Japan) [54,55,59,60], 2 in Europe (Germany and Portugal) [25,40], and 1 in the United States [52]. The years of publication were between 2018 and 2022.

Table 1. General information summaries of selected studies.

Study, year	Publication type (study location)	Research design
Afifi et al [52], 2021	Journal paper (United States)	Mixed methods
Baker et al [53], 2021	Conference paper (Australia)	Qualitative research
Coelho et al [40], 2020	Journal paper (Portugal)	Mixed methods
Huang and Yang [54], 2022	Journal paper (Taiwan)	Quantitative research
Klein et al [25], 2018	Journal paper (Germany)	Qualitative research
Niki et al [55], 2020	Journal paper (Japan)	Quantitative research with randomized crossover research design
Saredakis et al [56], 2020	Journal paper (Australia)	Mixed methods
Saredakis et al [57], 2021	Journal paper (Australia)	Quantitative research with multisite nonrandomized controlled trial
Webber et al [58], 2021	Journal paper (Australia)	Qualitative research
Xu and Wang [59], 2020	Conference paper (China)	Randomized controlled trial
Yahara et al [60], 2021	Journal paper (Japan)	Case study

Participant Characteristics

Table 2 lists the participant characteristics of the included studies. All the studies involved older participants, with an average age between 80 and 90 years in 6 studies and 70 and 80 years in 3 studies. Two articles did not specify the participants' ages. All but one study included participants with cognitive impairments. Three studies specifically stated that they recruited people living with dementia [40,53,59]. Three studies reported other health problems in their participants, including depression, anxiety, heart diseases, mental health issues, mobility challenges, hearing difficulty, Parkinson disease, and stroke [54,56,57].

Table 2. General participant information.

Study, year	Sample size, gender, and age	Cognitive or dementia conditions	Other health conditions
Afifi et al [52], 2021	• 21 residents (female: n=18, male: n=3; mean age 83.1, SD 3.72 y) with their family members (female: n=9, male: n=12; mean age 59.86, SD 14.12 y)	• Mild cognitive impairment (n=9) • Mild dementia (n=4) • Moderate dementia (n=8)	• Not specified
Baker et al [53], 2021	• 16 older adults (female: n=5, male: n=11)	• Not specified	• Hearing difficulty (n=4) • Need mobility aid (n=2) • Mental health problem (n=1) • Parkinson disease with communication or movement problem (n=1)
Coelho et al [40], 2020	• 9 individuals (female: n=6, male: n=3; mean age 85.6, SD 7.4 y)	• Dementia (n=9) • Moderate cognitive decline (n=3) • Moderately severe cognitive decline (n=3) • Severe cognitive decline (n=3)	• Not specified
Huang and Yang [54], 2022	• 20 participants (female: n=11, male: n=9; mean age 79.0, SD 7.8 y) • Among the 20 participants, 7 were assessed 3-6 mo after the intervention	• Very mild dementia (n=2) • Mild dementia (n=15) • Moderate dementia (n=3)	• Not specified
Klein et al [25], 2018	• 6 participants (female: n=3, male: n=3; mean age 74.67, SD 1.31 y)	• Dementia (n=4) • Cognitive impairment without an unequivocal diagnosis of dementia (n=2)	• Not specified
Niki et al [55], 2020	• 10 individuals (female: n=6, male: n=4; mean age 87.1, SD 4.2 y)	• Normal cognition (n=9) • Suspected mild cognitive impairment (n=1)	• Not specified
Saredakis et al [56], 2020	• 17 participants (female: n=10, male: n=7; mean age 87.3, SD 6.3 y)	• No or minimal cognitive impairment (n=10) • Mild cognitive impairments (n=3) • Moderate cognitive impairments (n=4)	• Depressive symptoms (n=6)
Saredakis et al [57], 2021	• Experiment group: 15 participants (female: n=10, male: n=5; mean age 81.7, SD 6.6 y) • Active control: 14 participants (female: n=9, male: n=5; mean age 85.9, SD 8.1 y) • Passive control: 14 participants (female: n=9, male: n=5; mean age 87, SD 8.7 y) • Total: 43 participants (female: n=28, male: n=15; mean age 84.8, SD 8 y)	• Memory-related dementia or Parkinson disease (n=5) • Memory-related dementia or Parkinson disease (n=3) • Memory-related, dementia or Parkinson disease (n=3) • Memory-related dementia or Parkinson disease (n=11)	• Depression (n=5) • Anxiety (n=5) • Heart disease (n=8) • Stroke (n=2)
Webber et al [58], 2021	• 6 participants + 1 participant in pilot study	• With signs of cognitive impairment (n=4)	• Not specified
Xu and Wang [59], 2020	• Virtual reality–based group: 10 participants (female: n=5, male: n=5; mean age 76.7, SD 5.5 y) • Photo-based group: 10 participants (female: n=8, male: n=3; mean age 79.4, SD 2.0 y) • Blank group (verbally guided): 10 participants (mean age 78.5, SD 3.4 y)	• Mild to moderate dementia	• Not specified
Yahara et al [60], 2021	• 2 participants (female: n=1, male: n=1; age 80 and 92 y)	• Mild cognitive impairment (n=2)	• Not specified

Research Designs

There was 1 randomized crossover trial [55] and 1 randomized controlled trial [59]. Two quasi-experiments with pre-post comparisons were included [56,57], one of which had a control group. Another quasi-experiment was conducted with pre-post comparisons, wherein the intervention was offered twice a week over a 3-month period. Assessments were performed immediately and 3 to 6 months after the intervention [53]. The remaining studies included 3 qualitative studies [30,43,47], 2 mixed methods studies [40,52], and 1 case study [60]. The sample sizes ranged from 2 to 43.

FIVR Instruments and Stimuli

Tables 3 and 4 summarize the VR-related information of the selected studies, including VR types and visual contents, outcome measures, measurement methods, and results.

Table 3. Virtual reality (VR) types and visual contents used in the selected studies.

Study, year	VR type	Visual content
Afifi et al [52], 2021	• Photo based • Video based • Computer graphic based	• Virtual adventures • Virtual life story • Virtual photos and videos
Baker et al [53], 2021	• Computer graphic based	• School hall and classroom
Coelho et al [40], 2020	• Video based	• Specific streets, squares, gardens, churches, and historical landmarks that were meaningful to participants
Huang and Yang [54], 2022	• Computer graphic based (with customized narration and music that was significant to the person)	• Historical type of residence commonly found throughout Taiwan from 1960-1980 • Interactive features: the participant could use controller to hold rice to fee chickens
Klein et al [25], 2018	• Photo based • Video based	• Time travel (Berlin, 1949-1970; Paris, 20th century), movie stars (1950-1960), Germany television shows (later 20th century), or handicraft images
Niki et al [55], 2021	• Photo based • Computer graphic based	• A theme park with 6 familiar situations to those aged ≥75 y
Saredakis et al [56], 2020	• Photo based	• Personal tailored content
Saredakis et al [57], 2021	• Photo based	• Personal tailored content (not specified)
Webber et al [58], 2021	• Photo based	• Personal nominated content
Xu and Wang [59], 2020	• Computer graphic based	• A Chinese rural cottage in the 1970s with an area of 30 m2
Yahara et al [60], 2021	• Photo based	• Personal memorable places (not specified)

Table 4. Measures, measurement instruments, and results.

Study, year	Measure	Measurement instruments	Results
Afifi et al [52], 2021	• User satisfaction and perceptions • Conversational and behavioral engagement • Kinesics engagement	• Self-report questionnaire • Coding analysis of video recording • Coding analysis of video recording	• VR[a] deemed to be safe, extremely enjoyable, and easy to use by residents and family members • Residents being more conversationally and behaviorally engaged with their family members in VR sessions than in the baseline telephone calls • Residents with dementia reporting greater immersion in the VR than residents with MCI[b] • Residents with MCI being more kinetically engaged while using the VR than residents with dementia.
Baker et al [53], 2021	• Older adults' ability to participate	• Questionnaire, interviews, screen-captured video, observation notes, photographs, and short video recordings	• The virtual environment playing an effective role in surfacing memories and scaffolding reminiscence
Coelho et al [40], 2020	• Engagement and behavior • Manifestation of psychological and behavioral symptoms • Specific symptoms associated with simulation experiences • Psychological and behavioral symptomatology and the quality of life • Caregivers' opinion	• Coding analysis of observation • Coding analysis of observation • Self-report questionnaire • Structured interview with a knowledgeable informant • Semistructured interview	• Participants being very interested in exploring the immersive virtual environment and addressing positive or happy memories with frequently spontaneous communications and without simulator sickness in most cases • No significant differences found in psychological and behavioral symptomatology and the quality of life • Potentially beneficial experience for most participants reported by caregivers
Huang and Yang [54], 2022	• Overall cognitive function • Cognitive impairment • Dementia status • Depression • Caregiver burden	• CASI[c] • MMSE[d] • CDR[e] and its CDR-SB[f] • CESD[g] • ZBI[h]	• No significant differences in cognition (MMSE and CASI), global status of dementia (CDR-SB), and caregiver burden (ZBI) scores before and immediately after the intervention • No significant differences in MMSE, global status of dementia (CDR-SB), and caregiver burden (ZBI) scores immediately after the intervention and 3-6 mo after the intervention • Significantly decreased cognitive abilities (CASI) 3-6 mo after the intervention compared with those immediately after the intervention • Significantly improved depression (CESD) symptom immediately after the intervention • Significantly improved depression (CESD) symptom 3-6 mo after the intervention, compared with those immediately after the intervention
Klein et al [25], 2018	• "Destructive" and "supportive" behaviors • Usability • Caregivers' recommendations and assessment of feasibility	• Rating with a qualitative behavioral protocol • Rating with ISO 9241-110 criteria • Semistructured interview	• The prototype fostering conversations between participants and caregivers, positive interactions, and more "supportive" behaviors (eg, recognition, celebration, relaxation, validation, and facilitation) than "destructive" behaviors (eg, outpacing, ignoring, and imposition). • The prototype deemed to be suitable for daily care but being needed to be more fluently and with a bigger angle by caregivers

Study, year	Measure	Measurement instruments	Results
Niki et al [55], 2020	• Anxiety • Satisfaction and side effects	• Self-report questionnaire • Self-report questionnaire	• VR reminiscence reducing anxiety without causing serious side effects. • VR with live-action images being preferred by participants than computer graphics images
Saredakis et al [56], 2020	• Apathy; side effect; realistic experience • Verbal fluency • Expectations or enjoyment • Debriefing	• Self-report questionnaire • Task • Self-report questionnaire	• Enjoyable and acceptable experience with some negative symptoms or side effects reported by all study particiapnts • Improved semantic scores but not phonemic fluency scores found in participants • Greatest cognitive improvements after a VR reminiscence experience found in participants with higher levels of apathy
Saredakis et al [57], 2021	• Apathy • Cognition • Depression; quality of life; loneliness; side effect • Staff's opinions • Attendance and responses	• Questionnaire • Examination • Self-report questionnaire • Staff questionnaire • Coding analysis of recordings	• Most participants in the VR group preferring to watch content in VR than on a flat screen. • Participants enjoying the process of reminiscence • Participants reporting their willingness to do reminiscence again. • No significant results observed for cognition, depression, quality of life, and loneliness after therapy • No reported significant side effects or discomfort
Webber et al [58], 2021	• Perceived value; varied forms of reminiscence; challenges • Motivation and expectation	• Observation, semistructured interviews, and questionnaire • Interviews with family members	• Various past memories being elicited for all participants with mixed feelings expressed by several participants. • Virtual visits prompting various forms of reminiscence without noticeably differences compared with tablet computers. • Diverse expectations about the potential value of virtual visits revealed by families
Xu and Wang [59], 2020	• Acceptability (motivation, presence, and VR sickness) • Autobiographical memory	• Self-report questionnaire • Rating with video recording	• The VR group and the photo group with higher scores in recalling autobiographical memory than the blank group, with no significant difference between the VR group and the photo group • Higher levels of interest, motivation and perceived security, and lower levels of anxiety and fatigue in participants in both the VR group and the photo group than those in the blank group • Significantly higher level of pleasure reported in the VR group than those in the photo group. • High levels of presence with negligible sickness symptoms in the VR group
Yahara et al [60], 2021	• Anxiety; side effect and satisfaction; motivation • The burden of care • Attitude toward participation in the study	• Self-report questionnaire • Questionnaire by family members • Coding analysis of observations and videos	• Reduced anxiety and the burden of care without serious side effects by IVR[i] reminiscence • Similar effectiveness found between remote IVR reminiscence and the face-to-face session

[a]VR: virtual reality.

[b]MCI: mild cognitive impairment.

[c]CASI: Cognitive Abilities Screening Instrument.

[d]MMSE: Mini-Mental State Examination.

[e]CDR: Clinical Dementia Rating.

[f]CDR-SB: Clinical Dementia Rating–Sum of Boxes.

[g]CESD: Center for Epidemiological Studies Depression.

[h]ZBI: Zarit Caregiver Burden Interview.

[i]IVR: immersive virtual reality.

The VR goggles developed by Oculus were used in most studies (n=8): Oculus Go in 5 studies [52,55,56,58,60], Oculus Rift in 2 studies [40,54], and Oculus Quest in 1 study [57]. Coelho et al [40] used Samsung Gear VR as a head-mounted display in addition to the Oculus Rift. Xu and Wang [59] adopted the HTC VIVE Focus headset. Huang and Yang [53] used the HTC VIVE Pro version. Klein et al [30] developed a VR goggle—the "Binoculars" prototype—for their own project.

We divided FIVR stimuli into three categories: (1) photo based, which used 360° photos of real environments; (2) video based, which used 360° videos of real environments; and (3) computer graphic based, which used 360° images or animations of virtual environments generated by computer 3D modeling programs. Seven studies used photo-based VR stimuli [25,52,55-58,60]. Five studies used computer graphics–based VR, one of which incorporated recorded customized narrative and simple interactive functions via VR handles [52-55,59]. Two studies applied video-based VR [3,30], whereas 3 adopted ≥2 types of VR stimuli [25,52,55].

Types of Reminiscence Interventions

Only the study conducted by Saredakis et al [57] specified the type of reminiscence intervention used: a semistructured simple reminiscence approach emphasizing positive memories. The 2 other possible approaches, "life review" and "life story review," were not found in the rest of the articles.

Reminiscence interventions in the selected studies can be categorized based on the way they were conducted (group or individual) and the people involved (certified therapists, caregivers, or researchers). Eight studies were conducted using an individual format. Only the study by Baker et al [54] investigated how VR applications facilitated group reminiscence, in which participants communicated with each other and with a facilitator who was determined before the conversation started. During the interventions, 5 studies used researchers as facilitators [40,53,56-58]. One study used a professional team comprising pharmacists, an occupational therapist, a clinical psychologist, a certified psychologist, and a pharmacy student [60]. Interventions in 2 studies were conducted by researchers accompanied by caregivers or nursing staff [55,59]. All but 2 were conducted only through face-to-face meetings [52,60]. Participants in the study by Afifi et al [52] experienced the FIVR scenarios simultaneously with their family members who lived at a distance, interacting with each other remotely.

Health-Related and Behavior-Related Outcomes

All studies reported health- and behavior-related outcomes after reminiscence interventions. For the participants, we identified seven types of health- and behavior-related outcomes reported in the studies: (1) anxiety, (2) apathy, (3) cognitive functions or dementia status, (4) engagement, (5) depression, (6) loneliness, and (7) fatigue.

Anxiety

Three studies examined the effect of FIVR reminiscence on anxiety [40,55,60]. Instruments for measuring anxiety included the State-Trait Anxiety Inventory Self-Report Questionnaire [55,60], the Cornell Scale for Depression in Dementia, and the Neuropsychiatric Inventory [40]. Niki et al [55] found that FIVR reminiscence interventions reduced anxiety in older adults after the first session, maintaining effectiveness after the second [55]. They discovered that 360° photos are more effective than computer-generated graphics. Yahara et al [60] compared face-to-face and remote FIVR reminiscence sessions in 2 participants with mild cognitive impairments. Both participants experienced significantly decreased anxiety after the face-to-face sessions. However, after shifting to the remote session, 1 participant displayed a slight increase in anxiety, possibly due to the difficulty in remote communication, whereas the other participant's anxiety level continued to decrease. In the study by Coelho et al [40], some participants exhibited mild or intermittent anxiety and agitated behaviors during VR reminiscence sessions, which might have been caused by the disruption of participants' daily routines and unfamiliarity with the experiment environment [40].

Apathy

Apathy is defined as a "lack of feeling or emotion" or a "lack of interest or concern" [61]. Four studies assessed participants' changes in apathy after FIVR reminiscence interventions [40,56,57,60]. Saredakis et al [56,57] evaluated the effect of FIVR reminiscence therapy on apathy through verbal fluency and the Apathy Evaluation Scale. Verbal fluency, as noted by the authors, demonstrates the capability for executive control and initiation. The decline in these executive functions was associated with decreased apathy. They found that participants had improved semantic scores—the ability to name as many words as possible, starting with specific letters but not phonemic fluency scores and the ability to list more words in the category of either animals or fruit or vegetables—after the reminiscence session [56]. In another study conducted by the same team, there was an improvement in participants' apathy scale scores after reminiscence interventions [57]. Using the Cornell Scale for Depression in Dementia and the Neuropsychiatric Inventory, Coelho et al [40] found no significant improvement of apathy. Yahara et al [60] assessed participants' motivations and found that the effects of FIVR reminiscence on participants' apathy levels were mixed.

Cognitive Functions and Dementia Status

Three studies assessed the effects of the FIVR reminiscence intervention on participants' cognitive functions or dementia status, using measurement tools including the Cognitive Abilities Screening Instrument, the Mini-Mental State Examination, the Clinical Dementia Rating, the Addenbrooke Cognitive Examination III, and the Psychogeriatric Assessment Scales [53,56,57]. Two studies reported nonsignificant findings [56,57].

Huang and Yang [53] noted no significant cognitive ability differences before and immediately after the intervention, but the scores significantly declined 3 to 6 months later, implicating that the intervention might help sustain participants' cognitive functions [53]. In addition, Saredakis et al [56] observed that participants with higher apathy levels showed greater cognitive improvement after the intervention.

Engagement

Engagement was evaluated in 3 studies through observations [25,40,52]. Afifi et al [52] stated that participants were more engaged in conversations and behaviors with their family after FIVR reminiscence sessions. Those with mild cognitive impairments exhibited more kinetic engagement than people living with dementia [52]. Coelho et al [40] and Klein et al [25] found that FIVR reminiscence interventions encouraged conversation and positive participant-caregiver interactions.

Depression

Depression was measured using the Center for Epidemiological Studies Depression and the Geriatric Depression Scale (Short Form) in 2 studies [53,57]. Huang and Yang [53] noted that participants experienced significant depression improvements immediately and 3 to 6 months after the intervention. In contrast, Saredakis et al [57] reported no significant influence on depression.

Loneliness

One study assessed intervention effects on loneliness using the Three-Item Loneliness Scale, finding no significant outcomes [57].

Fatigue

One study reported less fatigue in the reminiscence sessions supported by FIVR and photos, compared with the control group with no visual aids [59].

Quality of Life

Two studies concluded that FIVR reminiscence interventions did not significantly affect participants' perceived quality of life, as assessed by the European Health Interview Survey–Quality of Life (EUROHIS-QOL) 8-item Index and the Quality of Life in Alzheimer Disease 13-item Scale [40,57].

Caregivers' Burdens

Caregivers' burdens were examined in 2 studies. Yahara et al [60] found that the FIVR reminiscence intervention reduced caregivers' burdens, but Huang and Yang [53] reported no significant differences in the caregiver burden scores before and after the intervention.

Usability and Acceptability

The usability and acceptability of FIVR in reminiscence sessions were evaluated using various methods such as a self-report questionnaire [55], behavior observation and analysis [25,40,52], and interviews [58]. Most participants indicated that FIVR reminiscence effectively evoked their past memories and was both enjoyable and acceptable. However, 1 study reported that FIVR triggered unpleasant memories in several participants [58].

Of the 4 studies addressing adverse effects, Saredakis et al [56] reported "some" negative symptoms or side effects. In contrast, the other 3 studies found "no simulator sickness" [40], "no significant side effects/discomfort" [57], and "negligible sickness symptoms" [59].

Four studies included caregivers and family members as participants [25,40,58,60]. Both Coelho et al [40] and Webber et al [58] observed that caregivers and family members viewed the FIVR reminiscence experience as potentially beneficial and valuable. However, 1 study [25] noted that caregivers found the reminiscence intervention impractical in an ambulant daycare setting because of the lack of staff for individual sessions.

Comparison Between FIVR and Other Technologies

Three studies compared different effects between the applications of FIVR and other technologies in reminiscence sessions [57-59]. Two studies found that the use of FIVR and a flat screen for reminiscence did not result in noticeable differences among participants [57,58], although participants in the study by Saredakis et al [57] preferred the FIVR experience over a flat screen. Xu and Wang [59] reported that both FIVR and printed photos could elicit the recall of autobiographical memory with no significant difference. However, the participants experienced greater pleasure in FIVR than in printed photos. In addition, Yahara et al [60] compared remote and in-person FIVR sessions and found no significant differences in terms of effectiveness.

Study Limitations

All selected articles but one discussed their study limitations. Common limitations across multiple studies were (1) small sample size [40,52,53,55,57,60], (2) the absence of a control or comparison group [40,52,53,56], and (3) participant selection bias [53,57,58]. Other limitations were related to self-report errors [56,60], the lack of long-term or follow-up assessment [40,52], the unavailability of validated assessment tools for specific components [40], being affected by the COVID-19 pandemic [57,60], exclusion of participants with severe cognitive impairments [57,59], and imperfect FIVR contents [53,55].

Future Research Directions

The authors advocated for a well-designed study with control or comparison groups, an adequate sample size, and follow-up or long-term assessment for future research on FIVR reminiscence interventions [25,40,55,56,59,60].

They also identified an extensive range of future research directions, encompassing 16 directions across 6 aspects:

1. Caregiver aspect
   - Investigating training for family caregivers to safely use FIVR for reminiscence sessions [52]
   - Examining the effects of the caregiver in charge [25]
2. Health and behavioral improvement aspect
   - Further investigation of the effects of FIVR reminiscence on psychological or behavioral symptoms, cognitive functions, and quality of life [40,53]
3. Social or engagement aspect

- Examining the social aspect of FIVR and its application in older adult care settings, at home, or with family members [52,54]
- Examining how to improve participants' engagement and adherence to the FIVR intervention [40]
- Exploring how to develop remote options for FIVR reminiscence interventions to promote use among the individual, caregiver, and family members [60]

4. Operation, implementation, or ethical aspect
    - Establishing a metric to assure successful operation of the FIVR intervention [25]
    - Investigating the barriers for the FIVR implementation and related solutions [40]
    - Identifying ethical ramifications of applying the FIVR intervention to individuals with severe dementia [40]
5. Technical aspect
    - Exploring the possibility of using log data, eye-tracking data, machine learning, and artificial intelligence to assist in the design of future FIVR reminiscence intervention prototype [25,55]
    - Understanding the added value of FIVR in reminiscence interventions [40]
    - Comparing FIVR with traditional forms of reminiscence interventions [53]
    - Investigating the method to combine FIVR reminiscence interventions with the digital mapping of media from public sources or family archives [55]
6. Human–FIVR environment interaction aspect
    - Observing participants' limb movements during the session to analyze their movements in FIVR [53]
    - Investigate how people living with dementia interact with the FIVR environment [59]
    - Exploring how the FIVR environment can create charming experiences with specific therapeutic effects [59]

Discussion

Principal Findings

In total, 11 articles [25,40,52-60] detailing empirical studies on FIVR reminiscence interventions in older adults were selected for this review. All but 1 study focused on individuals with cognitive impairments or dementia. The results showed that the intervention enhanced engagement and reduced fatigue. Although some studies reported positive effects of FIVR reminiscence sessions on participants' anxiety, apathy, depression, cognitive functions, and caregiver burden reduction, the results were not consistent across all studies. Moreover, FIVR showed overall usability and acceptability with manageable side effects among older adults.

Effectiveness of FIVR-Assisted Reminiscence Interventions in Older Adults

Overall, the review results demonstrated that FIVR-assisted reminiscence interventions, as a nonpharmacological option, were effective in improving some health- and behavior-related outcomes such as engagement and fatigue in older adults. Their effects on depression, anxiety, and apathy were not consistent. There were no significant impacts on other measures such as cognitive functions or dementia status, quality of life, and loneliness. However, it may be too soon to conclude that FIVR may not help induce further health benefits through reminiscence activities, as only 11 studies with small sample sizes and limited time frames were included in this review. Additional studies are required to provide a clearer understanding of this topic.

Usability and Acceptability

Most participants in the selected studies felt that the FIVR technology was acceptable and enjoyable. However, a study reported that reminiscence interventions may induce negative memories leading to undesirable feelings or undesirable health results [58], which raised the alarm about the selection of visual content. Otherwise, the side effects of FIVR were deemed manageable, with only a few cases reporting motion sickness. According to Chang et al [62], VR motion sickness includes symptoms such as eye fatigue, disorientation, and nausea, which are often caused by viewing dynamic content. The authors contended that motion sickness usually occurred when a person is immersed in moving VR scenes that yields an illusory perception of self-motion but their body is still in a static (standing or sitting) state. Other causes of motion sickness may be related to the fidelity of the VR stimuli and human factors [62]. Although human factors such as genetics and brain reactions may not be easy to change, the fidelity of VR stimuli can be improved, for example, by increasing the resolution or realistic sense of the visual content. There are many web-based platforms offering rich VR resources such as YouTube and Google Street Views, which were adopted by some selected studies. However, this type of content may not be ideal considering some quality problems such as distortion, glare, and low resolution. Several studies selected for this review used this content as stimuli but did not discuss quality issues in their articles.

Impact on Caregivers' Burden

Globally, there is a serious shortage in the nursing workforce; consequently, people living with dementia or mild cognitive impairments or other chronic diseases are usually cared for by informal caregivers, most of whom are family members. The care time was approximately 27.1 hours per week per person in 2021 [39], which is a burden on caregivers, especially those who provide informal care but still need to work for a living. This burden may be exacerbated as the person experiences further decline in cognitive functions along with an increase in behavioral problems and the loss of independent living. The selected studies revealed that caregivers viewed FIVR-assisted reminiscence as beneficial and valuable for people living with mild cognitive impairments and dementia. The effects of such interventions on anxiety and apathy may potentially lower caregivers' burden and companion time. Additional functions that link other people with the people living with dementia remotely through web-based platforms can better involve more family members or friends in reminiscence, which also helps reduce caregiving burden. However, as the hardware and the activity need to be set up and a facilitator is often required during the process, the reminiscence intervention may instead become an additional burden to caregivers, especially those serving in institutional care facilities where a nursing staff member provides care to multiple people.

FIVR Versus Other Technologies

In the previous section, we outlined the timeline for the different technical aids used in reminiscence interventions. Since the mid-2010s, VR has gradually become a viable option for facilitating the recall of past experiences in older adults. This evolution began with nonimmersive VR [21,27,63], displaying the virtual world through an electronic screen such as a tablet, television, or computer screen. Semi-immersive VR emerged later as another option [23,24], offering a more realistic experience by using multiple large screens or a VR Cave Automatic Virtual Environment that forms an enclosed or semienclosed environment in which to display VR content. FIVR has been considered more effective in evoking memories and is therefore more favorable for reminiscence compared with other aids, because of its fully immersive features. However, this assumption was not fully supported by evidence from the selected studies. It was noted that the results were mixed when comparing FIVR with other technical aids. For example, Saredakis et al [57] and Xu and Wang [59] found that participants preferred using FIVR for visual content over a flat screen or printed photos, whereas participants in another study reported that FIVR did not provide richer reminiscence experiences than those from an iPad [47]. In addition, FIVR may present some challenges for the participant or caregiver in controlling and manipulating the technology [58]. Nevertheless, FIVR is a relatively new technology and its application in reminiscence interventions is still in its infancy. Therefore, it may be too soon to conclude that FIVR is superior or inferior to the other traditional aids. The suitability of using FIVR may depend on the type of reminiscence intervention, content of the visual stimuli, and specific person in the session.

FIVR for People With Mild Cognitive Impairments and People Living With Dementia

Most of the selected studies focused on individuals with mild cognitive impairments or people living with dementia, making their results applicable to these groups. Only 1 study compared the FIVR effects between the population with mild cognitive impairment and that living with dementia [52]. The results indicated that people living with dementia were more immersed in VR, possibly because the realistic environment captured their attention better than it did for those with mild cognitive impairment. This is important because a higher level of immersion may lead to more emotional engagement, which would trigger unpleasant memories or emotions, resulting in adverse outcomes. Moreover, individuals with mild cognitive impairments displayed greater kinetic engagement during FIVR sessions, potentially owing to better physical health and mobility. However, the exact reasons remain unclear. Notably, there's a scarcity of studies comparing patients with mild cognitive impairments or dementia with noncognitively impaired groups. Further research comparing multiple user groups, such as young adults, healthy older adults, patients with mild cognitive impairments, and people living with dementia, is essential.

Types of FIVR Reminiscence Interventions

Only 1 study specified its intervention type as semistructured simple reminiscence. The other 2 types of reminiscence, life review and life story review, were not examined in the selected studies. Our speculations are as follows: (1) life review and life story review require professionally trained staff, posing challenges for research teams; (2) these approaches might demand more time (≥45 min), and using VR goggles for over 20 minutes could induce negative side effects; and (3) most research teams were led by design or computer science professionals, focusing on developing and testing the FIVR prototype. Life review and life story review are vital for end-of-life care, particularly for patients with cancer [15]. Consequently, further research on FIVR-supported life review is critical to address this gap.

Limitations

The limitations of this literature review are related to the characteristics of the studies and the nature of the scoping review. As noted earlier, the selected studies had some common limitations. First, the sample sizes were relatively small, ranging from 2 to 43 participants (mean 17). Only 4 studies had 20 or more participants. A small sample size has been a common issue in studies involving older adults with cognitive impairment, possibly because of the difficulties in recruitment and retention. Second, most studies were quasi-experiments, case studies, or qualitative research. Only 2 studies used control groups. Third, most studies evaluated the short-term but not the long-term effects of the interventions. Fourth, because most of the studies were conducted by the teams that created the FIVR tools, the study foci were largely on usability aspects but not on health outcomes, although these were also measured.

We attempted to identify related articles through different databases; however, the number of included studies was small (N=11). Possible reasons were that FIVR was a relatively new technology that took some time to be developed and evaluated in this field and that some studies may have been published in non–English language journals. Furthermore, there may have been publication bias; studies that did not find any significant results may not have been published. In addition, the selected studies used various research designs, sample sizes, and measurements, which presented challenges for a systematic, rigorous review, or meta-analysis.

Implications

Additional Future Research Directions

In addition to the research directions raised in the selected articles, we identified the following topics, based on this scoping review results, to further address current research gaps: (1) evaluating the impacts of FIVR quality in terms of fidelity and resolution on the effectiveness of reminiscence sessions; (2) identifying the most effective types of FIVR content, including events, locations, objects, people, sounds, and music; (3) developing and testing feasible strategies to lower caregiver burden through FIVR reminiscence interventions; (4) evaluating a specific type of FIVR reminiscence (simple reminiscence, life review, or life review therapy); and (5) comparing the effects of FIVR reminiscence on multiple user groups, such as young adults, healthy older adults, people with mild cognitive impairments, and people living with dementia. Attention to these research topics would advance our knowledge in this field.

Recommendations for Practice

Overview

FIVR has become more affordable and accessible over the last decade and therefore could be used in any reminiscence activities led by therapists, certified professionals, caregivers, and family members. It is a relatively safe therapeutic option if developed and implemented appropriately. On the basis of the review results and what we learned from our ongoing pilot studies, we provide a list of recommendations for those who would like to create FIVR stimuli to be used in reminiscence activities:

FIVR Content

Content can come from a variety of resources including web-based video sharing platforms such as YouTube and Vimeo, self-produced VR media including photos and videos, and Google Street View images. VR content can be location or event based. These locations can be childhood homes, hometowns, churches, and neighborhoods, whereas events can be weddings, birthday parties, and anniversary ceremonies. The literature suggests that selecting the most familiar places or events or those with pleasurable memories may help maximize positive outcomes. The most recent models of 360° camera allow people to produce high-quality (4K+ resolution) VR photos and videos on their own. Common camera brands include Instra360, GoPro, and Ricoh, with prices ranging from US $200 to US $800 in 2022. To reduce the possibility of motion sickness, we recommend using a fixed camera, which means that the camera is not moving around while taking videos. Once 360° photos and videos are taken, they can be uploaded to YouTube or Vimeo with minimal editing effort. Another type of VR stimulus, computer graphic–based animations or images, is not recommended for public use because it requires well-trained professionals and considerable time to build the content.

FIVR Device

We recommend consumer-grade VR goggles for reminiscence interventions because they require minimal technical support and have a less steep learning curve compared with professional goggles. As shown in the selected studies, Oculus was the go-to brand for FIVR reminiscence. The newest model in 2022 is the Oculus Quest 2, which offers its own operating system and can be used independently without connecting to computers or game consoles. It provides easy access to different websites and apps, including YouTube, and VR videos stored in video memory cards.

Types of Reminiscence Intervention

Among the 3 types of reminiscence interventions introduced in this paper, simple reminiscence is the least structured and the easiest to carry out, whereas life review and life review therapy may require specific training for the facilitator. Depending on the goals of the intervention and the facilitator’s ability, a decision about the type of intervention to be used should be made collectively by the person and the person’s caregiver, family members, and health care providers for maximal benefit.

Facilitators

We support the claim by Molinari [9] that reminiscence interventions can be conducted by both laypersons and trained professionals. In addition to providing cues during the activity, the facilitator should be able to set up the device, assist the person with accessing the VR scene, provide surveillance to avoid possible side effects including motion sickness and negative emotions, and evaluate the effectiveness of the intervention.

It should be noted that users should double-check existing practices or patient safety guidelines before applying these recommendations.

Conclusions

The growing number of older adults living with dementia or mild cognitive impairments has amplified the crises of caregiver shortage and continuously rising health care costs. We reviewed existing empirical studies that evaluated FIVR reminiscence interventions. The results indicated that such interventions, if delivered appropriately, may help improve the user’s psychological and mental health and potentially decrease the burden on caregivers. The studies also revealed a positive experience with FIVR technology, which most participants found acceptable and enjoyable. On the basis of the literature review, we identified directions for future research and provided recommendations for practice in FIVR reminiscence interventions.

Data Availability

The original data are available in Multimedia Appendix 3 [25,40,52-60].

Authors' Contributions

All authors contributed significantly to this manuscript in terms of conception, research design, data extraction and analysis, and interpretation of the review results. ZL raised the initial research questions, led the review process, critically reviewed the selected articles, and interpreted the results. WW led the article search and screening process and data analysis. ZL and WW drafted the manuscript. WY and JHS edited the technology-related content. CLK and MO edited the sections related to public health issues, the practice of reminiscence therapies or interventions, and the interpretation and implications of the findings.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.
[DOCX File , 84 KB - games_v11i1e45539_app1.docx]

Multimedia Appendix 2
Article search and screening process.
[XLSX File (Microsoft Excel File), 24 KB - games_v11i1e45539_app2.xlsx]

Multimedia Appendix 3
Original data and data descriptive summary.
[XLSX File (Microsoft Excel File), 185 KB - games_v11i1e45539_app3.xlsx]

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Abbreviations

EUROHIS-QOL: European Health Interview Survey–Quality of Life
FIVR: fully immersive virtual reality
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews
VR: virtual reality

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Original Paper

An Exposure-Based Video Game (Dr. Zoo) to Reduce Needle Phobia in Children Aged 3 to 6 Years: Development and Mixed Methods Pilot Study

Pat Healy[1*], BSc, BA; Celine Lu[2*], BA; Jennifer S Silk[3], PhD; Oliver Lindhiem[4], PhD; Reagan Harper[1,5], MLiS; Abhishek Viswanathan[1], MSc; Dmitriy Babichenko[1], PhD

[1]University of Pittsburgh, School of Computing and Information, Pittsburgh, PA, United States
[2]University of Washington, Department of Psychology, Seattle, WA, United States
[3]University of Pittsburgh, Department of Psychology, Pittsburgh, PA, United States
[4]University of Pittsburgh, School of Medicine, Department of Psychiatry, Pittsburgh, PA, United States
[5]Duquesne University, Gumberg Library, Pittsburgh, PA, United States
[*]these authors contributed equally

Corresponding Author:
Pat Healy, BSc, BA
University of Pittsburgh
School of Computing and Information
135 N. Bellefield Avenue
Pittsburgh, PA, 15213
United States
Phone: 1 (412) 624 5015
Email: pat.healy@pitt.edu

Abstract

Background: Needle phobia, which affects 19% of children aged 4 to 6 years, prevents many children from receiving necessary or preventive medical treatments. Digital interventions have been made to target needle phobia but currently rely on distraction rather than evidence-based exposure.

Objective: We designed and evaluated a serious exposure-based mobile game called Dr. Zoo to reduce the fear of needles in children aged 3 to 6 years, where players administered shots to cartoon animals.

Methods: We conducted a mixed methods study with 30 parents (mean age 35.87, SD 4.39 years) and their 36 children (mean age 4.44, SD 1.11 years) who played the game for 5 days leading to a scheduled appointment that included an injection (eg, influenza vaccination). After the study, parents completed exit surveys and participated in semistructured interviews to evaluate ease of use, acceptability, and preliminary effectiveness of the game and to provide insights on their experience with the game to inform future developments. Interview transcripts were analyzed by 3 independent coders following an open coding process and subsequently coded and discussed to reach consensus.

Results: Parents rated their child's difficulty in completing the game as very low on average (scale 1-5; mean 1.76, SD 0.82) and were highly likely to recommend Dr. Zoo to other parents (scale 1-5; mean 4.41, SD 0.87), suggesting Dr. Zoo's strong ease of use and high acceptability. In the exit survey, parents rated their child's fear as significantly lower after participating in the study (scale 1-5; mean 3.09, SD 1.17) compared with that before participating (scale 1-5; mean 4.37, SD 0.81; z score=−4.638; P<.001). Furthermore, 74% (26/35) of the parents reported that the game had a positive impact on their child's fear or perception of needles (only 2 parents reported a negative impact). Qualitative analysis of the interview transcripts revealed potentially important features of the game in this positive impact, such as the game's interactive design, as observed in 69% (24/35) of our participants.

Conclusions: The results suggest that an evidence-based serious mobile game can be an easy-to-use, acceptable, and potentially effective intervention for changing young children's fear and perceptions of needles. Leveraging digital interventions may be a potential solution to needle anxiety as a public health concern.

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KEYWORDS

needle phobia; serious games; children; exposure therapy; cognitive behavioral therapy; anxiety; mobile phone

Introduction

Background

The fear of needles is a critical health barrier for millions of children worldwide, with approximately 19% of children aged 4 to 6 years experiencing needle or injection phobia [1]. Needle phobia in children is also associated with distress and avoidance of medical care for chronic pediatric conditions that require routine injections, such as cystic fibrosis [2] and diabetes [3]. Needle phobia typically begins in childhood, and if left untreated, can follow into adulthood [4], which can result in the reduced uptake of vaccines, such as the influenza vaccine [5] and COVID-19 vaccine [6], as well as avoidance of other routine procedures such as blood tests, pain relief measures, and blood donation in adults [7]. Therefore, there is a pressing public health need for acceptable, scalable, accessible, and lasting approaches to treating needle phobia in children.

Although cognitive behavioral therapies (CBTs) are considered highly effective in treating needle phobias [8-11], it is neither cost-effective nor feasible to engage every patient with a mental health professional to undergo CBT. In recent years, video games and other game-like digital interventions that leverage CBT, such as virtual reality exposure therapy (VRET), have been shown to be effective in treating a variety of anxiety disorders [12,13], but no digital interventions using CBT have specifically focused on needle anxiety. Designing a similar intervention to reduce needle anxiety in young children offers numerous advantages, including scalability, cost, reduced number of office visits, and entertainment value [14-16].

Our goal is to leverage these benefits of digital intervention to improve the design and to evaluate the ease of use, acceptability, and preliminary effectiveness of an engaging and scalable digital game called "Dr. Zoo" to reduce the fear of needles and injections in children aged 3 to 6 years. We have developed a pilot version of the game, which presents children with scenarios in which the players must deliver a needle injection to a sick animal to make it feel better. We hypothesized that through repeated exposure to the in-game needle, the players (ie, children) will become more comfortable with needles and shots, which in turn will reduce needle-related anxiety. We have pilot-tested a preliminary mobile version of this game with children and their families in the Greater Pittsburgh region. The goal of this paper is to describe the development process of Dr. Zoo, including the rationale for the design, game mechanics, and presentation modality decisions. Furthermore, we report the preliminary results of several user studies and a pilot feasibility study with 36 children.

Related Works

In recent years, video games using CBT approaches have been developed with the purpose of combating anxiety as an inexpensive alternative to more conventional therapeutic methods. For example, Carlier et al [17] created a video game (New Horizon) to reduce anxiety in children with autism through relaxation techniques pulled from CBT [17], and Heng [18] created ReWIND, a role-playing video game that embeds an antecedent-belief consequence model from CBT into gameplay to treat patients with generalized anxiety disorder [18]. In these 2 examples, we see support for the application of CBT strategies in serious games that target anxiety in children.

For our problem domain of needle anxiety in children, virtual reality (VR) games that distract patients during the injection process have recently become a popular intervention, although there is little support for their long-term effects on anxiety reduction. A systematic review and meta-analysis of 10 randomized controlled trials found that overall, VR as a distraction significantly reduced children's fear of needles while undergoing needle procedures compared with children who did not receive the VR distraction [19]. However, there is no empirical evidence supporting the effectiveness of distraction-based games in producing long-term changes in children's fear of needles beyond the immediate experience itself. This suggests that a child who fears needles would need to undergo the distraction intervention for each future needle procedure because their underlying anxiety is not being resolved.

Our study departs from this distraction approach, instead focusing on exposure, which has empirical support for decreasing anxiety in the long term. Unlike distraction, exposures aim to modify a child's perception of needles to reduce fear in the long term rather than merely providing an in-the-moment solution. Exposure is a core element of CBT for child anxiety, which has been shown to be particularly effective in treating needle phobia [20]. Exposure involves presenting a child with their feared stimulus, in this case a needle, in repeated trials until the child no longer has a fear response to the stimulus. Furthermore, a gradual exposure approach where a less-feared version of the stimulus is presented first (eg, a needle in a video game) before the actual feared stimulus (eg, an actual needle during a medical appointment) can make treatment more palatable to the patient and prevent treatment dropout [21]. Through habituation to the feared stimulus (ie, a needle), a child's fear of the stimulus decreases and they learn that they can manage the situation. Therefore, they no longer need to engage in behaviors to avoid the feared stimulus (ie, a needle) to see a decrease in fear. A cognitive shift follows exposures, altering a child's perceived threat of the stimulus and their ability to cope with the threat [21,22].

Although there is no established literature on games that leverage exposure to tackle needle anxiety, there is substantial prior work in VRET games that leverage exposure to combat other forms of anxiety. Our study does not concern itself with VR directly, because we developed a *normal* or *pancake* game (as in a video game that is not VR), but this body of work in VR is necessary to discuss because it is the typical modality of digital interventions that leverage exposure. As discussed by Walkom [23], VRET is a uniquely effective and safe form of exposure therapy because of the precise control the designer has on the appearance and intensity of the stimulus and the ability of the participant to quickly abandon the simulation if the stimulus becomes overwhelming [23]. A review of 23 studies comparing VRET approaches to classical face-to-face evidence-based treatments in treating anxiety disorders found that VRET was superior to the waitlist control and comparable to traditional methods in terms of efficacy, impact, and stability of results [11].

However, little is known about the effect of less-immersive, exposure-based games (ie, non-VR) on anxiety. Exposure-based serious games that are neither VR games nor augmented reality games are exceptionally rare. In our review of the literature, we found only 1 example: a game named Lumi Nova, which was developed to address a wide range of anxiety issues (generalized anxiety, separation anxiety, social anxiety, panic disorder, and agoraphobia) in children aged 7 to 12 years [12]. Given its broader approach to helping children address a wider range of anxieties, this game does not primarily focus on exposing players to visual stimuli that resemble the object of their anxieties, as in the VRET examples discussed, but instead delivers a narrative where the player engages in puzzles to help in-game characters overcome their anxieties and facilitate goal-setting for exposure activities the player engages in outside the game [12]. In a user study of Lumi Nova (n=30), Lockwood et al [12] found that the game led children to a small but statistically significant decrease in overall anxiety after 8 weeks of play, as assessed by the player's parent or guardian using the Spence Child Anxiety Scale [12].

Our game, Dr. Zoo, has a "flat" modality, which lends itself to two core advantages over VRET: (1) it is less expensive and (2) it is more scalable, not requiring any special VR hardware outside of a mobile device. The strengths of VRET over conventional therapies may also apply to the "flat" modality of conventional mobile games, such as the designer's ability to precisely control the intensity and duration of the stimulus, the safety that comes with the player's ability to abandon the game at any point if the stimulus becomes overwhelming, and the added dimension of empathetic experiences between the patient and nonplayer characters. The impact of "flat" exposure-based games on anxiety in clinical settings will be further explored in this study. Furthermore, unlike the distraction methodology that provides only a short-term remedy in serious games for needle anxiety [24], we opted for an exposure therapy approach to create a more sustained effect by altering patients' responses to, perceptions of, and ability to cope with needles.

Objectives

In this paper, we present (1) insights into the design of a digital game to change perceptions of needles and injections in children aged 3 to 6 years and (2) insights into the ease of use, acceptability, and preliminary effectiveness of a serious game based on feedback from the players' parents.

Methods

Design Approach

We designed Dr. Zoo, a 3D adventure game for mobile devices (tablets and smartphones), as a single-player serious game to assist children in reducing their fear of needles. Above all else, our goal was exposure therapy: we wanted to create a game that requires its players to observe and interact with needles. Therefore, we decided that the game should focus on repeating a scenario in which the player must administer a vaccine to a patient. This scenario would be free of distraction, with only minimal visual elements outside of the syringe and patient, compelling the player to directly engage with the syringe for the duration of the scene. After multiple informal unstructured interviews with parents and children in our prospective age group, we decided to represent in-game virtual patients as cartoon animals. On the basis of which animals were popular among these children and which 3D animated assets we had access to, we decided that the game should center around a dragon, a dog, a penguin, a polar bear, and an orca.

We anticipated that the game would be more successful in addressing needle anxiety if the player empathized with their "patients." Our goal was to show animals in distress, have the player comfort these animals to calm them down before injecting a medication, administer the injection, and see a positive effect of the injection.

We had originally conceptualized the game as a series of injection-focused scenarios, which meant a constant presence of needles in every scene. However, in early playtests, we noticed that if the needle was always on the screen and the player was coming into the experience with especially high needle anxiety, the presence of a needle prevented players from becoming emotionally invested in interactions with the animals. This insight led us to a design decision to alternate needle and nonneedle scenes. For each animal, the player first engages in an animal-specific minigame with no needles present to build a connection and empathy between the player and the animal; these scenes do not necessarily contain therapeutically relevant content directly, instead they focus primarily on building their relationship with the character. Once the player has familiarized themselves with the animal, the scene changes to a scenario in which the animal becomes sick, and the player must administer an injection to make the animal feel better.

Dr. Zoo

Dr. Zoo is a 3D adventure game we developed in Unity for mobile devices (Android and iOS smartphones and tablets). In a series of independent chapters, the player is introduced to an animal, plays a brief minigame to solve some problem that this animal is facing, and concludes the interaction by administering an injection to the animal. The version of the game deployed for the pilot study includes 4 chapters. Although the chapters were presented to players in a specific order (by animal; Figure 1), the players were free to select and play chapters in any order they liked.

The first 2 chapters present players with a patient (a dragon named Dominic, shown in Figure 2, and a dog named Max, shown in Figure 3) who is experiencing anxiety about their scheduled vaccination. In the first chapter, Dominic the dragon is anxiously flying around the game environment, and the player must use the microphone on their device to gently talk to him until he calms down. In the second chapter, the player must play fetch with Max to help him calm down, tapping the screen to toss a ball in a backyard environment.

Figure 1. The character-select screen of Dr. Zoo. This is the screen where players choose which animal they will help next.

Figure 2. The end of the Dominic the dragon chapter.

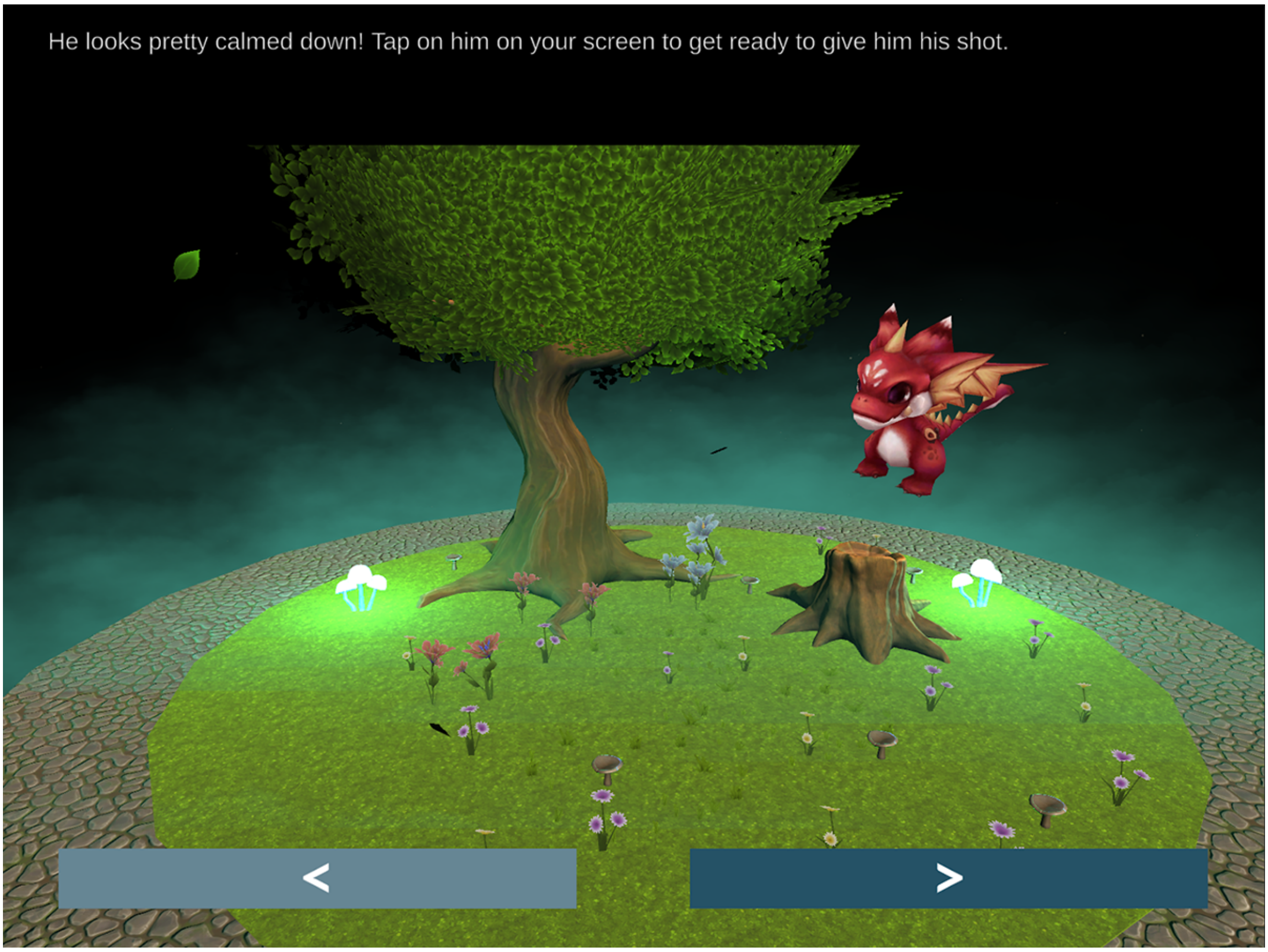


Figure 3. The player must play fetch with Max the dog in the second chapter.

The third chapter features a penguin named Penny, who lost track of her friend, a polar bear named Becky. The player must guide Penny along a short path to find Becky. The player indirectly moves Penny by tapping the ground to place fish, which Penny will walk toward and eat, as shown in Figure 4. Upon guiding Penny to Becky, Becky falls ill and requires an injection.

Figure 4. In the Penny the penguin chapter, the player must tap the screen to place the orange fish on the ground, which Penny will follow.

The fourth and final chapter features an orca named Sami, who cannot come to her appointment because her part of the ocean is full of trash. The player must search the game environment for pieces of trash among fish and other wildlife and tap on them to pick them up until all the trash has been collected, as shown in Figure 5.

Figure 5. In the Sami the orca chapter, the player must search through the small ocean environment to tap on trash objects.

The diverse set of animal-specific minigames that make up most of the content in all 4 chapters of Dr. Zoo was designed to offer an opportunity to grow fondness for the animal characters by having the player help them solve "health" problems with slightly different empathetic mechanisms. With Dominic the dragon, the player must engage verbally with the character to assist them in overcoming their anxiety. With Max the dog, the player must engage in open-ended play with a physical object (the ball), which looks to put both the player and, in the fiction of the game, the dog together in a flow state. With Becky the polar bear, the player's emotional connection is cultivated with a design strategy unique to games: searching for the character is a gameplay goal. Finally, Sami the orca's chapter takes a similar approach, pushing the player to empathize with the character through a simplified appeal to environmentalism, such that Sami only makes her triumphantly animated entrance after the player has cleaned up ocean trash. Therefore, we have 4 distinct modes of engagement with our animal patients: verbal conversation, flow-inspiring action, searching, and service.

This progression in the modes of engagement mirrors the progression in the player's relationship with the animal character, because the player experiences a wide range of character interactions from direct emotional support as if the player is a caregiver (dragon) to incidental emotional support through play (dog), to indirect care through a friend of the character (controlling the penguin to reach the polar bear), and to action that appears to have only mild relation to the character (orca). Overall, Dr. Zoo presents a useful spectrum of player and nonplayer character interactions in this context, allowing both an exploratory case study to further understand, through our feasibility study, which kinds of interactions may resonate most often in this context and, assuming players may individually differ in which interactions they prefer, crafting an experience where most players enjoy at least one of the nonplayer character interactions, even if that choice is not universal.

Our design was motivated by the idea that once a fondness for a given character is established, the player will become more invested in the impact of the injection on the animal's well-being, therefore encouraging the player to role-play as an advocate for the injection, both for their patient and, by extension, themselves. This hypothesized mechanism resembles prior work in the world of "identification," in which players self-identify with the characteristics of nonplayer characters [25]. In our game, we may see players self-identify with the courage of our virtual patients in the face of injections.

In addition, this mechanism is supported by social learning theory, which conceptualizes social behaviors as learned in part through observation and imitation [26]. In the case of Dominic the dragon's chapter, for example, the player is observing the nonplayer character's changing behavior as it manages its anxiety, so that the player may imitate that reduction of anxiety in their own conduct.

Each chapter concludes with the player administering an injection to their animal patient, as shown in Figure 6. In these scenes, the player must tap and drag a syringe into the animal's arm and hold it there for about 3.5 seconds. As the syringe is held in this position, a circular loading icon is filled, indicating progress. When the circle is filled, the syringe is removed from the screen and the patient becomes visibly more energized and does a celebratory dance with an audible cheering sound effect and confetti, as shown in Figure 7. From social learning theory, we can understand this celebration as a kind of vicarious reinforcement [26], as the player has watched the nonplayer character accept the injection and be rewarded with a celebration for being a good patient. Upon completing 1 chapter, the player is returned to a chapter-select screen to choose their next patient. The player cannot replay any chapters before completing all the 4 chapters, which triggers a finale sequence where all the animals celebrate the player's success and the game automatically restarts itself.

Figure 6. Characters in Dr. Zoo receiving an injection administered by the player.

Figure 7. A celebration sequence that occurs after the player has administered an injection.

Research Design

The pilot feasibility study followed a within-subjects design and compared parent report of child participants' fear ratings after the initial game session and final game session. The study also compared parent retrospective reports of their child's fear of needles and distress (eg, screaming, kicking, and crying) during needle-related activities in the past years before participating in the study and parent reports of their child's fear and distress during needle-related activities after participating in the study. Qualitative exit surveys were conducted to gain insights into the ease of use, acceptability, and preliminary effectiveness of the game. Furthermore, qualitative interviews were conducted to gain insight into parents' and children's experiences with the game, to inform changes for future development.

Participants

Participants were 36 children aged 3 to 6 years (mean age 4.44, SD 1.11 years) and 30 parents (mean age 35.87, SD 4.39 years). A total of 6 parents in the study enrolled 2 children to participate. Children were considered eligible for participation if they (1) were aged between 3 and 6 years; (2) previously experienced an injection, intravenous therapy, or any other activities involving syringes or needles as part of a medical treatment; (3) experienced needle anxiety based on parent report; and (4) had an upcoming medical appointment that involved syringes or needles (eg, influenza vaccination).

Children were excluded from participation if they either (1) had a fear of animals that were present in the game (ie, orca whales, penguins, polar bears, dogs, or dragons) or (2) had any seizure disorder, because some scientific literature suggests that video games could trigger seizures [27]. The demographic information of the participants is presented in Tables 1 and 2.

Table 1. Overview of participant demographics (children; n=36).

Variables	Values, n (%)
Sex	
Female	22 (61)
Male	14 (39)
Race	
White	28 (78)
White and Asian	2 (6)
White and Black or African American	1 (3)
Biracial other	3 (8)
Prefer not to answer	2 (6)
Ethnicity	
Non-Hispanic	28 (78)
Hispanic	8 (22)

Table 2. Overview of participant demographics (parents; n=30).

Variables	Values, n (%)
Sex	
Female	29 (97)
Male	1 (3)
Race	
Black or African American	1 (3)
White	26 (87)
White and Asian	1 (3)
White and Black or African American	1 (3)
Ethnicity	
Non-Hispanic	28 (93)
Hispanic	2 (7)
Income (US $)	
<24,999	1 (3)
25,000-49,999	2 (7)
50,000-74,999	4 (13)
75,000-99,999	3 (10)
>100,000	20 (67)

Ethics Approval

All research procedures were approved by the University of Pittsburgh's Institutional Review Board (STUDY20090225).

Procedures

Recruitment and Screening

Participants were recruited between May and November 2021 through a web-based university-sponsored research registry for families interested in participating in behavioral health research studies. Participants who indicated an interest in the study through the research registry were sent a prescreening Qualtrics (Qualtrics International Inc) survey to complete. Screening was performed in 2 phases. In phase 1, if the participants indicated that their child met the inclusion criteria, the research staff contacted the potential participant to schedule a web-based consent visit. A research assistant conducted the virtual consent visit either through phone or video call through Microsoft Teams, a videoconferencing platform, explaining the purpose of the study, overall procedures of the study, and risks and benefits of participation and answering any questions the parent had about the study. Parent participants then completed a web-based consent form via Qualtrics. In phase 2 of screening, following consent, participants were sent baseline surveys to complete, including a demographics survey and the Fear Survey Schedule for Children–Revised (FSSC-R) [28]. Final eligibility criteria were met based on parents reporting that their child had at least "some" fear on the FSSC-R needle phobia item.

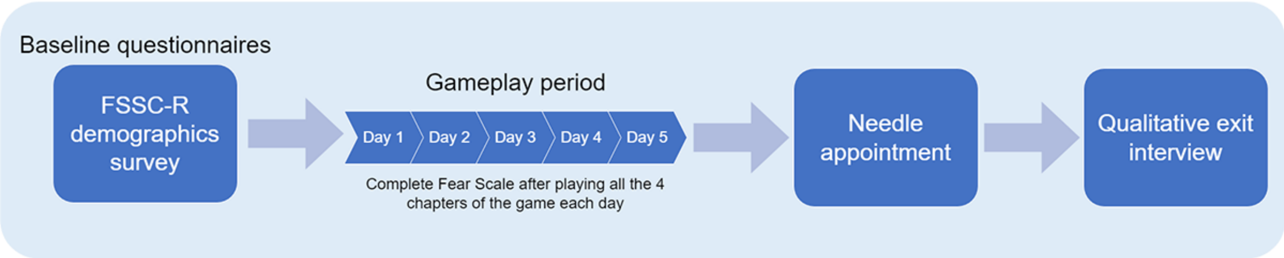
Gameplay

Approximately 2 weeks before the scheduled medical appointment involving needles or syringes, research staff instructed parents on how to download Dr. Zoo onto their smartphone or tablet device. Dr. Zoo is compatible with both Android and iOS devices. Given its low-polygon style and limited action, it does not require new or powerful hardware to run (it was tested with acceptable performance on an inexpensive Android tablet during development). Participants using an Android device were required to download and install an Android Package Kit file manually, whereas iOS users received the app through Apple's TestFlight platform. Parents were instructed to have their child complete all 4 chapters of Dr. Zoo each day for at least 5 days in a row, leading to their child's medical appointment. When their child finished playing for the day, parents completed the Children's Fear Scale [29] via a Qualtrics link embedded into the game to indicate their child's fear level while playing Dr. Zoo. No other instructions were given to parents on how to determine their child's fear level during the game. Parents also received daily SMS text message reminders to have their child play the game and complete the survey during their scheduled gameplay period.

Qualitative Exit Interview

Upon completing the medical appointment, the research staff scheduled and later completed an exit survey and interview using a semistructured interview guide with the parents (refer to Figure 8 for the timeline of assessments). Exit interviews were conducted and audio recorded on Microsoft Teams, with all but one parent (final sample of parent interviews, n=29) because the research staff were no longer able to reach the parent. The interviews lasted between 9.73 and 30.60 (mean 17.53, SD 5.38) minutes. For parents who enrolled 2 children in the study, the exit interview was conducted once with the parent while probing experiences for each child separately. The Microsoft Teams application autogenerated transcripts of the interviews, which research assistants later checked and revised manually for accuracy. Families were compensated US $20 for each child that participated in the study following the completion of the exit interview.

Figure 8. A flowchart depicting the timeline of assessments in the study. FSSC-R: Fear Survey Schedule for Children–Revised.



Protection of Health Information

Participant health information was protected using several methods. All data were stored in the university-managed OneDrive (Microsoft) database, which required research staff to log in using their university credentials to gain access. Participant data were tracked using password-protected Microsoft Excel sheets that only approved research staff had access to. Participant data were kept separate from their identifiable information, such as name, date of birth, or contact information. Furthermore, research assistants deidentified and then saved the qualitative exit interview transcripts by removing information such as name or date of birth.

Instruments and Measures

The Fear Survey Schedule for Children–Revised

The FSSC-R [28] was used to determine eligibility for the study. The measure is a widely used questionnaire that measures the number of fears and the overall level of fearfulness in children. The item used to determine eligibility for this study assesses children's fear of "Getting a shot from the nurse or doctor," on a 3-point Likert scale (0="none," 1="some," and 2="a lot"). Parents had to report that their child had at least "some" fear to be eligible for participation.

Demographics

Parents reported on demographic variables such as parent and child age, sex, race, ethnicity, and household income.

Children's Fear Scale

Parents completed the Children's Fear Scale [29] to measure children's fear levels while playing the game. This measure is a 5-point visual scale that presents 5 human faces with expressions showing different fear intensities (0: leftmost face="not scared at all" to 4: rightmost face="most scared possible"). Parents were asked to choose the face that best represented their child's response while playing Dr. Zoo. The Children's Fear Scale was used to measure the child's fear while playing the game each day.

Exit Interview

The exit interview consisted of a semistructured interview guide that asked participants about a combination of scaled questions (ie, exit survey) and open-ended questions. This allowed participants to elaborate and contextualize their responses to the scaled questions. The semistructured interview guide was developed with specific guiding questions to elicit feedback on (1) parents' and children's favorite aspects of the game, (2) parents' and children's least favorite aspects of the game, (3) parents' perceived impact of the game on their child's fear of needles or distress, and (4) suggestions for future development.

A semistructured interview guide consists of guiding questions and suggested probing questions to evoke more details from the participant, if needed. Questions can be asked in different orders to match the flow of the conversation based on the participants' responses.

To assess ease of use, we asked parents to rate how difficult it was for their child to understand how to play the game on a 5-point Likert sale (1="extremely easy" to 5="extremely difficult"). To assess acceptability, parents were asked how likely they were to recommend the game to other parents on a 5-point Likert scale (1="absolutely not" to 5="definitely yes") as well as how helpful they thought the game was in reducing their child's fear of needles on a 5-point Likert scale (1="did not help at all" to 5="helped a lot").

Finally, to assess preliminary effectiveness, parents were also asked to retrospectively rate their child's fear of needles during needle-related activities in the years before participating in the study and after participating in the study on a 5-point Likert scale (1="no fear at all" to 5="extreme fear"). Similarly, parents were asked to retrospectively rate their child's distress during needle-related activities (eg, kicking, screaming, and crying) in past years before participating in the study and after participating in the study on a 5-point Likert scale (1="completely calm" to 5="extremely agitated").

Data Collection and Analysis

Baseline and fear scale surveys were administered using Qualtrics.

Coding

A total of 3 coders—one of the first authors (postbaccalaureate) and 2 collaborators (1 master's student and 1 PhD graduate student)—were involved in the qualitative analysis process. To guide our qualitative coding process, we used a combination of deductive and inductive coding. As part of a deductive coding approach, we used the framework of the interview script to develop four distinct categories that potential codes could fall under: (1) facilitators of use, (2) barriers to use, (3) impact of the game, and (4) suggestions for future development. Then, coders used an open coding process, as described by Strauss and Corbin [30], and independently reviewed the same 6 transcripts, identifying important or repeated concepts in the transcripts, while placing them into 1 of the 4 categories. An initial codebook was then developed and used on 3 other transcripts, wherein each coder coded 1 transcript. The 3 coders met to discuss any concepts that the initial codebook failed to capture and revised the codebook to include new codes and changes to code definitions accordingly.

In the next phase, the 2 collaborators independently coded all transcripts using the revised codebook. Each transcript was coded by 2 coders, and the first coder of each transcript was responsible for segmenting the transcript into excerpts to facilitate the coding process. The coders were instructed to apply only 1 code to each excerpt. After all transcripts were double-coded, the 3 coders met to engage in an open discussion [31] to resolve any discrepancies between codes. Each coder explained their rationale for applying a specific code to an excerpt while the others listened. A final code was determined once the group reached a consensus on which code best suited the excerpt after hearing each other's rationale. Changes to the codebook were made as necessary to capture the codes better. All coding was performed using Microsoft Word and Excel.

Quantitative Analysis and Triangulation

Quantitative data were analyzed using SPSS 28 (IBM Corp). Logistic regressions were conducted to identify the relationships between participants' age and endorsement of certain qualitative codes. Triangulation of the data sources strengthened the validity of our findings and provided a more comprehensive depiction of participants' experiences with the game.

Results

Overview

In the following section, we describe quantitative, qualitative, and mixed methods findings that focus on the following aspects of the game: (1) facilitators of use (including ease of use and acceptability), (2) barriers to use, (3) impact of the game (ie, preliminary effectiveness), and (4) suggestions for future development.

Missing Data

We were unable to contact 1 parent participant after they completed their medical appointment, who did not complete the exit interview. One parent participant did not complete the fear scale survey for their child during their scheduled gameplay period. Finally, 1 parent participant was not asked to rate the difficulty in understanding because of researcher error.

Descriptive Statistics

The average scores for the FSSC-R needle phobia item were very high (scale 0-2; mean 1.89, SD 0.32), indicating a high level of baseline needle anxiety among the children in the sample. Participants completed the game on average for 5.11 (SD 1.21) days.

Transcripts were segmented into 360 excerpts in total. The codebook consisted of 17 codes, separated into 4 categories. Overall interrater reliability, as measured by Cohen κ [32], was high across all codes (pooled κ=0.86), ranging from moderate agreement to near-perfect agreement (0.59-0.98). Table 3 presents the frequency of codes, the percentage of participants who endorsed the code, and the respective κ statistic scores for each code.

Table 3. Frequency and κ statistic scores for qualitative codes by category.

Category and code	Frequency of code, n	Participants who endorsed code (n=35), n (%)	Cohen κ[a]
Facilitators to use			
Ease of use	8	8 (23)	0.93
Excitement to play game	24	18 (51)	0.98
Dominic the Dragon	22	15 (42)	0.98
Interactive	42	24 (69)	0.92
Barriers to use			
Difficulty navigating space	25	18 (51)	0.94
Injection sequence	24	14 (40)	0.93
Loss of interest	14	10 (29)	0.85
Other barriers	5	4 (11)	0.59
Impact of the game			
Positive impact on fear	31	21 (60)	0.79
Positive impact on physical reactions	21	17 (49)	0.89
Discussing health impact of vaccines	24	21 (60)	0.81
Preparation for appointment	27	21 (60)	0.78
No impact	14	10 (29)	0.88
Negative impact	4	2 (6)	0.59
Suggestions for future development			
More realistic	40	25 (71)	0.98
More variety	23	18 (51)	0.94
Technical improvements	12	11 (31)	0.82

[a]Cohen κ statistic score.

Facilitators of Use

Quantitative Results

A summary of all quantitative findings is displayed in Tables 4 and 5. The ease of use was high, with parents rating the difficulty of their children's understanding how to play the game as relatively low (scale 1-5; mean 1.76, SD 0.82). The acceptability of the game was relatively high, with parent participants being very likely to recommend Dr. Zoo to other parents (scale 1-5; mean 4.41, SD 0.87). In addition, parents rated the helpfulness of the game in reducing their child's fear of needles as moderately high (scale 1-5; mean 3.49, SD 1.27).

Table 4. Summary of descriptive statistics.

Item	Values, mean (SD)	Values, median (range)	Values (n=36), n (%)
FSSC-R[a] needle phobia item	1.89 (0.32)	2 (1)	36 (100)
Children's Fear Scale ratings across all days	0.867 (1.24)	0 (4)	35 (97)
Game difficulty	1.76 (0.82)	2 (3)	34 (94)
Likeliness to recommend game to other parents	4.41 (0.87)	5 (3)	29 (97)
Helpfulness of game	3.49 (1.27)	3 (4)	35 (97)

[a]FSSC-R: Fear Survey Schedule for Children–Revised.

Table 5. Summary of Wilcoxon signed rank tests.

Variables	Median values before and after the study (range)	*z* score	*P* value
Children's Fear Scale ratings	1-0 (4-4)	−1.624	.10
Fear ratings from the exit survey	5-3 (2-4)	−4.638	<.001
Distress ratings from the exit survey	5-3 (3-4)	−4.313	<.001

Qualitative Results

Parent participants reported many aspects of the game that they and their children found enjoyable. For example, 8 (23%) out of 35 children could "figure out what to do on their own" and that the game was "simple" for them to play. In addition, 18 (51%) out of 35 children were excited to play Dr. Zoo each day, either reminding their parents that they had not yet played the game for the day or even asking them to continue to play the game past the study play period.

Each of the chapters were favored by at least some of the parents and children, though the Dominic the dragon chapter was a clear standout, with 15 (43%) out of 35 children indicating that this chapter was their favorite aspect of the game. Parents felt that this chapter was the most helpful for their children and enjoyed hearing their children comforting the dragon by "mirroring" the phrases they would often use to calm down their children, such as the following:

> *It's gonna be okay. This will help you stay safe. It'll only hurt for a second.*

Furthermore, 24 (69%) out of 35 children enjoyed that the game was interactive, for example, by being able to choose the first animal in the beginning or being the one to give the animal a vaccination. Another interactive aspect of the game that children particularly enjoyed was the celebration sequence that occurs after administering the injection to an animal, which includes confetti and characters in the game exclaiming "Yay!" Parents felt that this sequence helped their children create a positive association with vaccines.

Barriers to Use

Quantitative Results

Though ease of use was rated overall as high as explained in the *Facilitators of Use* section, an ordinal regression revealed that an increase in age (expressed in years) was associated with a decrease in the odds of rating difficulty of understanding how to play the game as high, with an odds ratio of −0.794 (95% CI −1.464 to −0.124; Wald $^{2}_{1}$=5.389; *P*=.02). In summary, parents of younger children reported that their child had more difficulty understanding the game compared with parents of older children.

Qualitative and Mixed Methods Findings

Parents reported aspects of the game that proved to be unengaging, frustrating, or unappealing for themselves or their children. Although logistic regressions revealed that age was not associated with reporting any 1 barrier code in particular (all *P* values >.05; refer to Multimedia Appendix 1 for details), 1 notable barrier reported by 18 (51%) out of 35 participants included struggling to navigate the spaces in the Penny the penguin and Sami the orca chapters. Parents reported that their children became frustrated when "they couldn't figure out how to get to the polar bear, that you had to use those arrows to get around to see the polar bear." In these instances, parents would often help their child with this sequence to continue with the rest of the chapter. Similarly, some of the children became frustrated during the Sami the orca chapter because the pieces of trash to pick up were "too tiny" and they "didn't really get the whole rotating [the screen]." This issue was most prominent when families used a smartphone for the game rather than a tablet with a larger screen.

Another aspect of the game that 14 (40%) out of 35 participants had an issue with was the injection sequence. Parents reported that their child felt uncomfortable with the length of the injection sequence and were worried that their own vaccination experience would last as long as it did in the game. In addition, parents expressed concern over the "suction noise" sound effect that was paired with the injection and described it as "off-putting." Parents also reported that their child had difficulties using their finger to move the needle into place to start the injection sequence. Furthermore, 10 (29%) out of 35 children's engagement tapered off over the course of the study gameplay period "since it was this same exact thing every day." Other barriers experienced by 4 (11%) out of 35 children included thinking the game was "too loud" or there being technical difficulties where the sound did not play at all.

Impact of the Game

Quantitative Results

Quantitative and qualitative findings demonstrated that support for the game positively affected children's fears and physical reactions to needles. On the basis of retrospective reports in the exit survey, Wilcoxon signed rank tests revealed that parents rated their child's fear as significantly lower during needle-related activities after participating in the study (median 3; mean 3.09, SD 1.17) compared with their retrospective report of their child's fear in previous years before participating in the study (median 5; mean 4.37, SD 0.81; *z*=−4.638; *P*<.001). Similarly, parents rated their children's distress (eg, crying, screaming, and kicking) during needle-related activities as significantly lower after participating in the study (median 3; mean 2.97, SD 1.42) compared with their retrospective report of their children's fear in previous years before participating in the study (median 5; mean 4.37, SD 0.88; *z*=−4.313; *P*<.001). However, there was no significant difference between the initial fear scale ratings (median 1; mean 0.97, SD 1.18) and the final fear scale ratings (median 0; mean 0.69, SD 1.13; *z*=−1.624; *P*=.10).

Qualitative Results

Qualitative results further supported the positive impact the game had on children's experience with needles, with 26 (74%) out of 35 children experiencing a reduction in fear of needles (21/35, 60%) or physical reactions (17/35, 49%) at the time of the medical appointment involving needles (as reported by their parents). However, the extent of the reduction varied. Some parents described a drastic improvement in their children's fear and physical reactions after playing Dr. Zoo compared with their previous needle appointment before participating in the study:

> *Last year during [child's] checkup for her vaccines, she hid under the table and was crying. We also had to wrestle her out of her clothes, hold her legs down. [This time], she got up on the table, she got her arm out, and then she leaned into me... and she said, 'I'm ready, Mama... It's, it's just gonna be a pinch.' And she just took a deep breath, and it was done. And she*

> *looked at me and she said, 'That was easy.' And I was shocked. But it was amazing. And I think a big part of it was playing the game.*

For other children, they showed little fear before the appointment, but were "still screaming and kicking" when the time came for the actual injection. In contrast, some parents felt that their child was "still fretting a decent amount" about their needle appointment, but there was "no crying" this time around.

Parents of 21 (60%) out of 35 children also appreciated that the game provided an opportunity to mentally prepare their child for the vaccine appointment, making their child "less nervous when it comes to [the appointment] because it gives them time to sit down and talk about it every single night leading up to it." However, 1 parent described that she disliked when her son "repeatedly" asked why he was "playing this game and if that meant that he was going to get a shot himself." Furthermore, having the game opened up the conversation with their children about the purpose and health impact of vaccines, as reported by the parents of 21 (60%) out of 35 children. One parent recounted what she would say to her child after having them play the game:

> *There are times when we need it, and they help us. Just like our dog gets shots. They make us healthy. Sometimes if we're sick, we need them. And needles are not bad, they are just to help us.*

Nonetheless, the parents of 10 (29%) out of 35 children felt that the game had no impact on either their child's fear of needles or their physical reactions to needles. Furthermore, parents of only 2 (6%) out of 35 children in the study felt that the game potentially made their child's fear surrounding needles worse because the "anticipation" of knowing that their needle appointment was around the corner made them more anxious.

Suggestions for Future Development

Parents of 25 (71%) out of 35 children gave suggestions to add features to the game to be more realistic of their child's actual needle experience. For example, parents suggested having the child place a bandage on the animal after the injection sequence to make the animal feel better, because their children felt a level of comfort after receiving a bandage after their vaccination. In accordance with some participants' discomfort with the length and sound of the injection sequence, parents suggested reducing the duration of the injection sequence and changing the sound to a short click or having no sound at all. Another suggestion was to have the animals show some apprehension surrounding the vaccination but ultimately overcome their fear. Other suggestions included adding different medical procedures, such as blood draws and being able to place the needle in different areas of the body other than the arm. Parents of 18 (51%) out of 35 children also suggested including new animal chapters to "maintain the engagement level" throughout the gameplay period. Finally, parents of 11 (31%) out of 35 children suggested some technical improvements to the game, such as adding instructions on how to move the screen around using the arrows or being more explicit in how to interact with the animals in each chapter.

Discussion

Principal Findings

Overall, Dr. Zoo demonstrated strong acceptability, ease of use, and potential preliminary effectiveness in this pilot feasibility study. Parent participants provided insightful feedback on the facilitators of and barriers to use, which will be helpful in the future development of the game.

Both quantitative and qualitative results showed that participants' satisfaction with the game was high, with many children being excited to play the game each day. In addition, parents reported that the game was easy for their children to use, although younger children had a more difficult time using the game. In addition, the chapters that required greater input from the player proved to be a barrier for some players. In particular, players had issues with both the Penny the penguin and Sami the orca chapters, which required greater game literacy to navigate 3D spaces.

Dr. Zoo also demonstrated potential preliminary effectiveness in decreasing needle anxiety, although concurrent and retrospective data appear to be conflicting. Exit surveys and interviews indicated overwhelmingly that parents found the game successful, suggesting perceived decreases in fear of needles and improvements in distress to needles during appointments. However, fear scale ratings completed by parents at the end of individual play sessions indicated no decrease in children's anxiety. A possible explanation for these contradictory results could be that the fear scale rating questionnaires captured players' fear of the game itself rather than their fear of actual needles. Another potential reason for this result could be that the fear scale ratings demonstrated a floor effect, which could have prevented the detection of statistical significance. Low fear scale ratings after play sessions indicated that players did not experience high levels of fear while playing Dr. Zoo throughout the gameplay period.

Parents used Dr. Zoo as an opportunity to educate their child about the importance of vaccines to their health and prepare them for their needle appointment. Doing so may have helped normalize the experience of receiving a vaccination, provided context for the vaccination experience, and encouraged the child to communicate their fears with their parents, all of which may have contributed to Dr. Zoo's effectiveness, despite these experiences lying outside the gameplay itself. In contrast, being reminded of their needle appointment each day while playing the game had the opposite effect for 2 children, making them more nervous in anticipation of their appointment.

Dr. Zoo's success is especially notable given its uniqueness, when compared with prior work, as a serious game that applies in-game exposure therapy techniques without augmented reality or VR. Limitations in our fear measurements made our primary analysis qualitative, which made it difficult to directly compare the effectiveness of our intervention to the body of literature with more rigorous and quantitative support for the effectiveness of VRET solutions [11]. Parent-reported fear of needles in exit interviews changed from a mean rating of 4.37 to 3.09, exhibiting a 29% reduction in fear over the course of our study.

Garcia-Palacios et al [33], in their study with the largest effect size as summarized by Opriş et al [11], found that a VRET app reduced self-reported fear of spiders, from a spider fear questionnaire [34], from 97.42 on average to 57.42, or about a 41% reduction, which is superior to Dr. Zoo. Although burdened by similar limitations, we can roughly compare our results to the state-of-the-art interventions specific to needle anxiety in children. Compared with 2 VR distractions by Özalp Gerçeker et al [35], which reported approximately 25% fear reduction on average, Dr. Zoo appears comparable in effect while having the advantage of not changing procedures of the medical appointment itself.

The Dominic the dragon chapter was a standout favorite of the 4 chapters, despite it being the most limited of the chapters in terms of opportunities for interaction with meaningful gameplay consequences. It is noteworthy that the Dominic the dragon chapter is on the leftmost point in the chapter selection screen (refer to Figure 1) and therefore may have regularly been chosen as a player's first interaction with the game, suggesting that players may have been biased toward it as a result of sequencing rather than particular content. However, it is perhaps more compelling that, at odds with the frustration found in the Penny the penguin chapter, Dominic the dragon's chapter has comparatively little opportunity to frustrate the player with difficult verbs. In terms of how the software reacts to input, the player can only (1) rotate the game environment to better view Dominic and (2) speaking into their microphone could decrease the time it takes for Dominic to calm down from 30 seconds to a minimum of 15 seconds.

Neither of these inputs create opportunities for agency comparable to the direct manipulation of objects found in the other 3 chapters (ie, throwing a ball to make Max fetch, placing a fish to make Penny walk, or tapping on trash objects to make them disappear). However, the fiction of the interaction with Dominic proved very powerful. Exit interviews indicated that players took the opportunity to engage in an emotional mirroring dialogue with the character that fundamentally aligns with our proposed empathetic mechanism. Dr. Zoo bears some similarity to Lumi Nova [12], mentioned earlier in the *Related Works* section, in that it requires the player to help nonplayer characters through anxiety issues that may resemble the player's issues. This intersection suggests that the narrative premise of the player acting in a supportive role toward others with anxiety is a therapeutic design feature worth further deployment and study.

Limitations

While discussing this work, it is important to acknowledge its limitations. The children who participated in this study were overwhelmingly White and non-Hispanic. The parents of these children were overwhelmingly White, non-Hispanic, women participants, and of the highest income category (>US $100,000/y). Children in households with higher socioeconomic status have less weekly screentime on average (including specifically video gameplay) than children in households with lower socioeconomic status [36]. This means that our game had novelty with this particular audience that may not be generalizable to children of lower socioeconomic backgrounds. In addition, although this often differs by specific vaccine, high-income White mothers are a highly vaccine-hesitant demographic, being the most likely to refuse vaccines for their children [37]. Therefore, there may be a recruitment bias, where our sample is overrepresented by the even more specific demographic of high-income White mothers who are *not* vaccine hesitant, potentially inflating the acceptability of the game compared to the general population's attitudes.

Given our interpretation of the fear scale questionnaires, we are left with little rigorous means to quantify how much the game improved anxiety over time. Our only measure of children's needle anxiety comes from the FSSC-R needle phobia item assessed at baseline to determine eligibility and their parent's retrospective assessment in exit surveys and interviews, which one may criticize as an improper proxy.

Because this was a pilot feasibility study, we did not have a control group to compare children's fear of needles between those who played the game and those who did not. Although parents provided varied feedback on the game, it is possible that receiving compensation for participating in the study biased their feedback. In addition, variability in how much parents encouraged their child to play the game or whether they let their child know about the upcoming needle appointment was not systematically assessed or controlled. Therefore, parents' impact on their child's experience with the game could not be measured. Furthermore, the children's previous experience with other games was not assessed and therefore could not be controlled for in the analyses.

Future Work

Further iterations of Dr. Zoo will focus on integrating opportunities for emotional mirroring, as seen in the Dominic the dragon chapter, into other chapters. Similarly, rewrites of the game's narrative and dialogue may be necessary to further facilitate the prospective empathetic mechanism. Exit interviews indicated a pattern of confusion particularly around the Penny the penguin chapter, which focuses on Penny trying to search for Becky the polar bear, despite them standing next to each other in the main menu screen. In addition, none of the characters have any facial animation. Especially considering that we believe the player's empathy for these characters plays an important role in the effectiveness of this game as a treatment for needle anxiety, the narrative and animation of these characters should come under closer scrutiny in future iterations.

Future evaluation of Dr. Zoo should use more rigorous assessments of the game experience, such as the Game Experience Questionnaire [38], and the impact of the game on children's fear and perception of needles. A randomized controlled trial comparing needle anxiety in children who underwent the intervention to those who did not would clarify Dr. Zoo's effectiveness. In addition, standardized measures should be used both before and after playing the game to assess the reduction in fear more accurately. Furthermore, parents' involvement and children's previous experience with games should be assessed and controlled in future studies.

Conclusions

Dr. Zoo is one of the first exposure-based mobile games designed to reduce needle anxiety in young children aged 3 to

6 years. The results of this pilot feasibility study demonstrated that Dr. Zoo had high ease of use, acceptability, and potential preliminary effectiveness. Qualitative findings provided context for the quantitative findings and revealed that children had little difficulty playing the game and were excited to play the game each day. Furthermore, parents found the game to positively impact their child's fear of and distress toward needles. Taken together, these results suggest that an evidence-based serious mobile game can be an acceptable and potentially effective intervention for changing young children's fear and perceptions of needles. Exit interviews with parent participants revealed helpful suggestions for future iterations of the game, such as opportunities for children to display emotional mirroring with the animals and changes in ease of use. Leveraging digital interventions may be a potential solution to needle anxiety as a public health concern. As more mobile games are being developed to combat anxiety, it is imperative to integrate both evidence-based components and user input to achieve the highest impact.

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Data Availability

Data are available from the corresponding author upon reasonable request.

Authors' Contributions

JSS, OL, and DB conceptualized the study. CL, RH, and AV conducted formal analysis for the study. JSS and DB acquired the funding for this study. JSS, OL, and DB developed the methodology of the study. CL administered the study to the participants. PH designed and developed the game being studied. PH, CL, JSS, and DB wrote the manuscript. PH, CL, JSS, OL, RH, and DB reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Logistic regression analyses of children's age predicting various barriers to use factors.
[DOCX File , 13 KB - games_v11i1e42025_app1.docx]

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Abbreviations

CBT: cognitive behavioral therapy
FSSC-R: Fear Survey Schedule for Children–Revised
VR: virtual reality
VRET: virtual reality exposure therapy

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Original Paper

Social Presence, Negative Emotions, and Self-Protective Behavioral Intentions of Nonsmokers in Response to Secondhand Smoking in Virtual Reality: Quasi-Experimental Design

Miao Liu[1], PhD; Yicheng Zhu[1], PhD; Zihan Xu[1], BA; Sitong Meng[1], MA

School of Journalism and Communication, Beijing Normal University, Beijing, China

Corresponding Author:
Yicheng Zhu, PhD
School of Journalism and Communication
Beijing Normal University
19 Xinjiekou Outer St. Beijing Normal University
Haidian Dist.
Beijing, 100875
China
Phone: 86 13436952270
Email: yichengresearch@gmail.com

Abstract

Background: The application of virtual reality (VR) in health care has grown rapidly in China, where approximately half of the population is directly exposed to secondhand smoke (SHS). As VR headsets have become increasingly popular and short video platforms have incorporated 360° videos in China, new formats and opportunities for health campaigns about SHS have emerged.

Objective: In a simulated environment of exposure to SHS, this study aims to explore the emotional and behavioral responses to enhanced social presence brought about by VR in contrast to flat-screen videos. It also aims to examine whether and to what extent video modality (360° video vs flat-screen video) and contextual cues (high threat vs low threat) influence psychometric and intentional variables among viewers.

Methods: A total of 245 undergraduate and graduate students who were nonsmokers and from a large university in China participated in this study between October 2020 and January 2021. This study created 4 different versions of a SHS experience in a café with a 2 (360° video on a head-mounted display vs flat-screen display) × 2 (high threat vs low threat) experimental design. It developed and tested a path model examining the effects of experience modality and threat levels on social presence, emotions (anger and disgust), and eventually behavioral intentions (staying away and asking for help).

Results: We found that both video modality ($P<.001$) and threat level ($P=.005$) significantly influenced social presence, whereas the interaction of video modality and threat level did not have a statistically significant effect on social presence ($P=.55$). Negative emotions mediated the relationships between social presence and SHS-related self-protective behaviors. Specifically, anger positively predicted the intention to ask smokers to stop smoking through the waitress ($P<.001$). Disgust and fear both positively predicted the intention to stay away from the SHS environment ($P<.001$ for disgust; $P=.002$ for fear).

Conclusions: This study explored the potential mediating mechanisms that influence individuals' responses to the risks of SHS in public areas. The results demonstrated that social presence and negative emotions are 2 important mediators that underlie the relationship between video modality and behavioral intention regarding SHS in a VR setting. These findings suggest that an immersive environment could be a better stimulator of anti-SHS emotions and behaviors than flat-screen videos.

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KEYWORDS

virtual reality; VR; social presence; emotions; secondhand smoking

Introduction

Background

Secondhand smoke (SHS) is a severe yet understudied health issue in China. SHS could cause an increased risk of respiratory illness, heart disease, lung cancer, and asthma and worsen chronic obstructive pulmonary disease [1]. According to the Global Adult Tobacco Survey China, more than half of the Chinese people reported that they were exposed to SHS in the workplace and 44.9% of the respondents were exposed to SHS at home [2]. Data from the World Health Organization revealed that >700 million nonsmokers are exposed to SHS at least once a day in a typical week, and exposure to SHS causes 100,000 deaths annually in China [3]. Even though smoke-free policies prohibiting smoking in indoor public places came into force in certain metropolitan areas such as Beijing and Shanghai, SHS is still not rare in many restaurants, bars, and workplaces. The lack of implementation resources, together with a collectivist culture, makes it difficult to implement the smoking-free policies. The rate of exposure to SHS in public places is higher in China than in many other countries [4].

Antismoking mass media campaigns can effectively change smoking attitudes and beliefs, promote smoking cessation, and reduce adult smoking prevalence [5]. The 2006 Surgeon General's report indicated that the only way to protect nonsmokers from SHS was to eliminate exposure from smoking [6]. However, there are insufficient health campaigns targeting the SHS problem in China, and the message effect of these health campaigns has not been extensively examined and evaluated. Moreover, current SHS control programs have been mainly targeted at smokers such as male smokers [7] and smoking parents [8,9], whereas less effort has been made to encourage SHS self-protective behaviors of nonsmokers. Considering the high prevalence of SHS in indoor public places in China, interventions that target motivating SHS self-protective behaviors in nonsmokers are worth investigating. The purpose of this study was to explore the delivery channel and the content of health messages that could influence individuals' responses to SHS in public places.

Health Campaigns in Virtual Reality: The Role of Presence and Context

Virtual reality (VR) is broadly defined as a computer-generated environment that allows users to sense and interact with other objects and people as if they are in the real world [10]. Among the various types of VR technology applications, immersive virtual environments (IVEs) can be experienced by users through head-mounted displays (HMDs) such as Oculus Rift, HTC Vive, or Pico Pro. As one of the modalities of IVEs, 360° videos have become a new health communication tool and have been increasingly incorporated into health education and health promotion campaigns [11-13]. In the context of health education, a meta-analysis revealed that an IVE is more effective than other types of digital education in increasing health professionals' knowledge and cognitive skills [14]. Media messages that incorporate VR technologies can have a great impact on audiences' personal risk perceptions and thus motivate healthy behaviors. The study by Ahn et al [11] found that 1 week after exposure, a pamphlet coupled with an IVE led to less soft drink consumption than the noncoupled message (just a pamphlet). An IVE has also been used as a mode of cue presentation in smoking cessation programs [15]. However, the underlying mechanism by which VR technologies promote specific health behaviors has received scant attention.

The application of IVEs in health-related campaigns was found to be effective when the viewer is situated as a first-person *participant*. For users of an IVE, different person perspectives (ie, observer, partaker, and victim) provide distinct levels of social interactability for the intradiegetic actors. As a third person, the avatar in the virtual environment usually lacks the ability to socially interact with characters and objects. However, a first-person "victim" perspective could provide the user with an experience similar to an extrafictional victim's lived experience [16]. This study focuses on this first-person perspective of "victim" as it could most effectively position the user into the fictional experience of being harassed by SHS, where objects such as exhaled smoke or tossed cigarette butts could be oriented toward the user directly. As the study will review later, these fictional social interactions, along with the users' feeling of being forcefully engaged with socially undesirable interactions, are critical in arousing negative emotions.

Social presence, simply defined as the "sense of being with another" [17], is essential in creating effective first-person IVEs. Social presence as an inherent consequence of the modalities with varying levels of immersion has been well accepted in the VR literature [18]. Conceptually, immersion can be a technological affordance of virtual environments that works as a catalyst for the enhancement of psychological presence [19]. Although others have conceptualized immersion as a subcomponent of a larger presence construct [20], the effect brought by modality change on presence is well established. In the current case, 360° videos experienced in HMDs can arguably create a higher level of isolation for the user from the external world. More importantly, health behavior experiments using 360° videos are theoretically more interested in how the intentions of social interactive behaviors are influenced. Hence, this study focuses on social presence as a key theoretical nexus, instead of adopting a multidimensional focus on the larger concept of presence [21].

Previous studies have shown that individuals in 3D model–based and 360° video–based immersive environments experience a higher level of social presence than individuals who use flat-screen displays [22,23] because the VR setup could provide a wider range of sensory channels [24]. Apart from technological modality, contextual properties such as social cues and agency also influence social presence [18]. Social presence could be influenced by the psychological processes through which individuals interpret available social cues in a positive or negative way [18]. Studies have suggested that cues that indicate the social context (eg, the number of people) could lead to a higher level of social presence [25,26]. Similarly, the study by Lombard and Ditton [27] suggested that content variables such as human and nonhuman characters influence presence. Attentional bias toward threat suggests that people are more prone to direct their attention to threatening stimuli than to neutral stimuli [28]. Empirical research has shown that a higher level of threat could induce a prevention focus [29]. According to the explication of social presence by Cummings and Wertz [30], involvement, which manifests as focus or attention, is an important dimension of social presence. In this study, we propose that threat level is a contextual cue that influences the level of social presence. A high level of threat is expected to elicit a higher level of social presence. Thus, we propose the following hypotheses:

- Hypothesis 1: participants viewing the content in 360° video format with HMD (vs flat-screen display) feel more social presence.
- Hypothesis 2: participants viewing the content with high threat feel more social presence than those viewing the content with low threat.

However, the interaction between video modality and threat level is less certain. Studies have shown that immersive media forms could enhance the effectiveness of risk communication [31,32]. In addition, health messages with a higher level of threat are generally more persuasive than those with a lower level of threat [33]. One study found that modality (immersive VR vs flat-screen display) modulated different types of threats [34]. The study by Jin and Brown-Devlin [35] found that perceived threat is a moderator that can maximize the effects of social presence. In summary, threat emerges as an important contextual factor that influences the effect of modality on social presence. To our knowledge, there is no extant research that directly examines the interaction effect between modality and threat level on social presence. Therefore, we propose the following research question: Is there an interaction effect between video modality and threat level on social presence?

Social Presence and Emotion in the VR Setting

Generally, it has been found that IVEs have a stronger effect on eliciting emotions than the traditional flat 2D screen. The study by Jimenez et al [36] compared the player's responses to emotional content displayed on VR and flat screens. It has been found that after experiencing both conditions, VR provides a more intense and frightening experience than playing on a traditional monitor. The study by Susindar et al [37] found that emotionally charged stimuli in IVEs can effectively elicit anger and fear. Social presence, as a crucial component in creating realistic IVE experiences, is a key mechanism that produces the effect of modalities on individuals' emotional responses. Social presence is intrinsically linked to emotion. According to the study by Garrison et al [38], emotion is an indicator of social presence. The association between social presence and emotion has been demonstrated abundantly in VR research. A systematic review conducted by Diemer et al [39] showed that the association between presence and emotion has mainly been examined by means of correlations between these 2 measures. For example, 1 study found that socially anxious participants reported higher social presence than their peers in an interactive virtual environment [40]. Another study found a correlation between presence and fear in the text-anxious group in IVE [41]. Recent research has begun to explore the causal effect of social presence on emotional responses [42,43]. For example, it is found that social presence positively influenced empathy by making the user feel more comfortable in a virtual environment [44]. In health settings, the portrayal of the same antismoking message using spatial augmented reality statistically significantly influenced negative emotions through its effect on spatial presence compared with a 2D screen display [45]. On the basis of the previous literature, the following hypothesis is proposed:

- Hypothesis 3: social presence positively predicts negative emotions including anger (hypothesis 3a), fear (hypothesis 3b), and disgust (hypothesis 3c).

Effects of Emotions on Behavior in SHS Scenarios

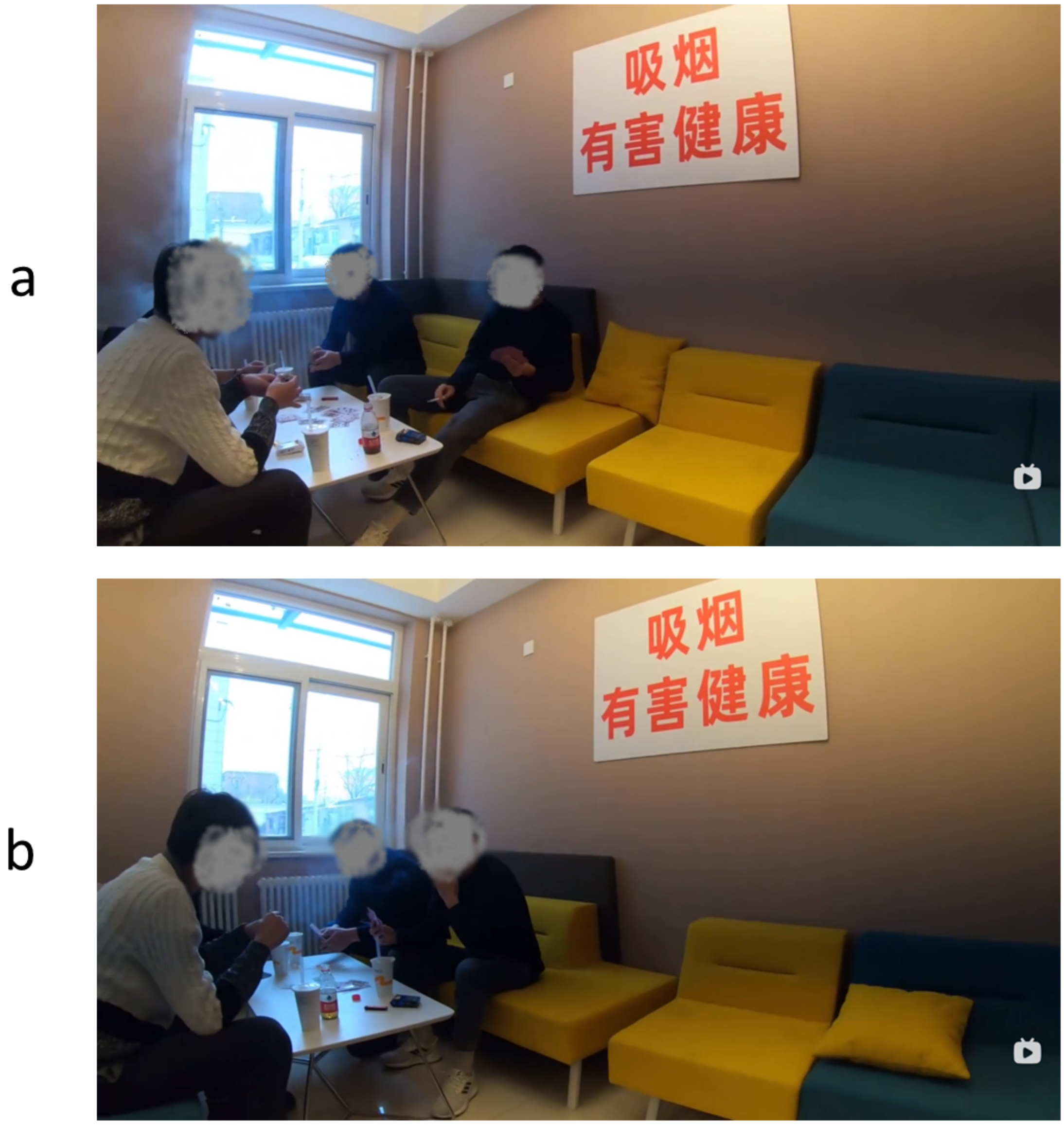
Emotion could trigger a set of responses (physiological, behavioral, experiential, and communication) that prompts individuals to address encountered problems quickly [46]. Negative emotions play a powerful role in influencing individuals' self-protective behaviors [47-50]. Eliciting negative emotional responses has been increasingly used as an effective strategy in persuasive health messages. An ample number of prior studies have demonstrated that emotionally charged information about the adverse effects of smoking could effectively promote positive behavioral change. Research has shown that emotionally arousing antismoking advertising is more likely to be recalled and promote high-order cognitive processing [51,52]. The antismoking information that aroused the strong negative emotions of fear and sadness was rated as more effective by youth participants [53].

Emotion has its action tendency. Generally, emotions can be categorized based on approach and avoidance tendencies. The approach or avoidance motivation model of emotions provides a theoretical foundation for the causal effects of emotions on behavior [54]. In this study, we focused on 3 distinct negative emotions, including anger, fear, and disgust, which are often associated with exposure to SHS or viewing antismoking messages [55-58]. Anger, characterized by approach or agonistic motivation, is often elicited by negative or offensive stimuli [59,60]. Research has suggested that anger has a motivational tendency to subdue offending stimulus [61]. Fear is associated with avoidance tendencies and inhibition [60]. In media effect research, fear is often induced by threat appeal [62]. Fear has the function of motivating efforts for self-protection [61]. Similar to fear, disgust is an avoidance or withdrawal emotion. Disgust is often associated with the appraisal theme of being too close to a potentially contaminating object [63]. Disgust is characterized by motivating physical avoidance of a disgusted object or behavior [64].

Previous research has examined the effects of personal traits and behavioral factors on SHS avoidance behavior [65]. In this study, we focused on the emotional antecedents of SHS avoidance behaviors. On the basis of a previous theoretical framework, anger, as a negative approach emotion, is hypothesized to predict the intention to ask smokers not to smoke through the waitress. Fear and disgust, both avoidance emotions, were hypothesized to predict the intention to stay away from SHS. The conceptual models are depicted in Figure 1A (model 1) and Figure 1B (model 2).

- Hypothesis 4: anger positively predicts the behavioral intention of asking smokers to stop smoking through the waitress.
- Hypothesis 5: fear and disgust positively predict behavioral intention to stay away from the SHS environment.

Figure 1. Screenshot of stimulus videos for flat-screen conditions: (A) high threat × flat-screen condition and (B) low threat × flat-screen condition.



Methods

Participants and Design

A total of 245 undergraduate and graduate students who are nonsmokers and from a large university in China participated in this study between October 2020 and January 2021 (mean age 22.16, SD 13.08 y). Individuals with a history of smoking, even if they were currently nonsmokers, were excluded from this study. The design and conduct of the experiment were preapproved and foreseen by the research ethics review board at the institution. The research recruitment flyer was distributed through the most popular Chinese social app, WeChat. Female students accounted for 166 (67.8%) out of 245 participants, whereas male students accounted for 79 (32.3%) of the participants.

A 2 (360° video in HMD vs flat-screen display) × 2 (high threat vs low threat) factorial experiment was conducted on the web and in the laboratory setting. All the participants were randomly assigned to 1 of the 4 experimental conditions. The HMD conditions included 122 participants, with 58 and 64 participants in the high-threat and low-threat condition, respectively. The flat-screen conditions included 123 participants, with 60 and 63 participants in the high-threat and low-threat condition, respectively.

Participants assigned to the flat-screen condition were asked to complete a questionnaire on the Qualtrics (Qualtrics International Inc) website using a computer, and those assigned to the VR condition (360° video in HMD) were asked to come to the laboratory. To ensure that all the participants in the flat-screen condition watched the video using a computer, we disabled the mobile function on Qualtrics and added highlighted instructions that the videos should be viewed in full-screen mode. Before the experiment, the participants electronically signed a consent form. The Pico Goblin 2 headset was used to present stimuli in the VR condition. The participants could look around in the virtual environment for the VR conditions of the study. In the VR condition, the participants were debriefed upon completing the survey. All participants who completed the study were rewarded with approximately US $5.

Power analysis assuming an α level of .05 and a power of 95% suggested that a sample size of 212 was sufficient to detect a medium effect size of *f*=0.25.

Message Manipulation

The experimental stimuli consisted of four 2-minute short videos created by the authors. The flat-screen stimulus was shot using a GoPro-4 camera, whereas the VR stimuli were shot using Insta 360 One X. All the videos were shot from the first-person perspective. Figure 1A depicts the mise-en-scène of the high-threat, flat-screen condition, and Figure 1B depicts the low-threat, flat-screen condition. The 360° videos were created using the same settings but with a 360° video camera. The HMD allowed viewers to view 360° videos under VR HMD conditions. At the beginning of the videos, the main character (the participant) was sitting in a café, where 4 men playing poker cards can be seen across the participant. In the high-threat condition, 4 smokers were smoking at the same time while playing poker cards. In the low-threat condition, there were 4 people playing poker cards but only 1 person was smoking in the video. Both the high-threat and low-threat stimuli were approximately equal in length. To ensure that the message content is the same across the 2 delivery channels, the experiment stimuli that had the same threat level were shot simultaneously.

Measures

Behavioral Intentions Toward SHS

A total of 2 SHS-related behavioral intentions were measured in this study: asking smokers to stop smoking through the waitress (mean 3.73, SD 1.03) and leaving the SHS environment (mean 2.89, SD 0.69).

Negative Emotions

Negative emotions, including anger, fear, and disgust, were measured using a self-report measure of discrete emotions [66]. Disgust was measured by 3 items: disgusted, sickened, and grossed out (mean 4.12, SD 0.68; α=.69). Fear was measured using 3 items: fearful, afraid, and scared (mean 2.89, SD 0.86; α=.73). Anger was measured using 4 items: irritated, angry, annoyed, and aggravated (mean 3.87, SD 0.87; α=.85). Participants were asked, “While you were in the virtual reality environment/watching the video, to what extent did you experience each of the following emotions?” (0=“none of this feeling”; 4=“a great deal of this feeling”).

Social Presence

Social presence was measured using the social presence–actor scale, originally developed by Lombard et al [21]. A total of 4 items from the scale were adapted in a study examining first-person social presence, of which 1 example item asked, “How often did you have the sensation that people you saw/heard and also see/hear you?” (1=“never”; 7=“always”) [12]. We used the same items whose scores were then averaged to form an overall measure (mean 3.15, SD 1.31; α=.87).

Control Variables

To determine whether any control variable should be included in the path model, we performed a randomization check on the distribution of age (continuous), gender (dichotomous), family income (categorical), and whether the participant was living with a smoker (dichotomous) across experimental conditions. Results of chi-square tests (on gender, family income, and living with a smoker) and an ANOVA test (on age) showed that there were no distributional differences in these demographic variables for age, family income, and living with a smoker. Thus, no control variables were included in the path model.

Manipulation Check

Perceived threat level was assessed by 1 question, “How much risk do you think is associated with SHS in the video you just watched?” (mean 3.95, SD 0.95).

Analysis Strategy

Path analysis based on the maximum likelihood estimation was conducted using Stata (version 15; StataCorp). Model fit was assessed based on conventional criteria, including chi-square test, root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), and comparative fit index (CFI). A value of ≤0.06 for RMSEA, <0.09 for SRMR, and ≥0.95 for CFI can be considered as a good fit [67]; we performed path analysis based on 5000 bootstrap samples.

Ethics Approval

The study was approved by the institutional review board of the School of Journalism and Communication at Beijing Normal University (protocol code BNUJ&C20200706001; July 6, 2020).

Results

Effect of Modality on Social Presence

The manipulation check was successful. A 2-way ANOVA was used to assess the effect of threat level on perceived risk. The threat levels induced statistically significantly different levels of perceived risk ($F_{1,244}$=4.87; *P*=.02). Participants in the high-threat condition were more likely to perceive the environment to be riskier (mean=4.08, SE=0.08) than those who were in the low-threat condition (mean=3.82, SE=0.09). Table 1 shows the bivariate correlations between all the variables included in the path model. The proposed models depicted in Figure 2A and Figure 2B were tested using path analysis.

Model 1 fit the data well (χ^2_7=11.1, *P*=.13; CFI=0.91, RMSEA=0.049, and SRMR=0.040). For model 2, the initial hypothesized path model did not fit the data well (χ^2_{11}=37.3, *P*<.001; CFI=0.71, RMSEA=0.099, and SRMR=0.077). On the basis of the fit indices of the hypothetical model and modification indices, we revised the model by correlating the error terms of disgust and fear. Finally, all the fit indices of model 2 were satisfied with the conservative criterion (final model: χ^2_{10}=14.4, *P*=.16; CFI=0.962, RMSEA=0.042, and SRMR=0.050). Figure 3A and 3B show the path diagrams with a standardized estimation of the final models.

Consistent with hypothesis 1, video modality was a statistically significant predictor of social presence (β=.87, SE=.23; *P*<.001). VR induced a higher level of social presence (mean 3.40, SD 1.23) than flat-screen displays (mean 2.85, SD 1.31). The threat level also positively predicted social presence (β=.34, SE=.16; *P*=.005). Participants in the high-threat condition perceived higher social presence (mean 3.29, SD 1.28) than those in the low-threat condition (mean 2.95, SD 1.30). Hypothesis 2 was supported.

Table 1. Zero-order correlations used in the path analyses[a] (N=245).

Variable	Video modality	Threat level	Interaction	Social presence	Anger	Fear	Disgust	Stay away	Ask for waitress's help
Video modality									
r	1	−0.01	0.59	0.22	−0.13	0.07	0.09	0.003	–0.04
P value	—[b]	.85	<.001	.001	.05	.27	.19	.97	.55
Threat level									
r	−0.01	1	0.57	0.13	0.06	0.15	0.05	0.06	0.02
P value	.85	—	<.001	.05	.34	.02	.42	.36	.79
Interaction									
r	0.59	0.57	1	0.14	0.002	0.19	0.15	0.10	0.02
P value	<.001	<.001	—	.03	.97	.004	.02	.10	.78
Social presence									
r	0.22	0.13	0.14	1	0.17	0.25	0.17	0.04	0.10
P value	.001	.05	.03	—	.009	<.001	.008	.56	.10
Anger									
r	−0.13	0.06	0.002	0.17	1	0.29	0.63	0.30	0.27
P value	.51	.34	.97	.009	—	<.001	<.001	<.001	<.001
Fear									
r	0.07	0.15	0.19	0.25	0.29	1	0.33	0.29	0.05
P value	.27	.02	.004	<.001	<.001	—	<.001	<.001	.44
Disgust									
r	0.09	0.05	0.15	0.17	0.63	0.33	1	0.40	0.25
P value	.19	.42	.02	.008	<.001	<.001	—	<.001	<.001
Stay away									
r	0.003	0.06	0.10	0.04	0.30	0.29	0.40	1	0.18
P value	.97	.36	.10	.56	<.001	<.001	<.001	—	.004
Ask for waitress's help									
r	−0.04	0.02	0.02	0.10	0.27	0.05	0.25	0.18	1
P value	.55	.79	.78	.10	<.001	.44	<.001	.004	—

[a]n=224.

[b]Not applicable.

Figure 2. Proposed path models: (A) model 1 (with asking waitress as the outcome variable) and (B) model 2 (with staying away as the outcome variable).

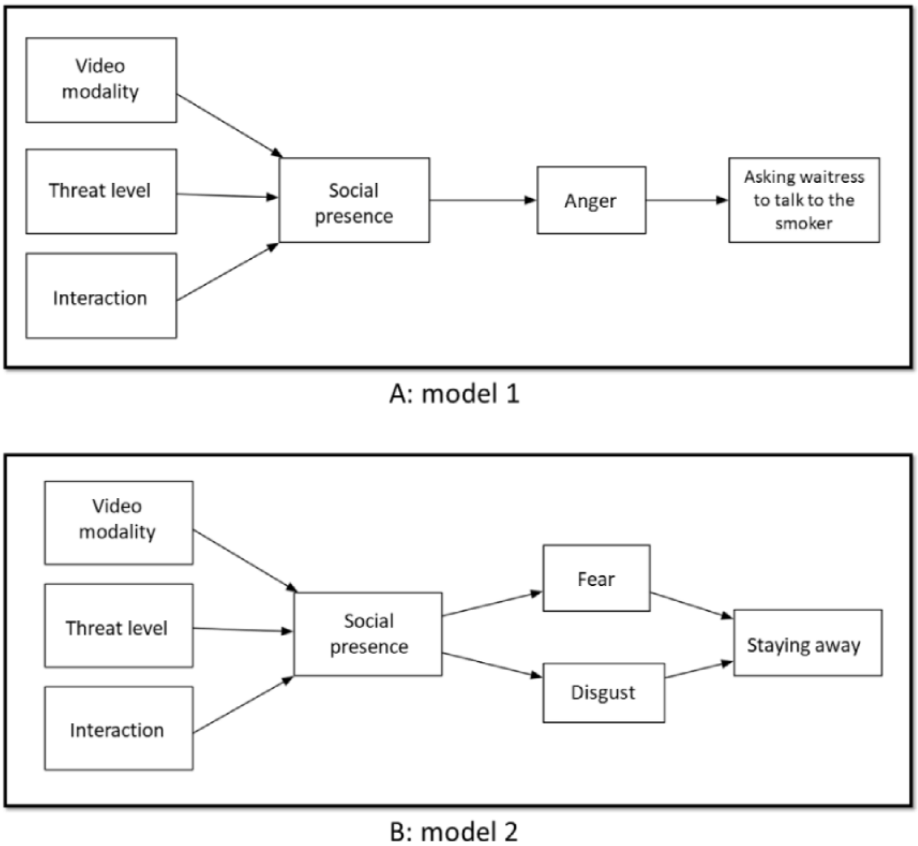
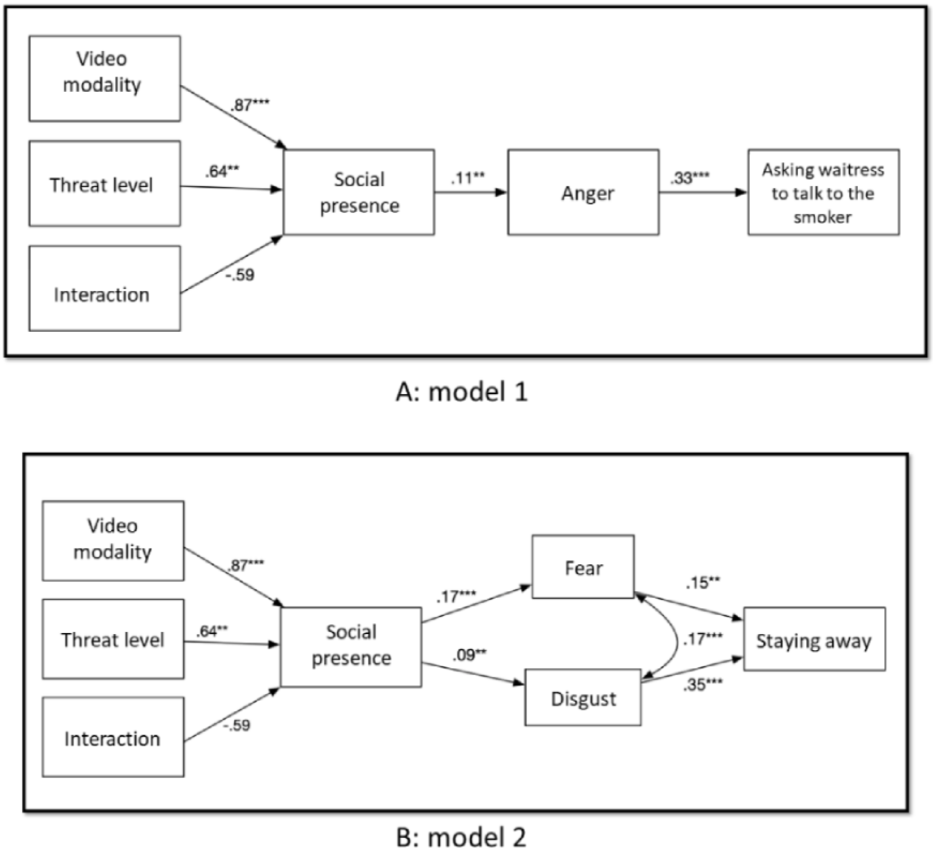


Figure 3. Proposed path models: (A) model 1 with path coefficients and (B) model 2 (adjusted) with path coefficients. ***P*<.01 and ****P*<.001.



Effect of Social Presence on Emotions

In terms of research question 1, the interaction between video modality and threat level was not associated with social presence (β=−.59, SE=.32; *P*=.06). Hypothesis 3 stated that social presence positively predicts negative emotions. Consistent with our hypotheses, social presence had a direct influence on anger (β=.11, SE=.03; *P*=.008), disgust (β=.09, SE=.03; *P*=.007), and fear (β=.17, SE=.04; *P*<.001).

Effect of Emotions on SHS-Related Behaviors

As stated in hypothesis 4, anger positively predicted the intention of asking smokers to stop smoking through the waitress (β=.33, SE=.07; *P*<.001). Disgust and fear both positively predicted the intention to stay away (β=.35, SE=.06; *P*<.001 for disgust; β=.15, SE=.07; *P*=.002 for fear), supporting hypothesis 5. For model 1, the conditional indirect effect of video modality on asking smokers to stop smoking through the waitress was statistically insignificant (95% CI −0.0002 to 0.0632), and the conditional indirect effect of the threat level of asking smokers to stop smoking was statistically insignificant (95% CI −0.002 to 0.049).

Consideration on Alternative Models

For model 2, the conditional indirect effect of video modality on the intention to stay away was 0.05 (95% CI 0.01-0.09) and the conditional indirect effect of threat level of asking smokers to stop smoking was 0.04 (95% CI –0.004 to 0.067). Because we were unable to confirm the causal relationship between emotion and social presence using cross-sectional data, we also tested the 2 alternative models to further validate the results. To test an alternative model 1, anger was tested as the predictor of social presence. Such an alternative model did not fit the data well (χ^2_7=40.9, *P*<.001; CFI=0.238, RMSEA=0.141, and SRMR=0.086). The second alternative model treats fear and disgust as the predictors of social presence. The second model also did not fit the data very well (χ^2_9=98.2, *P*<.001; CFI=0.222, RMSEA=0.201, and SRMR=0.120). To test for an alternative model 2, we then correlated the error term of disgust and fear for model 2, and the fit indices were not satisfactory either (χ^2_8=73.3, *P*<.001; CFI=0.431, RMSEA=0.183, and SRMR=0.104). As both alternative models did not fit the data well, we can conclude that the proposed models in Figure 2 are more theoretically solid.

Discussion

Summary of Findings

Despite the high prevalence of SHS in China, research that focuses on public reactions to SHS in public areas remains scarce. This study explored the potential mediating mechanisms that influence individuals' responses to SHS risks in public areas based on a college student sample. To our knowledge, this is the first study to explore the health message effect of VR on SHS-related behavioral intentions of nonsmokers. Overall, we found that compared with flat-screen stimuli, the VR stimuli statistically significantly increased participants' social presence, which in turn influenced negative emotions, and negative emotions statistically significantly mediated the relationships between social presence and SHS-related self-protective behaviors. However, there was no statistically significant interaction effect between threat and video modality on social presence, despite the fact that both threat and video modality had a statistically significant individual effect on social presence. The results of this study suggest that VR is a promising channel for delivering effective health campaigns to motivate nonsmokers' self-protective behaviors in the SHS environment.

Principal Findings

This study contributes uniquely to the evidence on the persuasive effects of VR messages on self-protective behaviors related to SHS. We found that the VR-based stimulus induced a higher level of social presence than the flat-screen stimulus. Moreover, threat level, as a contextual factor, also statistically significantly influences social presence. Smoke in this study serves as an important contextual cue that creates an immersive illusion. Therefore, 1 possible explanation for the link between threat level and social presence is that the more smoke is blown by the smokers, the more likely the participants feel they are physically in the SHS environment.

This study also demonstrates the influence of social presence on negative emotions. With a higher level of social presence, participants experienced more negative emotions. This finding supports the relationship between social presence and emotions, as has been confirmed in various contexts. This study also adds to the literature by showing that different negative emotions lead to different behavioral intentions regarding SHS. More specifically, fear and disgust, as avoidance emotions, positively predicted the intention to stay away from the SHS environment, and anger, which is characterized by approach tendency, positively predicted the intention to stop others from smoking through the waitress in public places. When it comes to persuasive health messages, negative emotions could influence viewers' perception of their future personal risk, and consequently, increase their motivation to adopt self-protective behaviors.

This study has theoretical and practical implications. Theoretically, the results of this study confirm the effect of social presence on negative emotions. We developed a coherent model of SHS-related self-protection behaviors by examining the underlying mechanism linking video modality and threat level to SHS-related self-protection behaviors. We also demonstrated the effectiveness of VR in presenting highly emotionally provocative information. Practically, the findings suggest that VR could be used as an effective tool to facilitate public health campaigns that aim to encourage self-protection behaviors in SHS environments. As the study by Guixeres et al [68] suggested, VR technology provides controllable, multisensory, and interactive 3D computer-generated stimulus environments that offers intervention options that are not possible using traditional methods. By providing an immersive and interactive experience, VR can deepen one's understanding of the importance and urgency of a particular social issue [44]. VR-based health messages targeting a specific health issue thus merit further research. VR could be strategically used in health communication campaign planning to promote nonsmokers' self-protective behaviors.

Comparison With Prior Work

Consistent with the previous literature, social presence is an essential factor that influences individuals' experiences in a virtual environment. The participants who watched the VR were more likely to feel that they were in the SHS environment than those who watched a video on a computer. This study builds on this immersive effect by adding contextual smoking cues.

Previous literature shows that anger is an emotion that reflects the motivation to respond directly to immediate social threat [69]. On the basis of the results of this study, we concluded that negative emotions play an important role in controlling the adverse effects of SHS. It is recommended that public health message designers consider message features that could effectively induce negative emotions, thereby promoting health behaviors. Our study also calls for the development of culturally tailored health intervention programs in China. In collectivist cultures, it is generally considered impolite or socially inappropriate to stop others smoking directly in public places. As previous research has suggested, collectivists generally prefer maintaining harmony and a nonconfrontational conflict style [70]. Our study highlights the potential of encouraging nonsmokers to ask others for help to communicate with smokers in a collectivist cultural setting. Further research on culturally oriented communication strategies for SHS prevention is needed.

Limitations

This study had several limitations. First, only participants in VR conditions completed the survey in the laboratory setting, whereas the rest of the participants in the flat-screen conditions completed the web-based experiment. Compared with laboratory experiments, web-based experiments have more environmental variabilities, such as noise, lighting, and technical aspects of the equipment [71] (eg, although the survey cannot be accessed on phones, the variance of the screen size among participants potentially exists, and we cannot ensure the same eye distance from the screen and body posture), which may influence the level of immersion as a predictor of the model.

Second, student samples are generally more homogenous than the general public. Female college students, who constitute a large proportion of the sample, are more likely to have a higher level of knowledge about SHS [72], as it has been found in previous literature that female individuals with at least college education or nonsmokers were more likely to choose restaurants and bars with restrictions on smoking [73]. College students are also less likely to be exposed to SHS, as Chinese college students are required to live on campus, and college students are generally nonsmokers or lighter smokers.

Third, we did not measure whether the participants have gambling disorder problems. Because the experiment stimuli contain the scene of smokers playing poker cards, it is possible that participants who are addictive to gambling are less sensitive to smoking in the VR environment. Finally, there could be unmeasured variables and other confounding factors, such as participants' previous VR use and attitude toward smoking, which could have influenced the results. Future studies should also consider these factors.

Future Directions

Further research is needed to determine whether the results of this study can be replicated in other age groups. As demonstrated in this study, VR could be an effective way to enhance the behavioral intention of stopping others smoking in public areas among college students. However, it is unknown whether these results can be replicated using different sampling frames. More augmented reality–based and VR-based health interventions that target specific populations are needed. Prospective studies examining the effect of VR on health behavioral outcomes and providing conclusive evidence of the mediating mechanisms are also recommended. In addition, future research can be built from this study by examining the effects of different message delivery methods.

Conclusions

In conclusion, our study demonstrates that social presence and negative emotions are 2 important mediators underlying the relationship between video modality and behavioral intention regarding SHS in a 360°-video VR setting. More specifically, we found that (1) smoke as a contextual risk factor increases social presence alongside video modality and (2) negative emotion can be a key factor relating to behavioral intention. Health practitioners are recommended to incorporate VR technologies into more public health strategies and practices.

Acknowledgments

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Data Availability

The data sets generated during and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

ML and YZ contributed to the conceptualization, validation, and resources and funding acquisition. ML contributed to the methodology, software, visualization, and supervision. ML, YZ, and SM contributed to the formal analysis. ZX and SM contributed to the investigation. ML, YZ, ZX, and SM contributed to data curation. ML contributed to writing—original draft preparation. YZ contributed to writing—review and editing—and project administration. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CFI: comparative fit index
HMD: head-mounted display
IVE: immersive virtual environment
RMSEA: root mean square error of approximation
SHS: secondhand smoke
SRMR: standardized root mean square residual
VR: virtual reality

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Original Paper

A Video Game Intervention to Prevent Opioid Misuse Among Older Adolescents: Development and Preimplementation Study

Kammarauche Aneni[1,2*], MBBS, MHS; Claudia-Santi F Fernandes[1,2*], EdD, LPC, MCHES; Lily A Hoerner[3], BA; Claire Szapary[4], BA, MPH; Tyra M Pendergrass Boomer[3], BSc, MEM; Lynn E Fiellin[1,3,4], MD

[1]Child Study Center, Yale University School of Medicine, New Haven, CT, United States

[2]Biomedical Informatics and Data Science, Yale University School of Medicine, New Haven, CT, United States

[3]Department of Internal Medicine, Yale University School of Medicine, New Haven, CT, United States

[4]Yale School of Public Health, New Haven, CT, United States

[*]these authors contributed equally

Corresponding Author:
Lynn E Fiellin, MD
Department of Internal Medicine
Yale University School of Medicine
2 Church Street South
Suite 515
New Haven, CT, 06519
United States
Phone: 1 203 785 2885
Email: lynn.sullivan@yale.edu

Abstract

Background: Opioid misuse and mental disorders are highly comorbid conditions. The ongoing substance misuse and mental health crises among adolescents in the United States underscores the importance of widely scalable substance misuse preventive interventions that also address mental health risks. Serious video games offer an engaging, widely scalable method for delivering and implementing preventive interventions. However, there are no video game interventions that focus on preventing opioid misuse among older adolescents, and there are limited existing video game interventions that address mental health.

Objective: This study aims to develop and conduct a formative evaluation of a video game intervention to prevent opioid misuse and promote mental health among adolescents aged 16-19 years (*PlaySmart*). We conducted formative work in preparation for a subsequent randomized controlled trial.

Methods: We conducted development and formative evaluation of *PlaySmart* in 3 phases (development, playtesting, and preimplementation) through individual interviews and focus groups with multiple stakeholders (adolescents: n=103; school-based health care providers: n=51; and addiction treatment providers: n=6). *PlaySmart* content development was informed by the health belief model, the theory of planned behavior, and social cognitive theory. User-centered design principles informed the approach to development and play testing. The Exploration, Preparation, Implementation, and Sustainability framework informed preimplementation activities. Thematic analysis was used to identify themes from interviews and focus groups that informed *PlaySmart* game content and approaches to future implementation of *PlaySmart*.

Results: We developed a novel video game *PlaySmart* for older adolescents that addresses the risk and protective factors for opioid misuse and mental health. Nine themes emerged from the focus groups that provided information regarding game content. Playtesting revealed areas of the game that required improvement, which were modified for the final game. Preimplementation focus groups identified potential barriers and facilitators for implementing *PlaySmart* in school settings.

Conclusions: *PlaySmart* offers a promising digital intervention to address the current opioid and mental health crises among adolescents in a scalable manner.

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KEYWORDS

videogames; serious games; opioid misuse; mental health; adolescents

Introduction

Background

The opioid crisis in the United States has affected many individuals and families. Although opioid misuse among adolescents and young adults has been declining in the past few years, death from opioids among this age group has been on the rise [1]. As a result of the COVID-19 pandemic, the mortality rate from drug overdose among adolescents aged 14-18 years has increased by 94% between 2020 and 2021 [1] and again by 20% between 2021 and 2022. The total number of fatal overdoses for 2022 was 1146 [1]. Opioid-related deaths accounted for up to 85% of drug-related deaths among adolescents between 2020 and 2022 [1].

In 2020 alone, 1.4 million young adults aged 18-25 years and 396,000 adolescents aged 12-17 years misused opioids [2]. Opioid misuse is “the unhealthy use of opioids to alter reality, bring about pleasure or relieve stress” [3]. It includes the use of heroin and prescription opioids in a different way than prescribed by a physician [2,4]. Opioid misuse among adolescents increases the risk of developing an opioid use disorder (OUD) and the risk of dying from opioids [5]. Opioid misuse can also increase the risk of negative mental health outcomes and lead to suicidal thoughts and behaviors [6]. Conversely, preexisting behavioral disorders, such as depression [7], anxiety [8], adverse childhood experiences [9] and posttraumatic stress disorder [10], and misuse of cannabis [11] and alcohol [12] increase the risk of opioid misuse. Approximately 65% of youth with substance use disorder have a co-occurring mental health disorder, and adolescents with these dual diagnoses are at an increased risk of adverse medical outcomes, suicide, incarceration, and interpersonal difficulties at school and at home [13,14]. This dire situation underscores the urgency for targeted preventive interventions that are easily accessible to adolescents and that address the intersection between opioid misuse and mental health.

Opioid misuse typically starts during mid- to late adolescence [15], suggesting that this is a crucial period for targeted and accessible preventive interventions. However, widely implemented interventions for adolescents that focus on opioid misuse prevention with mental health components are lacking [16]. As over 90% of adolescents are enrolled in schools and prior school-based interventions have demonstrated feasibility for substance misuse prevention [17,18], educational institutions offer a prime setting to meet adolescents where they are [19,20]. However, existing preventive interventions directed at opioid misuse among adolescents and young adults have either been conducted outside of the school setting [21,22], such as the emergency department [22], or require the involvement of trained clinicians [23-27], both of which can limit wide scalability.

Digital interventions, such as serious video games, have shown promise for targeting health outcomes among adolescents and young adults [17,18,28-30]. Given the near ubiquity of mobile device ownership in this population, over 90% of adolescents and young adults own mobile devices [31]. Digital interventions are also widely scalable and can reach more adolescents than would be possible with in-person interventions, particularly in light of the limited availability of trained personnel [32]. Serious video games—video games designed for a primary purpose other than entertainment [17,18,28-30,33]—are effective as interventions for adolescent substance misuse [34] and are a popular medium for adolescents, as over 95% of adolescents play video games [35]. Through simulated role-playing, which is a highly effective method used for learning purposes [36], serious video games allow individuals to practice behavioral skills in a safe and entertaining manner [37,38], increasing the likelihood of translating these practiced skills into real-life situations [39,40]. Because the same content is delivered to all adolescents in the same format, video games can allow for fidelity of the intervention content [41], allow for precise monitoring of how much content each adolescent has accessed [42], and may be more cost-effective [43]. Video game interventions have demonstrated efficacy in affecting behaviors related to health promotion and disease management in many areas, including chronic diseases, healthy lifestyles, and mental well-being [17,29,30,44-50]. Existing video game interventions that target opioid misuse among adolescents are limited [51,52], have not focused specifically on older adolescents [52], are not widely implemented, have yet to be rigorously evaluated in the school setting, and do not specifically address mental health risks [51,52].

In this paper, we describe the formative work of developing a serious video game intervention, *PlaySmart*, to prevent the initiation of opioid misuse among 16- to 19-year-olds at a higher risk for substance misuse. These efforts build on previous work at the play2PREVENT Lab, which developed and evaluated evidence-based video games for prevention among children, adolescents, and young adults [17,18,29,53,54]. *PlaySmart* is funded through the National Institute of Health Helping to End Addiction Long-Term Prevention Cooperative (HPC) Initiative. The National Institute on Drug Abuse ’s primary call for HPC was to address the opioid crisis among those who experienced greater risk among youth and young adults aged 16 to 30 years. HPC consists of a coordinating center and 10 research projects funded to test and implement evidence-based interventions designed to prevent the onset or escalation of opioid misuse among at-risk groups of youth and young adults.

Aims

The aims of the formative research were to (1) conduct focus groups and interviews to inform the content and storylines of the video game, *PlaySmart*, designed to prevent the initiation of opioid misuse among adolescents aged 16-19 years; (2) develop and conduct a preliminary evaluation (playtesting) of a video game, *PlaySmart*, in partnership with Schell Games and the National School-Based Health Alliance (SBHA) to be evaluated in a subsequent large-scale randomized controlled trial (RCT); and (3) conduct focus groups and interviews among key stakeholders to understand facilitators and barriers to implementing *PlaySmart* in school settings. An RCT is currently underway to evaluate the efficacy of this video game.

Methods

Theoretical Frameworks

A total of 3 phases of formative research (development, playtesting, and preimplementation) were guided by specific evidence-based theoretical frameworks.

Frameworks That Informed Development of Game Content

PlaySmart development was informed by 3 established theories: the health belief model [55], the theory of planned behavior, and social cognitive theory [56]. These theories describe how various ecological (individual, interpersonal, and environmental) factors influence the risk of engaging in substance misuse. The health belief model suggests that the likelihood that an individual will partake in a particular behavior (opioid misuse) is driven by their belief in how susceptible they are to its negative consequences and how effective they think a behavior will diminish their susceptibility to these impacts [55,57]. The health belief model consists of 6 constructs: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy [57,58]. The theory of planned behavior posits that an individual's behavior (opioid misuse) is driven by intentions that are influenced by attitudes, subjective norms, and perceived behavioral control (self-efficacy, external factors, and resources) [59-61]. Attitudes toward drug use and intentions to misuse are strongly influenced by the perception of the risk of harm [62]. As such, effective prevention interventions target these antecedent factors [28,30] to prevent eventual misuse. Social cognitive theory posits that learning occurs within a social context through an individual's interaction with their environment [63] and that the likelihood that an individual will engage in a behavior (opioid misuse) is driven by the individual's past experiences (reinforcement) and how the individual is influenced by internal factors (capability, self-efficacy) and their external environment (expectations, modeling) [63]. Social cognitive theory consists of 6 constructs: reciprocal determinism, behavioral capability, observational learning, reinforcement, expectations, and self-efficacy [63]. Improving self-efficacy is informed by the health belief model, the theory of planned action, and social cognitive theory and has been used in other video game interventions [28,30,34,64,65] targeting behavior change [65,66] such as substance misuse among adolescents [34] and found to be effective [67].

PlaySmart video game development was grounded in these theories with focus group and interview guides informed by them, and theoretical components are reflected in the game content (see focus group guide in Multimedia Appendix 1). *PlaySmart* aims to increase the perceived risk of harm from opioid misuse (primary outcome), as it has been shown to be inversely related to actual drug use [16,68,69]. Prior studies have demonstrated that older adolescents with low perception of the risk of harm from opioids are significantly more likely to misuse opioids [68,70]. The game provides opportunities to practice skills such as refusing misuse of opioids that bolster self-efficacy, model adaptive behaviors by observing the actions of other nonplayer characters in the game, and highlight avenues for resources that the player can relate to in their own life.

Framework That Informed Approach to Game Development

To guide our approach to game development, we used user-centered design principles. User-centered design is an iterative process that prioritizes the end user throughout the design and development phases [71,72]. It begins by identifying the needs of the end user and recognizing that their goals will ultimately determine the effectiveness and usefulness of the game. This is followed by the actual development of the game and its evaluation. A user-centered approach typically includes the use of multiple modalities, including focus groups, interviews, surveys, and user testing. Evidence has demonstrated that user-centered design increases the likelihood that interventions will be used by the end user [64,71,72] and has been used in the development of other digital interventions. A user-centered design has been used in the development of other digital interventions for substance use prevention among adults [73,74] and adolescents [75].

Framework That Informed Preimplementation

To inform the future implementation of *PlaySmart* in school settings, we conducted preimplementation focus groups to assist in understanding potential anticipated facilitators and barriers that could affect future implementation of *PlaySmart* in school-based settings. Preimplementation activities were informed by the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework [76]. The EPIS framework is an evidence-based tool that guides and facilitates its successful implementation. During the Exploration phase, the needs of the target end user are identified to determine the best practices that would ensure that those needs are met by the new product [76]. The Preparation phase allows potential barriers and facilitators to be successfully implemented and a plan for implementation to be developed [76]. During the Implementation phase, the developed plan is conducted with ongoing monitoring [76]. During the Sustainability phase, progress is monitored on an ongoing basis to identify when adaptation might be needed [76]. The EPIS framework has been successfully used in implementation programs for youth prevention [77]. During this formative work, we conducted activities in the Exploration and Preparation phases.

Design

Formative work for the *PlaySmart* video game intervention consisted of 3 phases spanning 2 years, from early 2020 to late 2021 (Table 1). Phase 1 consisted of focus groups and interviews with a variety of stakeholders to inform the development of video game intervention. During phase 2, pilot playtesting and focus groups with adolescents were conducted to gather feedback on game content and experience, which informed the finalization of the video game. Phase 3 consisted of focus groups with school-based providers to better understand the factors to consider for successful future implementation of *PlaySmart* (preimplementation).

Table 1. Overview of aims and participant activities by phase.

Phase, primary aims, and group description	Number of focus groups or interviews	Participants (N=166), n (%)
Phase 1 (2020)		
Develop content for *PlaySmart* video game		
Youth from 4 high schools in Connecticut	7 focus groups	37 (22.3)
SBHA[a]-established YAC[b]	3 focus groups	15 (9)
SBHA personnel	5 focus groups	25 (15.1)
OUD[c] treatment providers	6 interviews	6 (3.6)
Individual in treatment for OUD	1 interview	1 (0.6)
FCD[d] prevention specialists	1 focus group	6 (3.6)
Phase 2 (2020-2021)		
Playtesting for *PlaySmart*		
High school aged youth who played through all or portions of the game	9 focus groups	33 (19.9)
Phase 3 (2020-2021)		
Explore and identify potential barriers and facilitators to implementation		
SBHA personnel	6 focus groups	26 (15.7)
SBHA-established YAC	3 focus groups	17 (10.2)

[a]SBHA: School-Based Health Alliance.

[b]YAC: youth advisory council.

[c]OUD: opioid use disorder.

[d]FCD: Freedom from Chemical Dependency.

Participants

Development

Adolescents and adults from multiple local and national stakeholder organizations engaged in the development of *PlaySmart* through focus groups and individual interviews. Adolescents were recruited from our local partner high schools and targeted e-mails to the SBHA and their youth advisory council (YAC) members. SBHA is a nationwide organization that advocates school-based health care for children and adolescents through the support of school-based health centers across the country. The SBHA oversees over 2500 school-based health centers in 49 states and Washington, DC. The YAC is a youth service group established by the SBHA and is composed of adolescents aged 16 years or older who are passionate about advocacy and share their expertise on health topics that affect students' age. Adults recruited for the focus groups and individual interviews consisted of adult affiliates of SBHA, OUD treatment providers, an individual in treatment for OUD, and prevention specialists. SBHA adult affiliates were recruited through announcements, and flyers sent through internal listserves. OUD treatment providers and individuals were recruited from the APT foundation, a nonprofit organization and one of the oldest treatment centers in the United States. Finally, prevention specialists were recruited with assistance from officials at Freedom from Chemical Dependency Prevention Works, an international nonprofit organization that aims to provide substance misuse prevention programs in schools. All participants from the development focus groups and interviews received one US $30 gift card for their time.

Playtesting

Participants from the playtesting focus groups were recruited using informational flyers and social media advertising on Facebook and Instagram. Owing to COVID-19, the research team had to adapt to web-based recruitment methods and focus group procedures. Web-based recruitment methods involved distributing electronic posters to different social media platforms and via listservs of partner organizations, such as SBHA. Participants either participated in (1) a 2-hour session that consisted of playing a portion of the game, answering follow-up qualitative questions, and receiving US $30 for their participation or (2) six 1-hour sessions that consisted of playing the entire game, completing procedure-based follow-up questions, and receiving a total of US $60 for their participation.

Preimplementation

SBHA adult affiliates and YAC members were recruited during 2 of the annual national SBHA conventions. Participants in these groups received a US $40 gift card in 1 focus group session.

Procedures

Development

The focus groups and interviews ranged from 60-90 minutes in duration. Questions focused on knowledge of opioids, perception of the risk of opioid misuse, factors contributing to misuse, and narratives from those who were opioid naive or who had personal experience with opioids, such as providers, prevention specialists, or individuals in treatment (Multimedia Appendix 1). In addition, focus groups asked about current game use and what games (if any) participants engaged with to gauge their familiarity with playing games and get a sense of the prevalence of gamers in the focus groups. Focus groups and interviews were audiotaped. Two investigators attended each focus group and conducted the interviews. One investigator led the discussion (facilitator), whereas the other took notes on observable behaviors (note-takers). After each focus group, the investigators compiled a debrief summary. Audiotapes from the focus group and the interviews were transcribed using third-party services.

Playtesting

To assess and improve the acceptability and usability of *PlaySmart*, we conducted 60- to 90-minute playtesting sessions with adolescents. Each playtesting session consisted of 2 sessions. During the first part, the participants played the game. During the second part, they completed assessment questions using either surveys (1 group) or debriefing focus groups (7 groups). See Multimedia Appendix 2 for the questions asked during playtesting.

One group played through the entire game and completed 3 surveys on knowledge, perception of risk of harm, and gameplay experience. The knowledge survey was developed by the team consisted of 5 true or false questions related to knowledge about opioids (eg, “prescription opioids can be just as deadly as heroin when they are misused”). The perception of risk survey consisted of 5 questions from the Monitoring the Future Study related to participants’ perception of the risk of harming themselves from different forms of opioid misuse (eg, “How much do you think people risk harming themselves (physically or in other ways), if they try heroin once or twice?”) [78]. Options for the risk of harm scale consisted of no risk, slight risk, moderate risk, and high risk. The gameplay experience was assessed using 8 statements on how participants felt playing the video game. Sample questions include “Playing *PlaySmart* was interesting.” Responses ranged from 1 (not at all) to 5 (a lot).

The remaining 7 groups played different aspects of the video game (storylines and minigames) and responded to open-ended questions. We asked the participants what they thought the purpose of the game was, what they learned from playing the game, what challenges they experienced while paying the game, if gameplay prompts were easy to understand, if the storylines were realistic, and recommendations to improve the game.

Preimplementation

To optimize the implementation of *PlaySmart* in school-based settings, a total of 9 focus groups with adults from SBHA personnel and adolescents from the SBHA YAC were conducted. These groups focused on facilitators and barriers, as well as how school-based health officials might be able to implement the game, possible motivations for adolescents to engage with the game, and how the game might be used in their communities. The focus groups were 60-90 minutes in length. Two investigators attended each focus group. One investigator served as the facilitator, whereas the other investigator took notes. Following the completion of each focus group, the team met for a debriefing session and a summary from the debriefing session was compiled.

Analysis

Development

Our analysis was guided via the thematic analysis by Braun and Clarke [79] to provide storylines, character depictions, and other patterns noted in the data. After each focus group and interview, debriefing summaries and notes were completed by the note-taker and reviewed by the facilitator to generate salient themes. Then, using a reflexive approach [79], conceptualized patterns from the transcriptions were added. The research team iteratively reviewed and updated the content until 6 distinct storylines emerged.

Playtesting

Data from the participant feedback were qualitatively analyzed to identify common themes. Analyses focused on players’ gameplay experience, and input was used iteratively to improve the game content and design. In this phase, we also assessed knowledge through an analysis of participant feedback on gameplay mechanics and character relations. With the game nearing its’ final form, we verified through participant responses that they understood the themes of the game and acquired the knowledge we were targeting. Because of the limited number of participants (n=3) who completed the quantitative survey on knowledge of opioids, perception of risk of harm from opioids, and gameplay experience, we were unable to analyze these results (see *Limitations*).

Preimplementation

To analyze data from the focus groups, techniques from rapid analysis [80] were performed using notes from the focus groups and debrief summaries aligned with a template of the EPIS framework. Notes and debrief summaries were analyzed using the EPIS framework to identify salient themes on potential barriers and facilitators that could impact the future implementation of *PlaySmart*.

Ethical Considerations

All the study procedures were approved by the Yale Institutional Review Board (#2000026247). Individuals who expressed interest in participating in the development or preimplementation phase provided institutional review board–approved informational sheets for the study. Individuals provided verbal assent if they were younger than 18 years of age and verbal consent if they were older than 18 years before participating. A waiver of parental consent was obtained for adolescents younger than 18 years. For participants who participated in play testing, written consent was obtained if they were 18 years or older. Written parental consent and assent were obtained from adolescents younger than 18 years.

Results

Participant Characteristics

Development

Among the high school and YAC adolescents who participated in the developmental phase focus groups (n=52), the average age was 17.1 (SD 0.87) years. The majority were female-identifying (33/52, 63%) and of non-Hispanic descent (37/50, 74%). Approximately one-third (17/52, 33%) of the adolescent participants identified as mixed or other race (Table 2). The SBHA adult affiliates and treatment providers were predominately non-Hispanic White female individuals with average ages of 40.8 (SD 12.9) and 46.4 (SD 9.8) years, respectively (Table 2).

Table 2. Demographic characteristics of participants in phase 1—development work.

Characteristics	Interview with individual in treatment (n=1)	Treatment provider interviews (n=6)	YAC[a] FGs[b] (n=15)	SBHA[c] adult affiliates FGs (n=25)[d]	High school FGs (n=37)	Prevention specialist FG (n=6)
Age (y), mean (SD)	21 (NR[e])	46.4 (9.8)	17.7 (1.1)	40.8 (12.9)[f]	16.9 (0.7)	44.7 (17.2)
Sex at birth, n (%)						
Male	1 (100)	NC[g]	3 (20)	3 (13)	14 (38)	NC
Female	0 (0)	NC	12 (80)	20 (87)	21 (57)	NC
Intersex	0 (0)	NC	0 (0)	0 (0)	2 (5)	NC
Gender identity, n (%)						
Man	NR	2 (33)	3 (20)	3 (13)	14 (38)	1 (17)
Woman	NR	4 (67)	12 (80)	20 (87)	22 (59)	5 (83)
Transgender	NR	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)
Ethnicity, n (%)						
Non-Hispanic	1 (100)	6 (100)	14 (93)	21 (91)	23 (62)	6 (100)
Race, n (%)						
Asian	0 (0)	1 (17)	5 (33)	1 (4)	5 (14)	1 (17)
Black	0 (0)	0 (0)	2 (13)	6 (26)	8 (22)	0 (0)
White	1 (100)	5 (83)	4 (27)	14 (61)	11 (30)	5 (83)
Mixed or other	0 (0)	0 (0)	4 (27)	2 (9)	13 (35)	0 (0)

[a]YAC: youth advisory council.
[b]FG: focus group.
[c]SBHA: School-Based Health Alliance.
[d]n=23 (data were not collected for 2 participants).
[e]NR: not reported.
[f]n=21 (no age data were collected for any of the 4 participants).
[g]NC: not collected.

Playtesting and Preimplementation

Table 3 outlines the sample characteristics of participants in the focus groups and interviews for play testing (phase 2) and preimplementation (phase 3). Similarly, non-Hispanic female individuals comprised most of the participants in the 2 phases (Table 3).

Table 3. Demographic characteristics of participants in phase 2 (playtesting) and phase 3 (preimplementation).

Characteristics	Phase 2	Phase 3	
	Playtesting FGs[a] (n=33)[b]	SBHA[c] adult affiliates FGs (n=26)[d]	SBHA-established YAC[e] FGs (n=17)
Age (y), mean (SD)	16.8 (0.8)	44.0 (10.5)	16.9 (1.5)
Sex at birth, n (%)			
Male	19 (58)	3 (12)	4 (24)[f]
Female	14 (42)	22 (88)	12 (71)
Gender identity, n (%)			
Man	13 (39)	4 (16)	4 (24)[f]
Woman	18 (55)	21 (84)	11 (65)
Other	1 (3)	0 (0)	1 (6)
Ethnicity, n (%)			
Non-Hispanic	26 (79)	25 (100)	13 (76)
Race, n (%)			
Asian	2 (6)	1 (4)	4 (24)
Black	14 (42)[g]	7 (28)	8 (47)
White	11 (32)	15 (60)	3 (18)
Mixed or other	4 (13)	2 (8)	2 (12)

[a]FG: focus group.
[b]One participant did not report gender identity or ethnicity. Two of the participants did not report their race.
[c]SBHA: School-Based Health Alliance.
[d]n=25 (data were not collected for 1 participant).
[e]YAC: youth advisory council.
[f]Data not collected for 1 participant.
[g]Data were not collected for 2 participants.

Development: Focus Groups and Interviews

Overview

Multimedia Appendix 3 outlines the themes and accompanying quotes. Nine salient themes emerged from the development work with adolescents and providers, which were used to inform the content of *PlaySmart*: (1) mode of learning; (2) opioid identification; (3) perceived risk of harm: susceptibility, severity, sequences, or addiction; (4) prescription opioids; (5) opioid accessibility; (6) reasons to use; (7) mental health, (8) support systems, and (9) video game application: mechanics or game and content or storylines. The following section provides a brief description of each theme along with the associated key concepts that were included in the game to ensure that it was relevant, relatable, and accurate.

Mode of Learning

Generally, youth participants cited a lack of drug education, specifically pertaining to opioids. Even when they referenced their drug education, it was often limited to a specific grade level (eg, grade 9) or to a certain type of drug (eg, marijuana or alcohol; Multimedia Appendix 3). Many of their experiences highlighted sole exposure to opioids through the news, celebrities, or media, providing further evidence of the lack of formal opioid education in the youth population.

Opioid Identification

Across youth focus groups, many gaps in knowledge of opioids have emerged. Although most had heard the term “opioid” before, many were unable to accurately describe or categorize opioids. Adolescents reported that they recognized the names Percocet, Oxycontin, and Heroin, but did not classify them as opioids. This was especially true for heroin (Multimedia Appendix 3). A few participants incorrectly categorized other substances, such as marijuana, as opioids. Interviews with treatment providers confirmed this gap in knowledge, underscoring that adolescents only hold a vague understanding of opioids.

Perceived Risk of Harm

Drawing on this lack of knowledge, many youth participants perceived their susceptibility to risk from opioid misuse as low. A lack of opioid misuse prevalence in their age group was often cited as the primary reason for low susceptibility; many claimed that problems only existed in college students or older populations (Multimedia Appendix 3). When treatment providers reflected on their experiences with the youth, this false belief was further supported. Youth participants recognized the severity of harm from heroin but did not perceive prescription opioids to be as harmful. They attributed this logic to the mode of delivery of some opioids (eg, prescription pills and codeine drink) compared with heroin (eg, injection). Despite this, participants in both youth and provider focus groups generally understood the psychological, social, and physical harms of addiction (Multimedia Appendix 3).

Prescription Opioids

Youth participants often identified medical professionals as partly responsible for the opioid misuse crisis. Many shared stories of friends or close relatives prescribed opioids without proper information from the physician. Treatment providers confirmed that this was often how youth were introduced to opioids, either by their own prescription or by a prescription of someone they were close to (Multimedia Appendix 3). The participants shared that this initial prescription often led to misuse.

Opioid Accessibility

Participants in both the youth and provider focus groups shared that accessing opioids was often quite easy—in a medical setting, in their households, and around their peers. They attributed this to the normalized prescription of opioids and teens' general curiosity regarding foreign substances (Multimedia Appendix 3). Youth participants shared that if it was available, it was more likely and more easily used for recreational purposes. Similarly, many participants spoke of "lean" or "dirty sprite" (formally known as codeine) as fairly accessible, easily ingestible, and widespread (Multimedia Appendix 3).

Reasons to Use

Participants in both youth focus groups and provider interviews highlighted an array of potential reasons for opioid misuse. Peer pressure has been frequently cited as a catalyst for this behavior, although not in the stereotypical context. This peer pressure was more implicit and geared toward blending in rather than being perceived as "cool" (Multimedia Appendix 3). The youth and provider participants also cited maladaptive coping as a reason for opioid misuse. Participants reported a variety of reasons for the need to cope, including the death of a loved one, major stress, mental health issues, and "a way out" (Multimedia Appendix 3).

Mental Health

Youth participants mentioned an abundance of mental health concerns; some were related to opioid misuse, whereas others were independent of it. They specified a wide range of stressors that contribute to mental health issues and opioid misuse (Multimedia Appendix 3). While recognizing these stressors, they also described their own perceptions of someone experiencing mental health issues. Youth had a wide range of opinions on seeking help. Some were supportive of professional support, whereas others expressed strong hesitance. Stigma and the lack of trust were common reasons for this resistance, so the importance of finding a good match with a provider was heavily emphasized.

Support Systems

Most youth participants stated that adults were a necessary support system for resilience, recovery, and well-being, although they did not agree that adults should be parents or guardians. Many shared personal advice on how to support a peer but also recognized the limitations of peer-to-peer support (Multimedia Appendix 3). Youth participants also highlighted the importance of being emotionally in tune with themselves and how that alone could serve as a form of support (Multimedia Appendix 3).

Video Game Application

Of the 52 youths, 41 (79%) who participated in the development work mentioned playing or having played more than one game; 11 (21%) participants did not mention playing any games. More specifically to our intervention, youth participants provided their feedback on video game details, such as mechanics, esthetics, and storyline content. Generally, they recommended that the game be simple but challenging (Multimedia Appendix 3). In terms of storylines, all youth participants provided valuable information specific to interactions with parents, situations at parties, and even route friendships could take.

Development: PlaySmart Video Game Intervention

On the basis of the information gleaned from our development focus groups and interviews, our research team collaborated with our game development partners, Schell Games, to launch and finalize the video game intervention, *PlaySmart*. Game content was directly informed by focus groups and interviews, similar to other digital interventions targeting adolescents [29,30,53,54,75,81-84].

The cornerstones of the *PlaySmart* video game intervention are (1) six storylines that form the narrative foundation: *Trading Wisdom*, *Lean on Me*, *A Friend in Need*, *Grandma's Pills*, *Tough Love*, and *A New Direction*; (2) six minigames that provide skill-building opportunities: *Risk Sense*, *Stress Sense*, *Refusal Power*, *Social Media Game*, *Choice Power*, and *Know Power*; and (3) a participant tracker: *Future Sense*. At the beginning of the game, players review their future self in *Future Sense* to see how poorly their lives turned out because of opioid misuse and are tasked with changing their future by playing *PlaySmart*. The use of the future self-motivates players to do better in the present by drawing on evidence that shows that imagining the future self and highlighting similarities between the current and future self can influence positive behavior change [85].

These 6 storylines encompass major topics that address opioid misuse and mental health. In *Trading Wisdom*, the player learns to use opioid prescriptions safely, the consequences associated with misuse, and nonpharmacologic and nonopioid alternatives for pain management. In *Lean on Me*, the player learns about high-risk situations where opioid misuse is likely to occur (party), the role of peer pressure, how to refuse an offer to use opioids, and the dangers of misusing opioids. In a *Friend in Need*, the player learns about how mental stress increases the risk of opioid misuse, the benefit of seeking support from trusted adults, and how they can be supportive to their friends. In *Grandma's Pills*, players learn about the dangers of using prescriptions that do not belong to them, including overdose and strategies from refusing opioids when offered by family members. In *Tough Love*, the player learns to set boundaries in close relationships where opioid misuse is an issue, and how to support people close to you who are struggling with opioid misuse. In *A New Direction*, the player learns of mental health resources, existing myths around mental health and stigma and is empowered to seek mental health care when needed. Throughout gameplay, players have options to make a bad or good choice, thus practicing decision-making skills. In addition, we expect to increase the perception of the risk of harm among players through scenarios that highlight the dangers of opioid misuse. Links to other trusted websites such as the National Institute on Drug Abuse are embedded in the game and provide players with an opportunity to continue learning outside the game if they are interested.

Minigames provide a real-time opportunity to improve self-efficacy through adaptive skills such as decision-making and refusal skills that are relevant for avoiding opioid misuse. In *Risk Sense*, the player is tasked with working to prevent risks (impulsivity, ignorance, and relationship problems). By playing *Risk Sense*, players become aware of the risk factors for opioid misuse. In *Stress Sense*, players have an opportunity to practice cognitive reframing, a cognitive behavioral strategy [86] to address thought distortions (all or none, catastrophizing, and should statements) and seeing a particular problem in a different light that serves to reduce the emotional distress that can increase the risk of opioid misuse [86]. In addition to cognitive reframing, players learn several coping strategies, including exercise, talking to trusted adults, watching movies and music, reading, taking time off to rest and relax, sleeping well, and using distraction techniques to take the mind of stressful thoughts. In *Refusal Power*, the player helps the character resist peer pressure to engage in risky behaviors. In a *Social Media Game*, through posts on social media, players practice advocating for behaviors that deter drug misuse, encourage help seeking from trusted adults and mental health professionals, and support peers who are struggling. In *Choice Power*, players learn to communicate effectively with others to get the help they need or to avoid getting into trouble. In *Know Power*, players learn facts about opioids and opioid misuse through conversations with other nonplayer characters. *Choice Power* and *Know Power* are embedded within each storyline, whereas the other minigames are shown on the homepage (Figure 1).

Figure 1. The home page of the *PlaySmart* video game on the left and a screen from the *Stress Sense* minigame on the right. Licensed under Creative Commons 4.0.

The final version of *PlaySmart* is a web-based video game that is accessible to any device that can access the internet and has a browser. User data were stored in an SQLite database hosted on the Amazon Web Services. Data on players' progress in the game, such as what game levels have been completed and how many minutes were spent on the game, can be downloaded securely from the database.

Playtesting

Informed by user-centered design principles, the feedback obtained during playtesting was critical in modifying *PlaySmart* for its final form. Following the initial iteration of the game, participants were recruited to play the game. Participants generally agreed that the game was straightforward, engaging, and provided a wealth of information on opioid use and misuse. Feedback from these groups primarily consisted of recommendations for technical changes related to minigames, content of the text, or gameplay mechanics. For example, some of the feedback identified content in the game that was not relatable to adolescents and provided specific suggestions for how to improve it. Some felt that the initial set of avatars did not include enough variation to reflect a diverse group of adolescents. The use of avatars that players can relate to is critical because evidence indicates that players exhibit a higher sense of responsibility and attachment to avatars that look like them [87] and are more engaged when using avatars that look like them [88]. Some felt that some minigames needed a tutorial to orient the player. Some adolescents felt distracted by the background music and suggested a way for adolescents to modify the sound based on personal preference. Some players felt that some parts of the risk-sense minigame were not demanding, resulting in the addition of more tasks in the minigame that increased the challenge posed in the game. Other players felt that nonplayer characters in the game were too knowledgeable in contrast to their friends in real life. This feedback informed the modification of the game such that chats more realistically depicted the balance between friends who may be informed and others who may not be informed about facts relating to opioids. We used this feedback to improve the final version of the game alongside the game developers [89] (Figure 1). Through this testing, we solidified our procedures for the RCT.

Preimplementation

Participants from our preimplementation focus groups shared the potential barriers and facilitators to implementation as well as information specific to motivation around gameplay and engagement with the intervention. SBHA adult affiliates mentioned the importance of administrative buy-in before implementing *PlaySmart* in schools and clinical settings. They also provided examples of possible ways to engage youth with the game, such as through academic incentives, making it an activity in and of itself in schools, or implementing it as part of the process of visiting a clinic (eg, in the waiting room of a clinical setting). Youth from the preimplementation focus groups generally agreed that it could be used in their school community as an interactive way to learn, and most of their first impressions highlighted several positives of the *PlaySmart* game. For example, they spoke about liking the comic-book style of the game, the relatability of each storyline, and the interactive components of the storylines and minigames. They highlighted the importance of training both staff and students to equip them with the necessary troubleshooting skills and to ensure that they understand their rights to confidentiality and data privacy. Much of the discussion regarded optimal strategies for game delivery, and many participants believed that integrating *PlaySmart* into existing structures such as health classes, clinics, or school clubs would gain the best traction from both students and staff. Focus group participants emphasized the value of incentives for implementing the game in schools, especially because it was a new program and required some human resources to implement effectively. Common suggestions for greater incentives include promoting *PlaySmart* through social media youth ambassadors, incorporating gamification elements (eg, leaderboards or communication channels), and framing it as a novel health behavior tool rather than a more traditional form of prevention-based education. This information was used to create *PlaySmarts* educator’s manual, which was shared with implementation partners as a resource.

Discussion

Background

The public health impact of concurrent opioid and mental health crises cannot be overstated and underscores the need for innovative approaches for engaging adolescents and young adults in preventive interventions. Given these crises, and with support from the National Institutes of Health HPC Initiative, we developed a novel video game intervention to prevent opioid misuse among older adolescents. This is the first video game intervention to address opioid misuse and mental health issues among older adolescents. Existing game-based interventions for opioid misuse have focused on younger adolescents [52] and on addressing knowledge gaps [51,52], increasing the perception of risk of harm from opioid misuse [51], improving decision-making [52], changing attitudes [51] and beliefs, and improving self-efficacy [51]. We highlight the need to address mental health as well as the significant role that underlying mental disorders play in increasing the risk for opioid misuse, address stigma, confront existing myths associated with mental health problems, and underscore the importance of addressing seeking treatment for mental disorders in addition to substance misuse.

Our formative work revealed that mental health and its connection to opioid use were among the most prevalent themes that arose from the youth focus groups. Preexisting mental health problems such as depression can increase the likelihood of substance misuse, including opioids [7-9]. In addition, the stigma surrounding access to mental health services can be a barrier to early engagement in treatment. Serious video games, such as *PlaySmart*, offer an engaging way to prioritize mental health as a central focal point by empowering adolescents to be vocal and intentional about asking for help and by breaking down myths that mental health support is ineffective or worsens symptoms. In *PlaySmart*, the risk of opioid misuse driven by underlying mental health problems is woven throughout the game, while normalizing help seeking and adaptive coping strategies. To examine the impact of incorporating mental health factors into *PlaySmart*, our ongoing RCT will also assess the impact of *PlaySmart* on mental health outcomes.

In contrast to other game-based interventions to prevent opioid misuse [51,52], and consistent with our standard practice, we engaged our target audience of adolescents as cocreators in the process, and they were involved throughout the development and playtesting of *PlaySmart*. Involving the end user increases the likelihood of relatable storylines and provides an opportunity to improve the game based on player feedback [72,73]. Most of the youth who partook in the focus groups had not previously had education focused on opioid misuse, highlighting an existing gap in the current school curriculum while also demonstrating the need for this game to adequately address. In addition, important avenues through which adolescents learn incomplete information about drugs, such as music, media, or celebrities, are directly addressed in the game.

Our youth focus groups had good racial representation, including youth identifying as Asian, Black, White, and mixed race, in contrast to a similar study focused on opioid misuse prevention among adolescents [81]. However, representation from adult representatives was predominantly White, which mirrors the racial ethnic distribution of teachers [90,91] and health care workers [92] in the United States. Further evaluation following the completion of the RCT will explore whether there were any differences in the efficacy of response among different racial and ethnic groups.

Creating evidence-based interventions without a plan for real-world implementation can negatively impact effectiveness [93]. Our preimplementation work revealed ways to facilitate the uptake of *PlaySmart* in school settings, such as incorporating the video game into existing structures, such as a health class, which would allow for greater feasibility. Other suggestions for wide-scale uptake identified from preimplementation focus groups include making *PlaySmart* available through social media or as an intervention for adolescents waiting at an outpatient clinic, particularly if these measures are incorporated into existing clinic workflows.

Video games are very engaging and universally used by adolescents and young adults. Consequently, they offer an innovative way to deliver evidence-based prevention interventions that can potentially be lifesaving. In addition, the *PlaySmart* video game is a mobile web-based intervention that can be accessed repeatedly by a player through their phones, tablets, or computers, and can be delivered anywhere with internet access. Through this formative work, we demonstrated the feasibility of engaging a comprehensive group of stakeholders (eg, adolescents with and without opioid misuse, prevention scientists, addiction medicine providers, and school representatives) in developing a compelling video game and using user-centered design principles [71,72] in both the development and initial testing of the intervention. Informed by our focus group and interview participants and guided by user-centered design principles, we translated behavior change theories, specifically the health belief model, theory of planned behavior, and social cognitive theory, into relatable storylines and minigames. Through these game components, adolescents acquire accurate knowledge and perceptions of the risk of harm from opioid misuse, learn about the benefits of addressing mental health issues, and practice a range of critical skills around refusing invitations to misuse drugs, practicing cognitive reframing when stressed, and using coping strategies and mental health resources.

Limitations

During this formative work, specifically during playtesting, we had to switch from in-person procedures in schools to web-based procedures because of the COVID-19 pandemic. This occurred during playtesting and affected recruitment and retention during the playtesting sessions. As a result, we had only one group of participants (n=3) who played the entire game and were able to complete *quantitative* assessments of knowledge of opioids, perception of risk of harm, and gameplay experience. As such, we were unable to provide *quantitative* summary data on whether there was improvement in knowledge about opioids or perception of risk of harm from opioids in this formative evaluation. In the ongoing RCT, we are evaluating improvements in opioid knowledge and perception of the risk of harm from opioids (primary outcome) and will provide these results following the completion of the RCT. Only 1 participant with OUD participated in this study, which may have impacted the video game content, although this is a preventive intervention primarily targeting adolescents without opioid misuse. Although we assessed factors that would impact usability and engagement during gameplay, the questions did not specifically assess whether adolescents would be motivated to play the game. We are currently assessing factors that would influence motivation in ongoing RCT. Future formative work can assess the factors that can influence motivation, which may influence the final game design. We assessed how familiar adolescents were with video games during the focus groups, but we did not assess perceptions of the game between those who were hard-core gamers and those who were not, which may have informed game design to have the broadest reach across different levels of gamers. Future formative studies on game development should include this information.

Conclusions

The ongoing dual opioid and mental health epidemics underscore the need for effective prevention interventions that can engage adolescents and address accurate information and skill-building in these areas. Video games provide an appealing medium to engage adolescents while translating evidence-based theories into a digestible, easily accessible format that allows for repeated practice of behaviors necessary to prevent opioid misuse and promote mental health in adolescents in real-world settings. Engaging the target audience and other key stakeholders in the development and testing of this digital health intervention ensures that it reflects their voices and perspectives for the greatest impact and reach.

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Data Availability

We have provided our focus group guide, synthesized results from the focus group analysis, and questions used during the playtest. Owing to the sensitive nature of the data from the focus groups, including the presence of potentially identifiable information, we cannot share the data from the focus groups.

Authors' Contributions

CSFF, TMP, and LEF were involved in the conceptualization. CSFF developed the focus groups and interview guides. CSFF and TMP were involved in individual interviews, focus groups, and thematic analyses. KA, CSFF, LAH, CS, TMP, and LEF were involved in the interpretation of study findings. KA, CS, and LAH drafted the manuscript. All authors have reviewed, edited, and approved the final draft of the manuscript.

Conflicts of Interest

LEF is the founder and on the Board of Directors of a Yale company, Playbl, which distributes game products. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Focus group guides.
[DOCX File , 22 KB - games_v11i1e46912_app1.docx]

Multimedia Appendix 2
Playtesting assessment questions.
[DOCX File , 16 KB - games_v11i1e46912_app2.docx]

Multimedia Appendix 3
Themes and sample quotes from PlaySmart development.
[DOCX File , 23 KB - games_v11i1e46912_app3.docx]

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Abbreviations

EPIS: Exploration, Preparation, Implementation, and Sustainment
HPC: Helping to End Addiction Long-Term Prevention Cooperative
OUD: opioid use disorder
RCT: randomized controlled trial
SBHA: School-Based Health Alliance
YAC: youth advisory council

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Original Paper

Effects of a Gamified Agent-Based System for Personalized Elderly Care: Pilot Usability Study

Diogo Martinho[1], PhD; Vítor Crista[1], BSc; João Carneiro[1], PhD; Kenji Matsui[2], PhD; Juan Manuel Corchado[3], PhD; Goreti Marreiros[1], PhD

[1]Research Group on Intelligent Engineering and Computing for Advanced Innovation and Development, Polytechnic of Porto - School of Engineering (ISEP), Porto, Portugal

[2]Osaka Institute of Technology, Osaka, Japan

[3]Grupo de investigación en Bioinformática, Sistemas Informáticos Inteligentes y Tecnología Educativa, Salamanca, Spain

Corresponding Author:
Diogo Martinho, PhD
Research Group on Intelligent Engineering and Computing for Advanced Innovation and Development
Polytechnic of Porto - School of Engineering (ISEP)
R. Dr. António Bernardino de Almeida 431
Porto, 4249-015
Portugal
Phone: 351 911007406
Email: diepm@isep.ipp.pt

Abstract

Background: The global percentage of older people has increased significantly over the last decades. Information and communication technologies have become essential to develop and motivate them to pursue healthier ways of living. This paper examines a personalized coaching health care service designed to maintain living conditions and active aging among older people. Among the technologies the service includes, we highlight the use of both gamification and cognitive assistant technologies designed to support older people and an application combining a cognitive virtual assistant to directly interact with the older person and provide feedback on their current health condition and several gamification techniques to motivate the older person to stay engaged with the application and pursuit of healthier daily habits.

Objective: This pilot study aimed to investigate the feasibility and usability of a gamified agent-based system for older people and obtain preliminary results on the effectiveness of the intervention regarding physical activity health outcomes.

Methods: The study was designed as an intervention study comparing pre- and posttest results. The proposed gamified agent-based system was used by 12 participants over 7 days (1 week), and step count data were collected with access to the Google Fit application programming interface. Step count data after the intervention were compared with average step count data before the intervention (average daily values over a period of 4 weeks before the intervention). A 1-tailed Student *t* test was used to determine the relationship between the dependent and independent variables. Usability was measured using the System Usability Scale questionnaire, which was answered by 8 of the 12 participants in the study.

Results: The posttest results showed significant pre- to posttest changes (P=.30; 1-tailed Student *t* test) with a moderate effect size (Cohen d=0.65). The application obtained an average usability score of 78.

Conclusions: The presented pilot was validated, showing the positive health effects of using gamification techniques and a virtual cognitive assistant. Additionally, usability metrics considered for this study confirmed high adherence and interest from most participants in the pilot.

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KEYWORDS

gamification; cognitive assistants; elderly care; coaching system; older people; technology; virtual assistant; cognitive; usability; intervention; physical activity; agent-based system

Introduction

We are currently witnessing an increase in the world's population, which is also growing older. According to United Nations' World Population Ageing Report [1], the global population aged 65 years or older was 727 million in 2020 and is expected to reach over 1.5 billion in 2050. With the increase in the number of older citizens living in today's society, there has been a growing necessity to research and develop assistive technologies that can support older people [2,3], especially in intelligent environments [4,5]. Among the already available technologies, we highlight the use of gamification and cognitive assistants in this context.

Gamification refers to enhancing services with features that can offer "gameful" experiences to their users and keep them motivated and engaged, increasing their activity, social interaction, and the quality and productivity of their actions [6]. In other words, gamification can be seen as improving applications developed for serious contexts using game-like features that can potentiate user experience and motivate and encourage the user to pursue desired behaviors.

Companies are extending (and gamifying) their existing services, and more investments are being made in developing gamified applications and serious games [6]. Likewise, recent research has led to advancements in gamification and serious games in health care [7-10] with great focus on different health domains, such as promoting both physical and cognitive activity [11-23], promoting behavioral changes [7,24] and providing personalized health care services at all ages [25]. These services can bring innovative and cost-effective solutions and treatments to the most fragile and isolated groups in our society, such as older people and those with chronic diseases [14,26]. Furthermore, personalization becomes essential for these kinds of services, as individual necessities and capabilities are even more impactful to this age group. The lack of personalized mechanisms could lead to quick loss of interest in using the health care service. In elderly care, this could easily result in the deterioration of health conditions.

Cognitive assistant research and development has seen significant advances in the literature over the last decade. Cognitive assistants can be endowed with social and emotional processing [27,28] to interact with humans and improve their capabilities while not replacing them in specific tasks. In a more formal definition, cognitive assistants can be described as intelligent mechanisms that interact and learn with the user and can provide adequate feedback to improve behaviors that otherwise would be difficult to accomplish. As such, cognitive assistants will augment human intelligence and assist in decision-making and action-taking [29]. In recent years, exciting approaches have been proposed targeted toward elderly care to enhance the daily lives of older people and improve both their cognitive and physical capabilities.

In sum, the development of intelligent mechanisms and algorithms to adjust the interaction and support provided to the older person, including serious games with a scalable difficulty as well as robots that play games and communicate with older people using different emotions, is fundamental to ensure interactive and personalized systems that are tailored to each user [30].

Existing research on combining the use of a gamified application with the use of a virtual cognitive assistant for the context of elderly care is still lacking. According to a previous study [31] and most recent proposals in the literature, the majority of the available approaches using some kind of assistant either consider the use of a physical robot or a virtual companion (usually a pet) to interact with the older person; neither approach considers the user's progress as a variable in their design. As a result, these approaches cannot follow the evolution of the user over time and are most frequently used for one-time interactions. Because of that, they can represent user progress in adopting improved, healthier behaviors only in a very limited way. Therefore, the major novelty proposed in this work is a cognitive virtual assistant that can take advantage of the outcomes of a gamified health care application. Such an assistant can not only react emotionally to the user's progress (in terms of achieved health goals and challenges) but also learn how to interact and improve the feedback provided to them by learning their behaviors, interests, and current capabilities. In this regard, we studied the use of processes to provide feedback and rewards to the older person, make it possible to increase the cognitive and physical load as the user becomes more proficient with the system, and adopt methods that enhance and promote social interaction, which can result in more personalized elderly care solutions. Furthermore, adapting the support provided to the older person according to their interests, capabilities, and necessities, as well as the surrounding environment, will improve health and well-being, capture interest and ensure positive engagement, facilitate social interaction, and decrease the impact of many medical conditions.

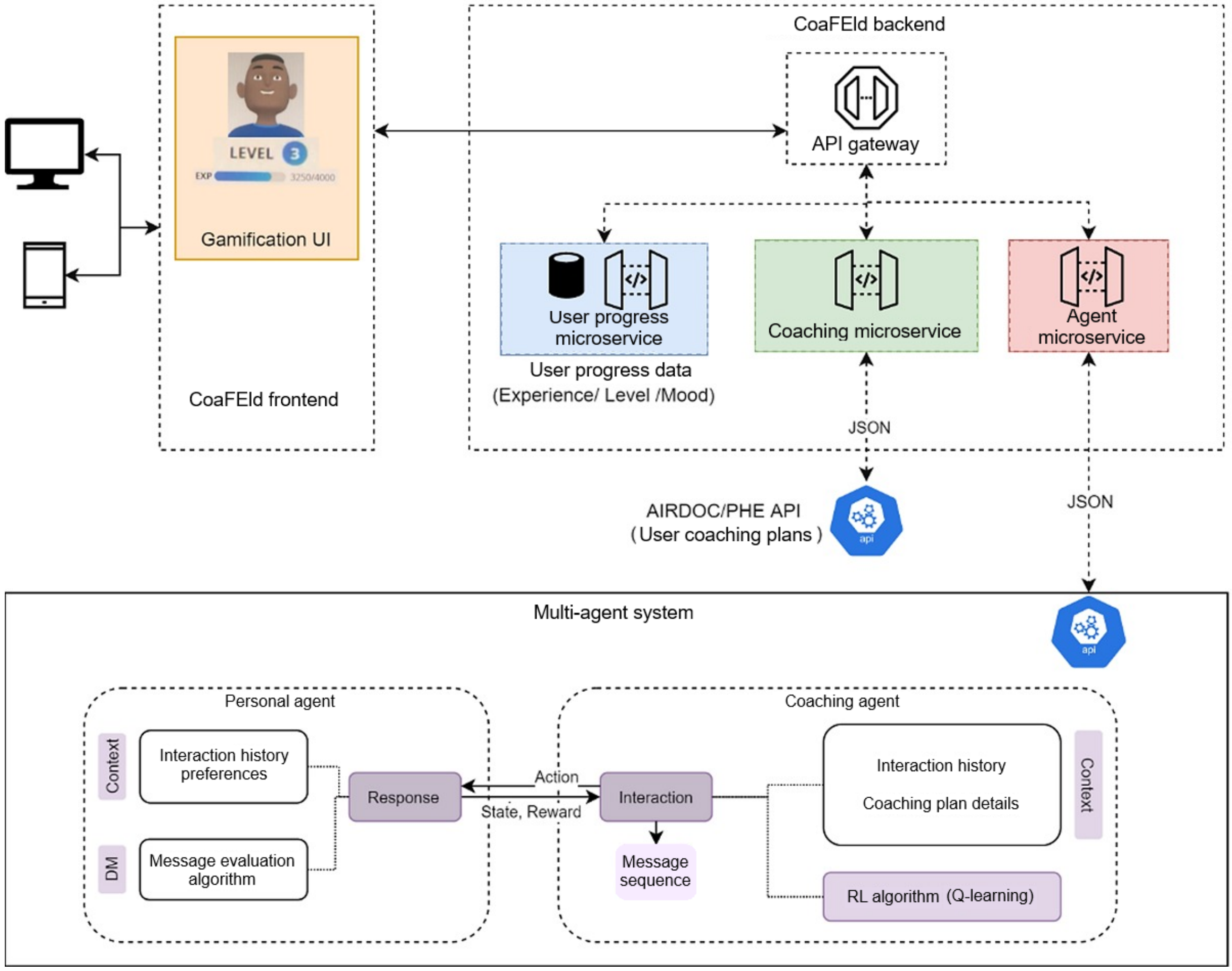
Considering all these ideas, this study aims to perform an initial validation to compare outcomes after using a health care application developed for older people named CoaFEld (Coaching for Elderly) and to determine its overall acceptability and usability after the experiment period is completed. For this, we chose user step count data as the primary outcome. We formulated a hypothesis through a paired 1-tailed Student *t* test to compare step count data obtained before and after the intervention.

Methods

CoaFEld System Design

CoaFEld was developed following a microservice-oriented architecture (Figure 1), divided into 3 main components: a user web application, an application programming interface (API) gateway, and a set of microservices. These microservices communicate and store specific user information regarding user progress while using the application (using different gamification components), health status (derived by the performance of established coaching plans), and user interactions with the feedback that is provided to the user (personalized message interactions based on user preferences).

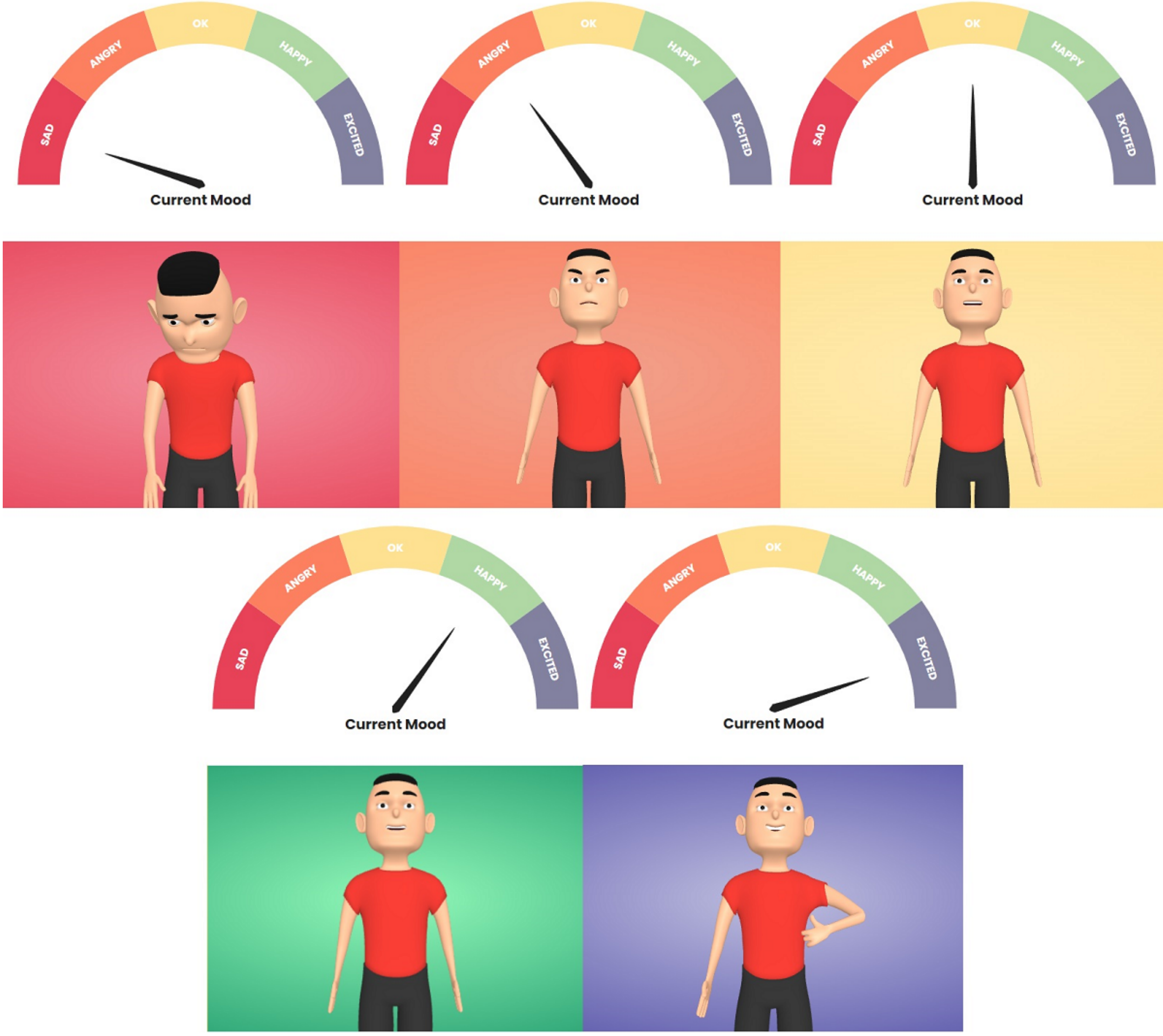
Figure 1. The proposed coaching system architecture reproduced from Martinho et al [30] which is published under Creative Commons Attribution 4.0 International License [32]. AIRDOC: Aplicação móvel inteligente para suporte individualizado e monitorização da função e sons respiratórios de doentes obstrutivos crónicos; API: application programming interface; CoaFEld: Coaching for Elderly; DM: decision making; RL: reinforcement learning; PHE: personal health empowerment; UI: user interface.



The coaching application that has been developed is gamified with consideration of the main findings of Martinho et al [31], who reported the most successful gamification techniques in the context of elderly care. These techniques include features such as experience or levels and points as the system's currency to unlock new content. Additionally, the developed application presents a cognitive virtual assistant with different emotional queues depending on the positive or negative progress of older people as players and users of the coaching application. Following Martinho et al [30], the current emotional state shown by the cognitive assistant is based on all coaching plans assigned to that user and an evaluation of the number of goals that have been successfully achieved by that user vs the total number of goals in the coaching plan. The details of these plans are described in more detail in our previous work [33].

We consider 5 main emotional states to represent user progress (Figure 2). These emotional states were inspired by Russell's [34] circumplex model of affect, which is based on 2 dimensions (arousal and valence) and is ranked according to degree for both of these dimensions.

Figure 2. Representation of the 5 different emotional states of the cognitive assistant reproduced from Martinho et al [30] which is published under Creative Commons Attribution 4.0 International License [32].



(1) The "sad" or "depressed" emotions are the most negative (with negative degrees for both arousal and valence); (2) "angry" represents the second most negative emotion (with a positive degree for arousal and a negative degree for valence); (3) the "OK" or "calm" emotions are moderate (with a negative degree for arousal and a positive degree for valence); (4) "happy" represents the second most positive emotion (with a neutral degree for arousal and a positive degree for valence); (5) "excited" represents the most positive emotion (with positive degrees for both arousal and valence).

An API gateway was developed in the proposed work with the main goal of encapsulating a set of several microservices and providing an API specific for each client (thus serving as a single entry point into the system). It is also the responsibility of the API gateway to include authorization and authentication functionalities and assure asynchronous communication between the requests sent to the available microservices. Three microservices have been developed to store and provide information related to both user progress and health outputs:

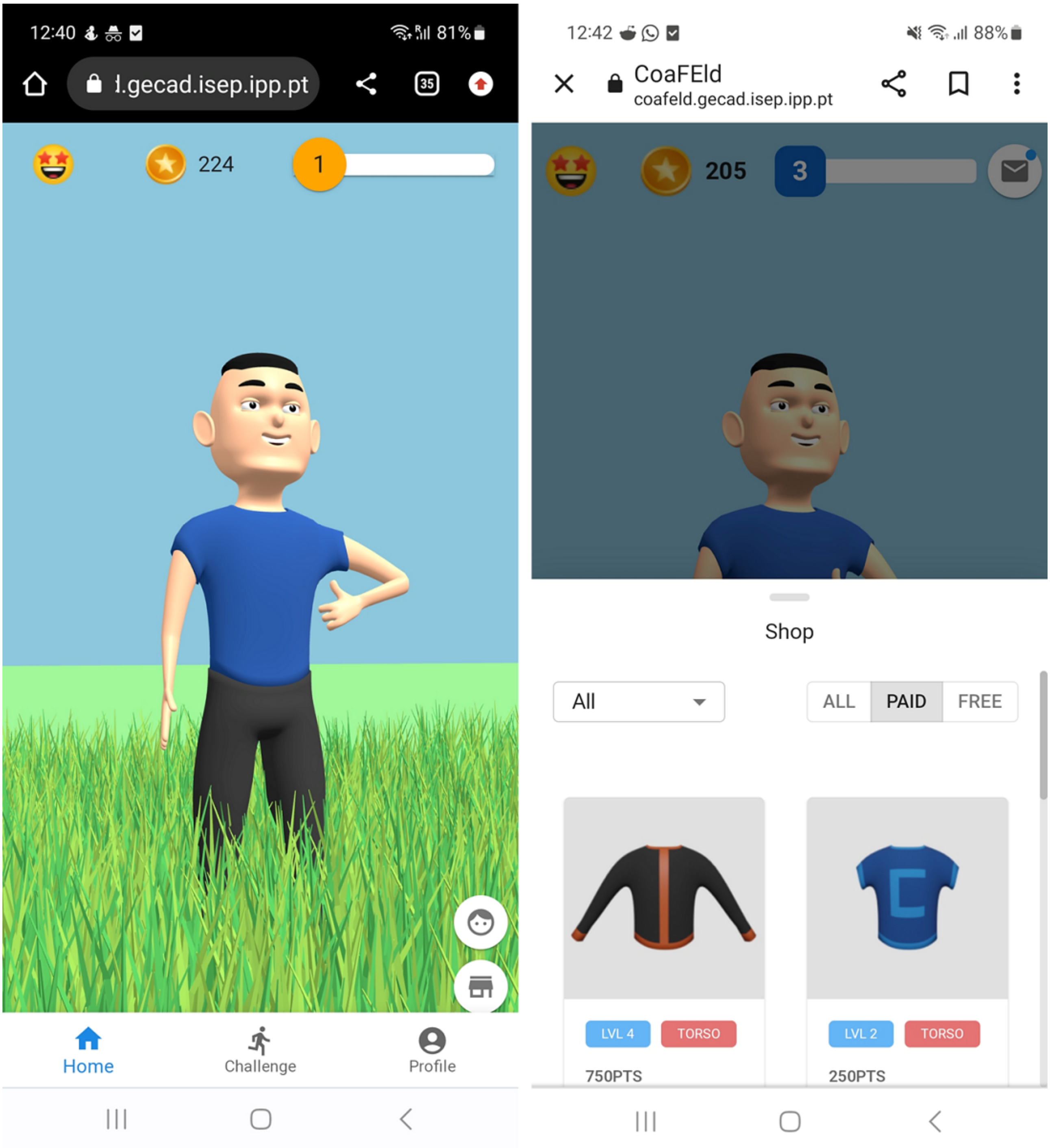
The "user progress" microservice manages data related to user progress and actions within the coaching application, including all the information on current game experience, level, and points; unlocked content; in-game purchases; cognitive play session results; and virtual assistant configurations and emotional state. The "coaching" microservice, developed by Martinho et al [33], is a generic mechanism to configure and evaluate coaching plans with health-related goals that can be dynamically updated with increasing or decreasing difficulty depending on the user's performance. The "agent" microservice, developed by Martinho et al [35], uses a personal agent that returns the interaction (message queue) to be sent directly to the user and evaluates the feedback provided by the user and a coaching agent that applies reinforcement learning to understand what interactions should be next sent to the user at specific moments of the day based on previous interactions with that user.

Mobile Interface Design

The CoaFEld application was developed to establish an environment where users can improve different aspects of their daily lives. In this preliminary validation, the study focused on accessing the user's current physical condition, specifically daily step data, which is retrieved from the Google Fit API (after the user grants permission to access this information). After this, daily step challenges are proposed to the user based on the number of steps they have taken weekly. Multimedia Appendix 1 shows the algorithm used to combine the step data information retrieved from the Google API.

One of the most important features available in the application is the home interface with the virtual assistant, which interacts with the user (Figure 3). The application incorporates various gamification techniques. First, the emoji located in the top left corner serves as a visual representation of the user's emotional feedback (according to the virtual assistant's current emotional state), indicating positive or negative progress throughout app use. Second, the star coin shows the points earned upon completion of daily challenges, which can be used to exchange and unlock content available in the store, such as clothing items. This feature improves the relationship between the user and the virtual assistant with individual character customization. Third, the blue progress bar, also shown on the screen, represents the user's earned experience points (XP) and their corresponding level within the application. This visual representation allows users to track their progress and observe their evolution as users of the application.

Figure 3. Home interface showing the virtual assistant and gamification components.



The application also includes a Challenge screen (Figure 4) for the user to see their current goals and daily performance, showing the overall progress achieved on each day along with a detailed breakdown of the user's performance, including aspects such as more and less active hours during the day, points, and experience to be acquired.

Finally, in the Profile screen (Figure 5), the user can access the virtual assistant profile, including purchased items, completed challenges, and emotional progress, creating a way to track the user's progress and achievements.

Figure 4. Challenge interface showing the user's daily performance.

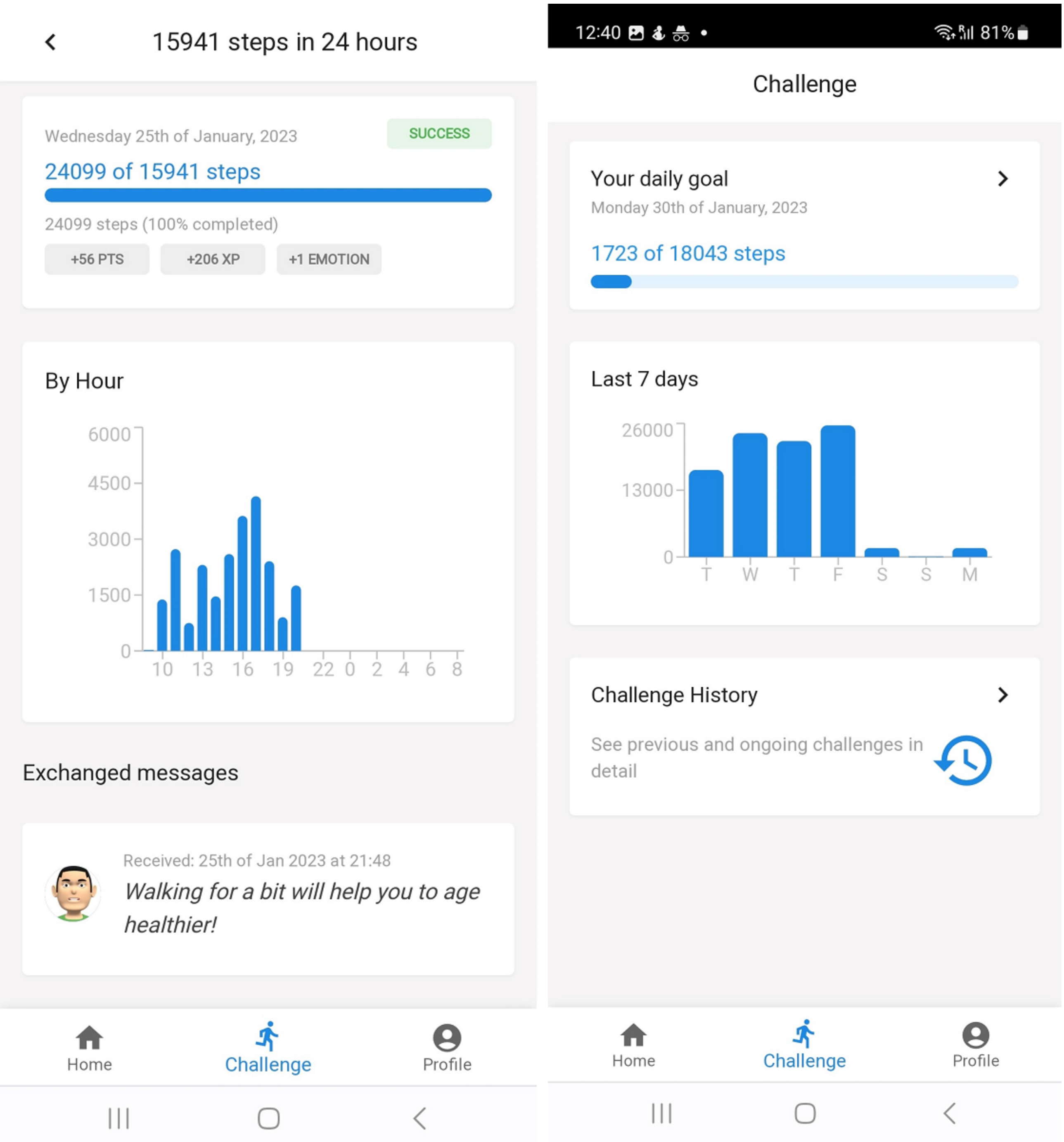
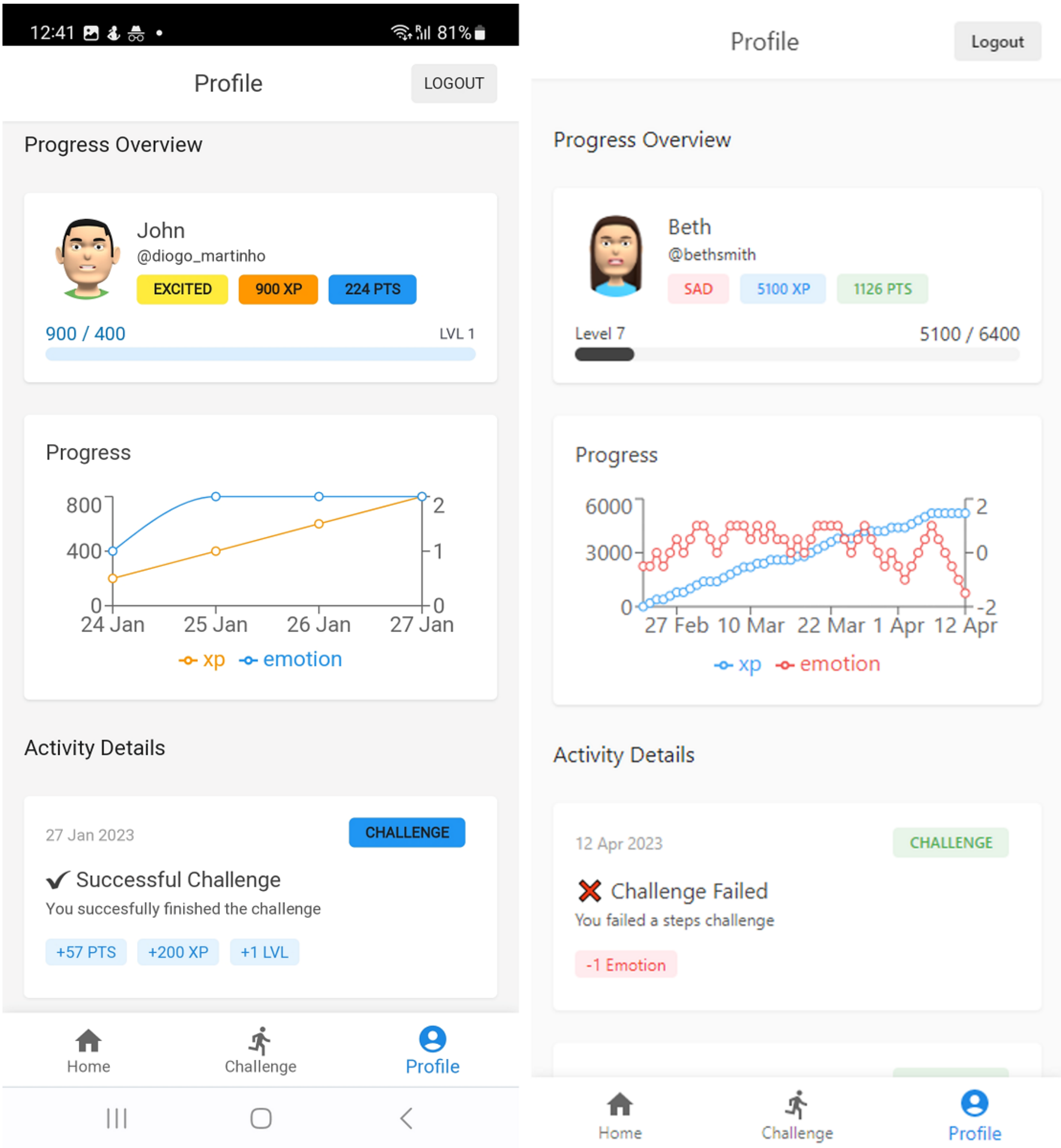


Figure 5. Challenge interface showing the virtual assistant progress.



Recruitment

The eligibility criteria for participants to enroll in the study were a minimum age of 55 years and an active Google Fit account. We initially recruited 16 participants. However, 3 users dropped out due to smartphone incompatibility with the Google Fit app and 1 due to not having Google Fit data past study enrollment. As a result, the proposed gamified agent-based system was used by 12 participants with a median age of 62 (IQR 12.5) years over 7 days (1 week), and step count data were collected with access to the Google Fit API. Step count data after the intervention were compared with average step count data before the intervention (average daily values over a period of 4 weeks before the intervention). A paired 1-way Student *t* test was used to determine the relationship between the dependent and independent variables. The null hypothesis ($H_0 \leq 0$) and the alternative hypothesis ($H_1 > 0$) were established by comparing the difference between pre- and posttest step count values.

Questionnaires

After completing the study, each participant was requested to fill out the System Usability Scale (SUS) questionnaire to provide feedback regarding their overall user experience during the period of experimentation.

Ethical Considerations

No ethics approval was applied for. All participants had access to the data privacy statement with information on data privacy, storage, access, and use within the study, to which they agreed before joining the study. User data were collected according to the permissions each user provided with the use of the Google Fit API. The study was performed according to the privacy policy and policy for the acceptable use of technologies of information and communication of our institution (Polytechnic Institute of Porto). The study was designed as an intervention study comparing pre- and posttest results and was conducted according to the principles of the Declaration of Helsinki and following the General Data Protection Regulation.

Results

Statistical analysis was performed using an Excel (Microsoft Corp) data analysis toolkit for *t* tests paired with 2 samples for the means method. Step count data were compared for the average of 7 days of experimentation with the average step count data of each corresponding day for the 4 previous weeks (28 days total; average 4 days for each 1 corresponding day).

The step counts were significantly higher after the intervention than before the intervention (mean 4931, SD 5056 steps vs mean 2532, SD 2049 steps and median 3826, IQR 5343 steps vs median 2169, IQR 4888 steps). These data were statistically significant at a 95% confidence level (P=.03; Student *t* test). The measured effect size (Cohen *d*) for paired samples according to was 0.65, which is between moderate (effect size >0.5) and large (effect size >0.8).

Looking at average daily differences (Table 1), it is possible to observe a positive difference on all days, with a slight decrease on the third day of the study, which can be explained by the fact that the highest virtual assistant emotional state is achieved after completing 2 daily challenges, starting from the baseline emotional state (0), and on the third day the emotional state no longer improves after successful completion of challenges. Despite this, by establishing a mechanism to reward users with enough points by allowing them to unlock additional content after 5 to 6 days of correct goal completion, it is possible to observe a significant increase in the average daily step count on the last 2 days of the experiment. The last 2 days have the highest average daily difference in step count between pre- and posttest, indicating a positive improvement as the experimentation period continues.

Table 1. Average daily difference between step count data before and after the intervention.

Day	Steps, n
1	2572
2	2138
3	975
4	1861
5	1547
6	3031
7	3178

Regarding usability, 8 of the 12 participants completed the SUS questionnaire, which comprises 10 questions, with response options ranging from “strongly agree” to “strongly disagree,” to measure the usability of software, mobile devices, websites, and applications. The answers are then normalized to obtain a usability score to describe the evaluated product. In the case of the developed application, after accessing all the answers provided by the users, we calculated an average usability score of 78 (on a scale of 0-100), corresponding to high usability. Participants were also asked to provide additional comments regarding their experience while using the CoaFEld application, and the overall comments were positive, with only a few suggestions to improve the login interface (since there was no “recover my password” feature implemented and the users were logged off the application automatically after each day).

Discussion

Principal Findings

As the world population grows older, it becomes essential to study and develop new personalized health care services that can support older people and promote healthier and active aging. As observed in various studies, different solutions are already being developed that take advantage of intelligent engagement strategies to interact with, persuade, and motivate older people to pursue more positive behaviors in their daily lives. In this context, gamification to enhance traditional health care services, especially when supporting older people, has already been shown to be a strong approach that can provide many advantages that contribute to improved health behaviors.

This study used the CoaFEld application, previously introduced by Martinho et al [30], which was developed with the main goal of supporting older people and offering different functionalities to motivate and persuade them to follow healthier lifestyles. This application includes gamified elements to motivate and enhance user experience, as presented in the design section of this paper. It includes a virtual assistant to interact with the older person and provide feedback on the progress in their health. As was also explained, different emotional states representing the user’s progress are shown, which improve as the user achieves health goals or worsens if they do not.

In our study, we validated the impact of the virtual assistant and the overall gamified solution developed for the CoaFEld application with the participation of users aged 55 years or older. We obtained significant results regarding the approach’s usability, acceptability, and effectiveness. More specifically, our study supports the importance and positive effect of combining gamified elements and a social engagement strategy with a virtual assistant to achieve user progress in a health care setting. The results favor the use of the CoaFEld app, with improved health outcomes after the intervention when compared to the health data obtained before the intervention (P=.02, calculated with the Student *t* test when P<.05) with a Cohen *d* effect size of 0.77, which is moderate yet close to large (ie, effect size >0.8). Additionally, the results of the SUS questionnaire confirmed high acceptability and usability, with an average usability score of 78 along with overall positive comments from the participants, expressing their intentions to keep using the application after the intervention period was completed.

Limitations

Two main limitations were observed during this validation study. The first limitation relates to the sample size, since 12 participants was an insufficient number to cover all older age groups. As explained in a previous section of this paper, the median age was 62 years, with the oldest participant being aged 70 years. However, as all the users who participated in this study were aged between 55 and 70 years, we can confirm the success of the intervention within this age group. Another limitation was related to the intervention period. For the intervention, participants were asked to use the CoaFEld application for 1 week and, as observed, this allowed us to obtain positive results. However, these results can only confirm a short-term improvement, and a more comprehensive, long-term study is necessary in light of the results obtained in this study.

Conclusions

Our findings highlight the use and importance of new, intelligent tools and methods to provide personalized support to promote healthier and more active aging among older people. In this context, different engagement strategies have been studied to motivate older people to adopt healthier lifestyles, which include gamifying more traditional health care applications targeted at this age group. These ideas are considered in this study, and a health care service for older people is presented and validated, showing the positive effects of gamification techniques and a virtual cognitive assistant that can enhance the user experience, encourage progress, and provide feedback. Additionally, usability metrics considered for this study confirmed most participants' high adherence and interest.

Further studies need to be performed on the effectiveness of this approach among older people and to measure the long-term performance of the developed service.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Challenge step count algorithm.
[DOCX File , 20 KB - games_v11i1e48063_app1.docx]

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Abbreviations

API: application programming interface
CoaFEld: Coaching for Elderly
SUS: System Usability Scale
XP: experience points

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Original Paper

TACTICS VR Stroke Telehealth Virtual Reality Training for Health Care Professionals Involved in Stroke Management at Telestroke Spoke Hospitals: Module Design and Implementation Study

Steven Maltby[1,2,3], BSc, PhD; Carlos Garcia-Esperon[2,4], MBBS, PhD; Kate Jackson[5]; Ken Butcher[6], MD, PhD; James W Evans[7], MBBS; William O'Brien[7]; Courtney Dixon[5]; Skye Russell[5]; Natalie Wilson[5]; Murielle G Kluge[1,3], PhD; Annika Ryan[2,8]; Christine L Paul[2,8], BA, PhD; Neil J Spratt[2,3,4], BMed, PhD; Christopher R Levi[8,9], BMedSci, MBBS; Frederick Rohan Walker[1,2,3], BSc, PhD

[1]Centre for Advanced Training Systems, The University of Newcastle, Newcastle, Australia
[2]Hunter Medical Research Institute, New Lambton Heights, Australia
[3]School of Biomedical Sciences & Pharmacy, College of Health, Medicine & Wellbeing, The University of Newcastle, Callaghan, Australia
[4]John Hunter Hospital, New Lambton Heights, Australia
[5]NSW Agency for Clinical Innovation, St Leonards, Australia
[6]School of Clinical Medicine, University of New South Wales, Sydney, Australia
[7]Department of Neurosciences, Gosford Hospital, Gosford, Australia
[8]School of Medicine and Public Health, College of Health, Medicine & Wellbeing, The University of Newcastle, Callaghan, Australia
[9]John Hunter Health & Innovation Precinct, New Lambton Heights, Australia

Corresponding Author:
Frederick Rohan Walker, BSc, PhD
Centre for Advanced Training Systems
The University of Newcastle
Medical Sciences Building - Room 317
University Drive
Newcastle, 2308
Australia
Phone: 61 249215012
Email: rohan.walker@newcastle.edu.au

Abstract

Background: Stroke management in rural areas is more variable and there is less access to reperfusion therapies, when compared with metropolitan areas. Delays in treatment contribute to worse patient outcomes. To improve stroke management in rural areas, health districts are implementing telestroke networks. The New South Wales Telestroke Service provides neurologist-led telehealth to 23 rural spoke hospitals aiming to improve treatment delivery and patient outcomes. The training of clinical staff was identified as a critical aspect for the successful implementation of this service. Virtual reality (VR) training has not previously been used in this context.

Objective: We sought to develop an evidence-based VR training module specifically tailored for stroke telehealth. During implementation, we aimed to assess the feasibility of workplace deployment and collected feedback from spoke hospital staff involved in stroke management on training acceptability and usability as well as perceived training impact.

Methods: The TACTICS VR Stroke Telehealth application was developed with subject matter experts. During implementation, both quantitative and qualitative data were documented, including VR use and survey feedback. VR hardware was deployed to 23 rural hospitals, and use data were captured via automated Wi-Fi transfer. At 7 hospitals in a single local health district, staff using TACTICS VR were invited to complete surveys before and after training.

Results: TACTICS VR Stroke Telehealth was deployed to rural New South Wales hospitals starting on April 14, 2021. Through August 20, 2023, a total of 177 VR sessions were completed. Survey respondents (n=20) indicated a high level of acceptability, usability, and perceived training impact (eg, accuracy and knowledge transfer; mean scores 3.8-4.4; 5=strongly agree). Furthermore, respondents agreed that TACTICS VR increased confidence (13/18, 72%), improved understanding (16/18, 89%), and improved awareness (17/18, 94%) regarding stroke telehealth. A comparison of matched pre- and posttraining responses revealed that training improved the understanding of telehealth workflow practices (after training: mean 4.2, SD 0.6; before training: mean 3.2, SD 0.9; $P<.001$), knowledge on accessing stroke telehealth (mean 4.1, SD 0.6 vs mean 3.1, SD 1.0; $P=.001$), the awareness of stroke telehealth (mean 4.1, SD 0.6 vs mean 3.4, SD 0.9; $P=.03$), ability to optimally communicate with colleagues (mean 4.2, SD 0.6 vs mean 3.7, SD 0.9; $P=.02$), and ability to make improvements (mean 4.0, SD 0.6 vs mean 3.5, SD 0.9; $P=.03$). Remote training and deployment were feasible, and limited issues were identified, although uptake varied widely (0-66 sessions/site).

Conclusions: TACTICS VR Stroke Telehealth is a new VR application specifically tailored for stroke telehealth workflow training at spoke hospitals. Training was considered acceptable, usable, and useful and had positive perceived training impacts in a real-world clinical implementation context. Additional work is required to optimize training uptake and integrate training into existing education pathways.

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KEYWORDS

virtual reality; technology; medical education; telehealth; stroke management; stroke workflow

Introduction

Background and Rationale

Ischemic stroke is a leading (and increasing) cause of adult-acquired disability worldwide [1]. Longer time to reperfusion treatment has severe and negative impacts for patients with ischemic stroke [2], with a progressively increased likelihood of poor patient outcome with every hour of delay before reperfusion treatment is started [3]. Variability in clinical care is a major contributor to delayed treatment [4], particularly in rural areas, and there are numerous challenges in delivering best practice stroke management in rural contexts in Australia [5] and worldwide [6]. One significant contributor to delays at rural sites is the nature of the workforce, which is typically more junior, nonspecialist, and transient than the workforce at metropolitan hospitals, as well as having less access to continuing professional development training [7-9]. There is extensive clinical trial evidence to inform best practice stroke workflow to deliver reperfusion therapies (eg, thrombolysis and endovascular thrombectomy). However, additional research is needed to inform the implementation of effective workflow processes and training in real-world clinical settings, particularly in rural areas.

To address variability in stroke care in rural settings, telestroke networks have been developed in Australia [10,11] and worldwide [12,13], where rural spoke hospitals are supported by comprehensive centers. Locally, in New South Wales (NSW) in Australia, we first initiated a telestroke network in 2013 with a single rural hospital, which expanded over subsequent years to include 5 rural sites linked to a single comprehensive stroke center. The telestroke service aims to provide urgent access to a stroke neurologist, improving access to reperfusion therapies as well as outcomes at rural sites. To date, the service has documented increased thrombolysis treatment rates [14] and highlighted the value of multimodal computed tomography (CT) imaging for stroke diagnosis in rural areas [15]. The successful initial implementation of the local telestroke service provided pilot data [14] and is a cornerstone of the current statewide NSW Telestroke Service, which has undertaken a progressive rollout providing services to 23 rural hospitals [16,17]. The implementation of the statewide service started in March 2020, with staggered rollout across the 23 sites through June 2022. We proposed that virtual reality (VR) training to support telestroke service implementation would be useful at both existing and new sites as a complement to support existing training, new staff inductions, training refreshers for existing staff, and initial site onboarding.

Acute stroke management workflow is complex, and efficient team coordination and the sequencing of processes are challenging. The effective delivery of timely reperfusion treatment in acute ischemic stroke requires structured stroke workflow processes. Intensive quality improvement processes aimed at optimizing stroke workflow pathways by enhancing team communication and implementing site-specific processes can markedly improve reperfusion treatment delivery times [18-20], for example, the implementation of multifaceted implementation strategies via targeted quality improvement at 2 Australian comprehensive hospitals effectively reduced time to treatment [18,19]. However, site-specific stroke workflow pathways are often not applied at rural hospitals where there are gaps in local training and resourcing, transient workforces, and limited effective application of quality improvement activities. In this context, stroke telehealth services can complement local processes by providing access to expert neurologist support and implementing a structured routine for stroke workflow. Importantly, the successful integration of telestroke services requires training local staff to increase awareness, confidence, and competence in telestroke processes.

Staff education and training are critical for the delivery of evidence-based stroke management, but this is limited in rural settings. Less than two-thirds of Australian physicians and nurses involved in stroke management report having received any interactive or competency-based training, including approximately 60% of nurses and 40% of physicians [21]. Stroke management staff in regional areas, at sites with fewer annual stroke admissions (<75/year), and at sites without a dedicated stroke unit were less likely to have opportunities for professional development (63%, 62%, and 64%, respectively) [22]. Stroke workflow training is typically delivered by neurology specialists via traditional face-to-face workshops. This training happens infrequently, has high logistical complexity and costs, and cannot be readily accessed by all staff at a given rural hospital. The delivery of training via this traditional model was further impaired during the COVID-19 pandemic, when travel between sites was restricted [23]. On the basis of our previous work developing and implementing VR-based workflow training for health care staff in hyperacute stroke management in rural settings [24], we proposed VR-based training specific for stroke telehealth to support the implementation of the NSW Telestroke Service.

In medical fields, VR-based training consistently increases student engagement and motivation [25,26] and is effective for practical skills acquisition [27,28] and knowledge development [29-31]. VR technology has previously been applied in the context of both stroke management and medical education [32-34]. To date, VR applications for stroke have primarily targeted patients rather than health care professionals (eg, in the context of limb rehabilitation [35,36]). In the broader medical education context beyond stroke, most VR training applications for health care professionals have only been assessed in small pilot trials or in the context of medical school or residency training (systematic reviews and meta-analyses [37-39]).

In a nontelehealth context, we previously developed and implemented a novel fit-for-purpose VR-based stroke workflow training application called TACTICS VR Hyperacute Stroke Management [24]. During initial implementation in the first trial cluster of 7 hospitals, TACTICS VR users reported a high degree of usability, acceptability, utility, and feasibility [24]. Trainees self-reported increased confidence in their ability to make improvements in stroke management after training [24]. The application is currently actively being assessed in the Trial of Advanced CT Imaging and Combined Education Support for Drip and Ship, which is implementing a *package intervention* to support advanced CT imaging and streamlined workflow training at rural sites in 3 Australian states and will also report effects on clinical behavior and patient outcomes [40]. On the basis of the initial success of implementing TACTICS VR training in rural hospitals within a clinical trial context, we proposed the development of a second TACTICS VR module to support the implementation of the NSW Telestroke Service in this study.

Study Objectives

This paper describes the development and implementation of TACTICS VR Stroke Telehealth, a VR training module for spoke hospital workflow processes. The platform was conceptualized to support the NSW Telestroke Service rollout and provide improved training and awareness on effective stroke management to health care professionals at spoke hospitals involved in stroke management (eg, physicians, nurses, and radiographers). The study aims to assess TACTICS VR Stroke Telehealth implementation against critical elements that typically predict the future adoption and uptake of new technologies in educational practice. This includes the feasibility of the platform as a training resource in a real-world clinical setting, specifically in rural areas. Furthermore, end user acceptance, including perceived usefulness and usability, and perceived training impacts are assessed via survey feedback.

Methods

Ethical Considerations

Ethics approval for the overall NSW Telestroke Service research protocol was granted by the Prince of Wales Hospital Human Research Ethics Committee. Because of the practical constraints of ethics approval being governed at a local health district level, the collection of user survey feedback was limited to a subset of sites within a single local health district (n=7) via ethics approval from the Hunter New England Human Research Ethics Committee (REGIS Ref 2019/ETH01238 and HNEHREC Ref 18/09/19/4.13) lodged with The University of Newcastle Human Research Ethics Committee (H-2019-0343). Before the deployment of TACTICS VR training, all study sites provided consent to participate. Individual user participation was voluntary, and users were able to use TACTICS VR without participating in the study. Participants were advised that their consent was implied by the completion of the surveys.

Project Conception and Scoping

The NSW Telestroke Service was jointly funded by the NSW and Australian federal governments in 2019, with service delivery at the first rural sites starting in March 2020 [16,17]. It is a collaboration between the Prince of Wales Hospital, eHealth NSW, the NSW Agency for Clinical Innovation (ACI), and the NSW Ministry of Health in partnership with the Australian Stroke Foundation. The NSW Telestroke Service was rolled out progressively to its total coverage, with the final sites activated in June 2022, providing services to 23 rural hospitals across NSW [41].

TACTICS VR Stroke Telehealth was initially conceived through discussions among the Centre for Advanced Training Systems (ATS) at The University of Newcastle, the ACI, and the NSW Telestroke Service in 2019, informed by the development and implementation of the first TACTICS VR Hyperacute Stroke Management module within the TACTICS trial [24,40].

Study Methodology and Protocol

Overview

A descriptive survey study approach was applied to the creation and deployment of TACTICS VR Stroke Telehealth. Quantitative and qualitative data were collected during the development (from May 1, 2020, through April 14, 2021) and implementation of the training module across 23 hospitals in NSW (from April 14, 2021, through August 20, 2023). A particular focus was placed on assessing elements that typically predict technology adoption, including end user acceptance (perceived usability and usefulness), training impacts, and the practical challenges of technology delivery within a real-world health care setting.

TACTICS VR Stroke Telehealth Module

TACTICS VR Stroke Telehealth was developed for the stand-alone Oculus Quest 2 enterprise-enabled headset (Oculus or Meta) using the Unity platform (Unity Technologies). A detailed overview of included scenes, key features, objectives, and user interactions is provided in Table 1, with representative images presented in Figure 1. Users initially enter a 3D VR infinity space containing the application menu and brief overview text about the application. Upon initiating training, users are requested to provide brief demographic information (eg, hospital location and position title) and are provided a video overview of the training module and instructions on how to use the VR technology. Users then proceed through a single real-world stroke case from the prenotification and initial assessment phase through multimodal CT imaging, consenting, treatment with thrombolysis, and patient transfer for endovascular thrombectomy. Specific emphasis is placed on 3 telehealth consults for assessment, imaging interpretation, and consenting and treatment, with all other aspects of the workflow streamlined to minimize the total length of training. Users interact with elements in the VR environment, including avatars (eg, patient and nurse), equipment (eg, telephone and computer), and question and answer prompts to gather case information and prompt active decision-making. Suboptimal decisions result in immediate feedback (via text or audio) and time penalties, providing an element of gamification. For each user interaction, the accuracy was calculated as the number of suboptimal decisions selected (including both suboptimal decisions made and optimal decisions missed) as a percentage of total possible decisions. Time penalties for each suboptimal decision (or missed optimal decision) were arbitrarily determined through context expert feedback based on the perceived priority and impact that the specific decision would have on real-world workflow times (ie, suboptimal decisions deemed more serious were assigned larger time penalties). A stroke clock and an estimate of neuron loss are displayed at the top of the screen to emphasize the importance of accurate and timely workflow and model the real-world consequences of delayed or inaccurate decision-making. At the end of the module, users are provided with feedback on their training, including time spent in training, errors, and time penalties.

TACTICS VR Stroke Telehealth was integrated into the existing TACTICS VR training platform, which includes a public-facing supporting website [42] and backend automated database and password-protected reporting environment (Figure 2). A detailed overview of the TACTICS VR training platform has been published previously [24]. In this study, the public website was updated with a streamlined design to include information about the VR training module, the development process, funding sources, and contributors and stakeholders [42]. The database and reporting environment were duplicated from the first TACTICS VR module and updated to reflect locations, user interactions, and scenes from the TACTICS VR Stroke Telehealth module to support the automated tracking of training implementation. The developed training module was endorsed by the Australasian Stroke Academy.

Table 1. TACTICS VR Stroke Telehealth scenes, key features, objectives, and user interactions.

Scene	Features	Objectives	User interactions
Start and introduction	• VR[a] infinity space • Contributor and funding information • Demographics capture (location, position title, department, experience, and previous TACTICS VR use)	• Initiation of training • Demographics capture • Overview of training application (objectives and functionality)	• Navigation buttons • Q&A[b]: demographics • Talking head video
Prehospital notification and initial assessment	• VR ED[c] environment • Patient assessment (case details, symptoms, previous function, and history)	• Familiarization with stroke assessment processes and resources • Clarification of critical data required	• Avatars: patient, next of kin, paramedic, and nurse • Q&A: workflow processes and team interactions
Telehealth consult 1: initial assessment	• Telephone consultation • Communication of critical data • Coordination of local team and imaging staff • Patient transfer to imaging department	• Familiarization with telestroke processes • Workflow decision-making and team coordination	• Telephone interaction: telestroke neurologist
Radiology and imaging	• Virtual radiology suite with CT[d] machine	• Clear communication to initiate imaging • Timing of telehealth follow-up	• Avatars: patient and radiographer
Telehealth consult 2: imaging	• Virtual web conferencing communication • Patient transfer to ED or resuscitation suite	• Interpretation of imaging • Treatment decision-making	• Audiovisual: imaging with neurologist commentary • Q&A: workflow processes, treatment decision, and team coordination
Telehealth consult 3: consent and treatment	• Virtual ED or resuscitation suite with workstation on wheels	• Familiarization with consenting process • Treatment administration • Considerations for patient EVT[e] transfer	• Avatars: patient, next of kin, and nurse
Feedback	• User performance (time, errors, and penalties)	• User receives feedback on performance • User provides feedback on training utility	• User feedback on training (based on a scale ranging from 1 star to 5 stars)

[a]VR: virtual reality.
[b]Q&A: question and answer.
[c]ED: emergency department.
[d]CT: computed tomography.
[e]EVT: endovascular thrombectomy.

Figure 1. Screenshots and key features of TACTICS VR Stroke Telehealth. (A) Starting scene. (B) Representative scene, including avatars and user interactions. (C) Representative talking head video and tablet view for patient information. (D) User feedback scene.

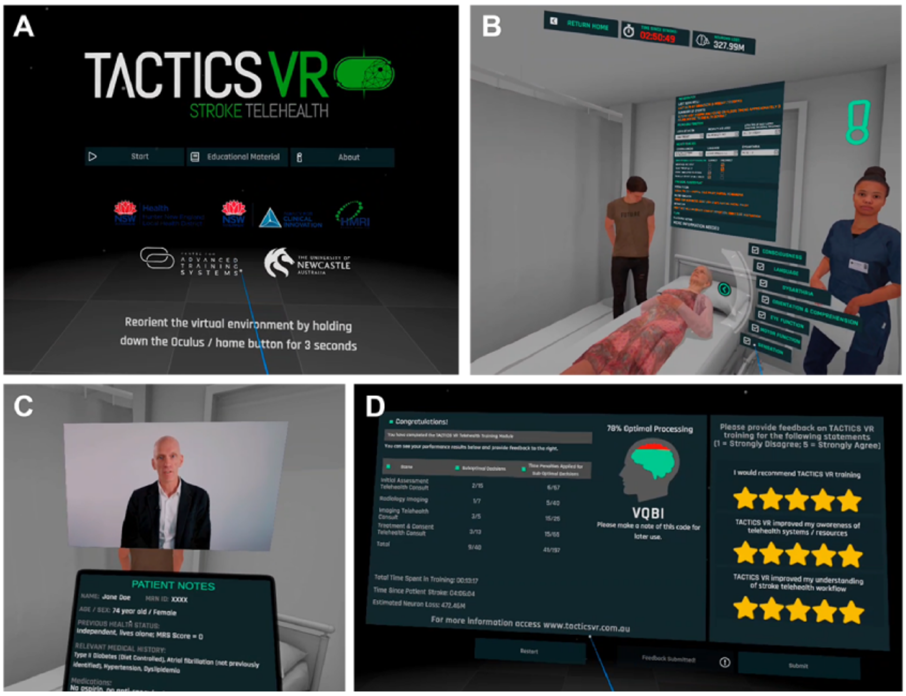
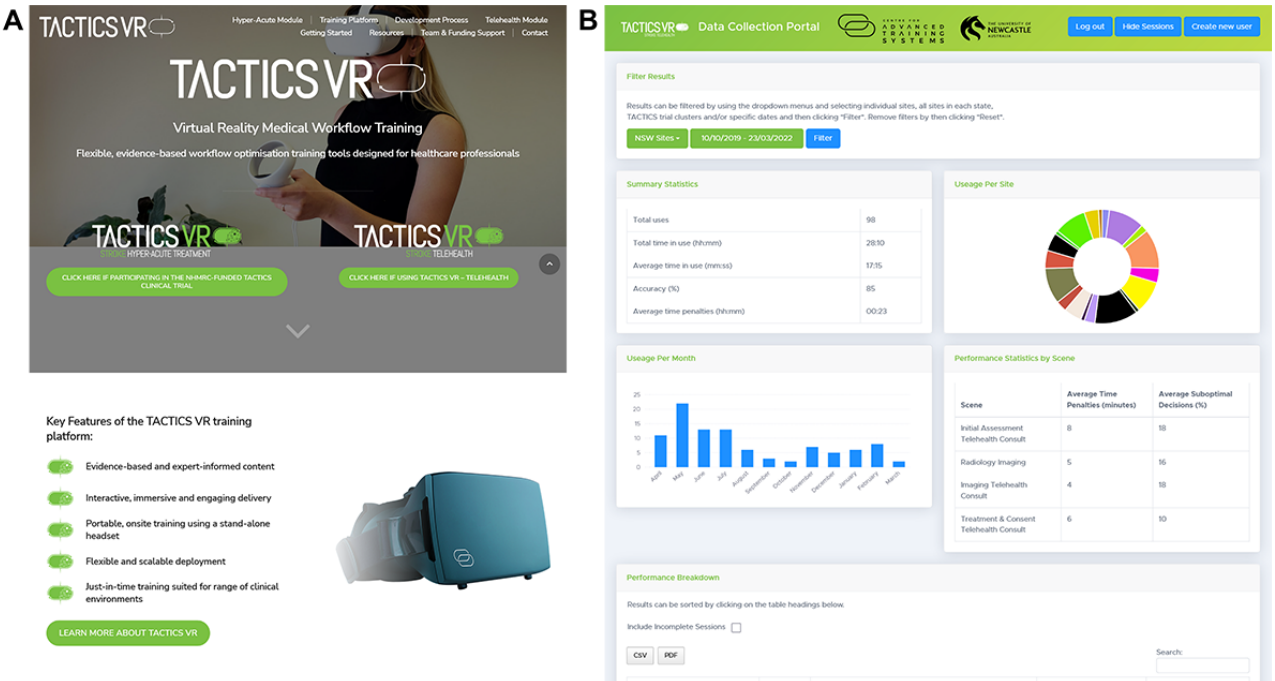


Figure 2. TACTICS VR training platform. The preexisting TACTICS VR platform was updated to integrate (A) a publicly accessible website for user support and educational resources as well as (B) an automated backend analytics portal for the collection of training uptake and user performance data.



Study Participants and Recruitment

Stroke coordinators at spoke hospitals were requested to encourage any relevant health care staff involved in stroke management at their site to use TACTICS VR Stroke Telehealth training. All health care staff who tested the application were invited to participate in the data collection regarding its utility and training impact. Health care professionals from any background (eg, physicians, nurses, and radiographers) involved in stroke care and as identified by the stroke telehealth coordinator, were encouraged to explore TACTICS VR and provide automated anonymous feedback within the headset. Additional structured pre-post survey data were collected from this population at 7 spoke sites, with corresponding ethics approvals.

Measures: Self-Report and Survey Data

Self-report data (qualitative and quantitative in nature) were collected both automatically within the headset for all users and via separate structured pre-post surveys deployed at specific locations, with corresponding ethics approvals.

Within the TACTICS VR Stroke Telehealth module, basic demographics information and user feedback (location, position title, relative stroke management experience, previous use of TACTICS VR, and user ratings) is automatically collected via user prompts within the headset and automatically transferred via Wi-Fi to the password-protected reporting environment. These data are presented as TACTICS VR *user data* throughout this manuscript.

Additional structured survey responses were collected from trainees at the 7 spoke sites before and after TACTICS VR Stroke Telehealth training. Surveys collected more detailed feedback on training usability, usefulness, and perceived training impact. All survey data are referred to as *TACTICS VR survey response data* provided by *respondents* throughout this manuscript.

The administered surveys were generated by the research team and adapted from previous studies to accommodate the limited availability and time constraints of health care staff. Informed by the technology acceptance model [43-45], the survey items and domains focused on perceived acceptability, usability, usefulness, and training impacts and included individual items from validated scales, where appropriate [46,47].

Items within the pretraining survey aimed to collect relevant demographic information (eg, specialty area, position title, previous stroke telehealth experience, and VR experience), general expectations of VR-based training, and anticipated learnings. Items within the posttraining survey aimed to collect feedback on TACTICS VR Stroke Telehealth training (eg, hardware comfort, design, user interactions, and areas of improvement), usability, and usefulness and perceived value. Items relating to stroke workflow awareness, knowledge, and skill confidence aligned with TACTICS VR learning objectives and were included in both pretraining and posttraining surveys to assess training impacts via pretraining survey versus posttraining survey statistical comparisons.

The full lists of questions and responses are provided in Tables S1 and S2 in Multimedia Appendix 1.

Data Analysis

Self-report data were summarized and presented as mean (SD) or absolute number of responses, using Prism (version 8.0; GraphPad), and every response was included.

Statistical analysis was performed using Prism (version 8.0). Comparisons between pre- and posttraining responses to matched questions were analyzed using paired Wilcoxon tests for nonparametric data. *P* values of <.05 were considered statistically significant for all analyses.

Because of the limited number of open-ended survey responses, no formal analysis of qualitative data was performed. Points that were repeatedly mentioned in the open-ended responses were identified by the study investigators, and examples are provided in the *Results* section (a full list of responses is provided in Table S2 in Multimedia Appendix 1).

Results

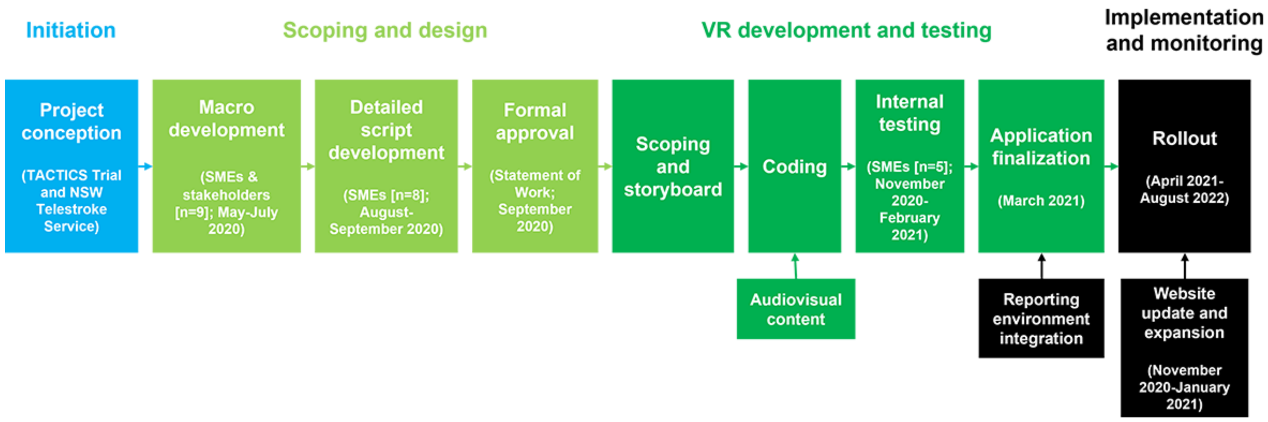
Development of TACTICS VR Stroke Telehealth

The overall concept and philosophy for TACTICS VR Stroke Telehealth built on the preexisting TACTICS VR module and training platform [24]. TACTICS VR Stroke Telehealth was developed using a structured stepwise approach throughout (an overview schematic is presented in Figure 3). Most importantly, the development involved and actively included subject matter experts (SMEs) and stakeholders. Specifically, members from the ATS, the ACI, and the NSW Telestroke Service as well as experts, including specialist neurologists, nurses, and radiographers, were consulted and were active creators of the platform from concept to software development.

An initial *macrolevel* overview of stroke telehealth workflow was generated based on NSW Telestroke Service workflow protocols, training resources, existing education materials, and informal SME interviews. This process identified key aspects of workflow procedures and provided contextual insights. A working group of SMEs was formed to review draft script documents and provide insights into common mistakes that delay telestroke workflow. All feedback was integrated into a single statement of work, which was reviewed by stakeholders via web conferencing. Subsequent meetings with SMEs informed the development of a detailed script document specifying specific user interactions, questions and answers, user feedback, and digital media content for inclusion (eg, reference images and talking head videos). The completed workflow was summarized into a single document and formally approved by SMEs as well as members of the ATS, the ACI, and the NSW Telestroke Service. The approved statement of work was circulated to content developers to inform quotes and development. This process was chosen to ensure the development of a fit-for-purpose training tool that would be accepted by trainees and experts in the field.

Software development proceeded stepwise through four key phases: (1) VR scoping and concept creation, (2) content development and refinement, (3) internal beta testing, and (4) application finalization.

Figure 3. TACTICS VR Stroke Telehealth development pathway. Development occurred via a structured process from initiation through scoping and design, content development, iterative rounds of internal testing, implementation, and monitoring. NSW: New South Wales; SME: subject matter expert; VR: virtual reality.



TACTICS VR Stroke Telehealth Implementation

TACTICS VR was deployed as part of the NSW Telestroke Service, which embeds stroke coordinators at telehealth spoke sites and includes structured education and training, communications (eg, communities of practice), the deployment of technology (eg, workstation on wheels and web conferencing), and ongoing support.

Headsets were shipped out to telestroke site coordinators at 23 participating locations. Using enterprise-enabled headsets allowed the remote monitoring of activations, battery status, and the update deployment of the software, removing the management burden from the telestroke coordinators and making it the responsibility of a dedicated centralized position. Telestroke site coordinators were initially briefed and trained with the VR headset on a site-by-site basis via web conferencing and provided supporting documents (eg, a quick-access guide and an instruction manual). Site coordinators were then requested to encourage any health care staff involved in stroke management at their spoke hospital to use TACTICS VR training (in particular, members of the stroke team as well as emergency department and radiology and imaging staff [eg, physicians, nurses, and radiographers]).

A total of 177 TACTICS VR sessions were logged at 20 (87%) of the 23 NSW Telestroke Service sites between April 14, 2021, and August 20, 2023. The number of completed training sessions per site ranged from 0 to 66 (mean 7.3, SD 13.1; median 4.5).

The mean time spent in VR training was 17 minutes 14 seconds per session, equating to a total of 50 hours 48 minutes across all sessions.

TACTICS VR User Data

TACTICS VR user data collected within the headset showed that those who used the platform primarily worked in acute stroke or neurology (94/177, 53.1%) and emergency care (63/177, 35.6%), followed by intensive care (7/177, 4%), radiology (4/177, 2.3%), stroke rehabilitation (2/177, 1.1%), and other (7/177, 4%). Users were employed as physicians (*in training*: 79/177, 44.6%; staff specialist: 25/177, 14.1%) or nurses (nurse: 50/177, 28.2%; nurse practitioner: 2/177, 1.1%), with the remainder being radiographers (4/177, 2.3%) or other (16/177, 9%). Of the 177 users, 33 (18.6%) had previously used a TACTICS VR training module. The users had a range of previous stroke management experience in terms of both total patient numbers and years, with a bimodal distribution of users reporting low or high experience (Table 2).

The mean user response accuracy was 87.2% (SD 8.3%) overall, resulting in an average of 22 (SD 19) minutes in time penalties per session. User accuracy was highest for each of the scenes relating to treatment and consent telehealth (91%), followed by each of the scenes for initial assessment telehealth consult (83%), radiology imaging (83%), and imaging telehealth consult (83%). Upon completing training, users provided positive in-headset feedback on TACTICS VR training by rating statements on a scale ranging from 1 star to 5 stars: “I would recommend TACTICS VR training” (n=127): mean 4.6, SD 0.8; “TACTICS VR improved my awareness of telehealth systems/resources” (n=126): mean 4.6, SD 0.7; and “TACTICS VR improved my understanding of stroke telehealth workflow” (n=126): mean 4.6, SD 0.7 (Table 2).

Table 2. TACTICS VR users have a diverse range of stroke experience and report positive training impacts of the TACTICS VR Stroke Telehealth module in the headset. For both stroke management queries, n=177; N values are included for the TACTICS VR feedback fields (n=126-127).

Stroke management experience	Response in VR[a] headset
Stroke management experience, n (%)	
<10 patients	90 (51)
11-20 patients	27 (15)
21-30 patients	12 (7)
31-40 patients	7 (4)
>40 patients	41 (23)
Stroke management experience, n (%)	
0 years	51 (29)
1-5 years	68 (38)
6-10 years	31 (18)
11-15 years	20 (11)
16-25 years	5 (3)
>25 years	2 (1)
TACTICS VR feedback[b], mean (SD)	
TACTICS VR improved my understanding of stroke telehealth workflow (n=126)	4.6 (0.7)
TACTICS VR improved my awareness of telehealth systems and resources (n=126)	4.6 (0.7)
I would recommend TACTICS VR training (n=127)	4.6 (0.8)

[a]VR: virtual reality.

[b]Responses collected in VR headset on a scale from 1-5 stars.

TACTICS VR Survey Response Data

A total of 21 pretraining and 20 posttraining survey responses were received from 4 sites (from a total of 26 VR sessions across the 7 survey-eligible sites; completed between May 2021 and September 2022; 21/26, 81% response rate during the survey deployment time frame). Survey respondents primarily worked in emergency care (14/21, 67%); there was also representation from acute stroke and neurology (3/21, 14%), intensive care (1/21, 5%), and other (stroke dietitian, research, and general or acute medicine: 3/21, 14%). Of the 21 respondents, 10 (48%) were employed as nurses, 10 (48%) as physicians, and 1 (5%) as a stroke dietitian; in addition, 3 (14%) were currently involved in a training program. Respondents had a range of previous experience in both stroke management and telestroke (Table 3). Of the 21 respondents, 2 (10%) indicated that they were prone to motion sickness when asked a binary yes or no question (17/21, 81% answered *no*).

Respondents had minimal previous experience with VR technology in any context (Table 3), and 3 (14%) of the 21 respondents had previously used any TACTICS VR training module. Before completing training, respondents indicated that they were likely to use telehealth in the future (19/21, 90% answered: mean 4.2, SD 1.0; 1=strongly disagree and 5=strongly agree) and were somewhat confident in their ability to effectively assess and treat patients with stroke (21/21, 100% answered: mean 3.5, SD 0.9; Table 3). Before the training, respondents were somewhat confident in managing the technical aspects of VR training (21/21, 100%: mean 3.6, SD 0.8; Table 3) and considered VR an effective method to teach or transfer knowledge about stroke telehealth workflow (21/21, 100% answered: mean 3.8, SD 0.8; Table 3).

After completing TACTICS VR Stroke Telehealth training, respondents provided positive feedback on the hardware, user interface, and training content across a range of aspects, including comfort, enjoyment, utility, accuracy, effectiveness in transferring knowledge, realism, and the quality of feedback (mean scores ranged from 3.8 to 4.4; 1=strongly disagree and 5=strongly agree; Table 4). Furthermore, respondents agreed that TACTICS VR Stroke Telehealth training increased their confidence in stroke telehealth (18/20, 90% answered: mean 3.8, SD 0.8; 13/18, 72%: agree or strongly agree), improved their understanding of stroke telehealth (18/20, 90% answered: mean 4.2, SD 0.8; 16/18, 89%: agree or strongly agree), improved their awareness of stroke telehealth (18/20, 90% answered: mean 4.3, SD 0.6; 17/18, 94%: agree or strongly agree), and indicated that as a result of TACTICS VR Stroke Telehealth training, they were more likely to use stroke telehealth in the future (19/20, 95% answered: mean 4.0, SD 0.8; 14/19, 74%: agree or strongly agree; Table 4).

A comparison of responses to matched questions between pre- and posttraining surveys indicated that TACTICS VR training increased user confidence in the understanding of telehealth workflow processes (after training: mean 4.2, SD 0.6; before training: mean 3.2, SD 0.9; median 4, IQR 4-5 vs median 4, IQR 3-4; $P<.001$), knowledge around accessing stroke telehealth (mean 4.1, SD 0.6 vs mean 3.1, SD 1.0; median 4, IQR 4.00-4.25

vs median 3, IQR 2-4; *P*=.001), awareness of local stroke telehealth services or processes (mean 4.1, SD 0.6 vs mean 3.4, SD 0.9; median 4, IQR 4.00-4.25 vs median 4, IQR 2.50-4.00; *P*=.03), ability to optimally communicate with colleagues to enable effective treatment (mean 4.2, SD 0.6 vs mean 3.7, SD 0.9; median 4, IQR 4-5 vs median 4, IQR 3-4; *P*=.02), and ability to make improvements to how stroke care is provided (mean 4.0, SD 0.6 vs mean 3.5, SD 0.9; median 4, IQR 4-4 vs median 4, IQR 3-4; *P*=.03; Table 5). A nonsignificant trend was also noted toward increased confidence in the understanding of general workflow practices to manage patients with acute stroke (mean 4.3, SD 0.5 vs mean 3.9, SD 0.6; median 4, IQR 4-5 vs median 4, IQR 4-4; *P*=.15), noting that self-reported pretraining confidence was already relatively high. Of the 20 respondents, 3 (15%) reported that they experienced motion sickness, but all were able to complete training. None of the respondents reported technical issues using TACTICS VR Stroke Telehealth, and the majority (13/18, 72%) believed that additional TACTICS VR training modules should be developed.

When asked an open-ended question on which elements of the TACTICS VR Stroke Telehealth training module were most beneficial, respondents primarily noted the VR virtual environment, interactions or interactivity, content presentation, and the overview of the complete workflow process. Selected comments are provided herein (all responses are available in Table S2 in Multimedia Appendix 1):

- Visual environment and scans, feedback on selections made, and step-by-step process
- Explanation of telestroke workflow and input
- Easy to follow
- Instant feedback: “awesome”
- Explanations provided at each decision point
- Feedback or interaction

Respondents were also asked which elements of TACTICS VR Stroke Telehealth could be improved, and they primarily identified aspects relating to VR technology familiarity, site-specific differences in processes, and areas for future development or expansion (eg, role-specific workflow modules). Comments included the following:

- Mock scenario at beginning or instructions on how to navigate through scenarios
- Perhaps the selections could be more clear regarding only selecting the first step in parallel (ie, “checklist that you tick”)
- Role oriented (not nurse specific; “seems more medical officer”)
- Further information regarding interpreting scans, including information regarding contraindications to tissue plasminogen activator or endovascular clot retrieval (stroke treatments)

Respondents who indicated that the additional TACTICS VR training modules should be developed (13/18, 72%) were asked what additional modules would be useful. Responses included the following:

- Allied health team involvement (or physiotherapist, speech therapist, and dietitian to demonstrate the whole of team care)
- Trauma survey and cardiac thrombolysis
- Procedural skills training

Table 3. Pretraining survey respondents have a range of stroke management experience, limited virtual reality (VR) experience, and existing attitudes to VR training.

Stroke, telestroke, and virtual reality experience	Survey response
Approximately how many acute stroke patients have you cared for or treated over the course of your career? n (%)	
Less than 10 patients	7 (33)
11-20 patients	4 (19)
21-30 patients	2 (10)
31-40 patients	2 (10)
41 patients or more	6 (29)
Approximately how many stroke telehealth cases have you been involved in? n (%)	
0 patients	8 (38)
1-4 patients	8 (38)
5-9 patients	0 (0)
10-14 patients	2 (10)
≥15 patients	2 (10)
Not applicable to my practice	1 (5)
What is your experience with virtual reality technology? n (%)	
Over 100 hours of usage	0 (0)
50-99 hours of usage	0 (0)
10-49 hours of usage	1 (5)
Less than 10 hours of usage	6 (29)
No experience	14 (67)
Pretraining confidence and attitudes[a], mean (SD)	
I am likely to use telehealth services in the future	4.2 (1.0)
I am confident in my ability to effectively assess or treat acute stroke patients	3.5 (0.9)
I feel confident in regards to managing the technical aspect of the VR training tool	3.6 (0.8)
I believe that VR can be an effective method to teach or transfer knowledge about stroke telehealth workflow	3.8 (0.8)

[a]Pretraining survey responses collected on 5-point Likert scale (1=strongly disagree and 5=strongly agree; n=19-21).

Table 4. Survey respondents provided positive feedback on TACTICS VR Stroke Telehealth training and reported perceived training benefits.

	Posttraining survey response[a], mean (SD)
Feedback on TACTICS VR stroke telehealth	
The VR hardware (eg, headset and controller) were comfortable and easy to use	4.1 (0.9)
The TACTICS VR Telehealth user interface was straight-forward and easy to use (eg, menu system, buttons, etc)	4.4 (0.7)
I enjoyed TACTICS VR Telehealth training	4.2 (0.6)
TACTICS VR Telehealth provided useful information to be useful for trainees and staff in the management of acute stroke	4.2 (0.4)
TACTICS VR Telehealth provided accurate information	4.2 (0.7)
TACTICS VR Telehealth was an effective tool for transferring knowledge about stroke telehealth practices	4.4 (0.5)
The simulation was of sufficient realism to communicate the critical aspects of workflow	3.9 (1.0)
The feedback provided at the end of the VR training module was constructive and useful	4.0 (0.6)
Perceived training impact	
TACTICS VR Telehealth improved my awareness of stroke telehealth approaches	4.3 (0.6)
TACTICS VR Telehealth improved my understanding of stroke telehealth approaches	4.2 (0.8)
TACTICS VR Telehealth increased my confidence in stroke telehealth workflow	3.8 (0.8)
As a result of TACTICS VR Telehealth training I am more likely to use stroke telehealth services in the future	4.0 (0.8)

[a]Survey responses collected on 5-point Likert scale (1=strongly disagree and 5=strongly agree; n=17-20).

Table 5. Survey respondents provide positive feedback on perceived training effects regarding confidence, via comparison of posttraining versus pretraining survey responses.

Self-reported stroke management confidence	Pretraining survey response[a], mean (SD)	Posttraining survey response[a], mean (SD)	*P* value
I am confident in my understanding of telehealth workflow processes	3.2 (0.9)	4.2 (0.6)	<.001
I am confident in my knowledge around accessing telehealth for acute stroke assessment or treatment	3.1 (1.0)	4.1 (0.6)	.001
I am aware of local stroke telehealth services and processes	3.4 (0.9)	4.1 (0.6)	.03
I am confident in my ability to optimally communicate with my colleagues to enable effective treatment of acute stroke patients	3.7 (0.9)	4.2 (0.6)	.02
I am confident in my ability to make improvements to how acute stroke care is provided to patients presenting to this hospital	3.5 (0.9)	4.0 (0.6)	.03
I am confident in my understanding of workflow practices to manage acute stroke patients	3.9 (0.6)	4.3 (0.5)	.15

[a]Survey responses collected on 5-point Likert scale (1=strongly disagree and 5=strongly agree; n=17-21).

Discussion

Principal Findings

This paper describes the development and pilot implementation of TACTICS VR Stroke Telehealth, a VR-based training application specifically tailored for stroke telehealth workflow training. The TACTICS VR module was developed to address an identified training gap to support the rollout of the NSW Telestroke Service by, and with, involved stakeholders. In this study, we evaluated the acceptability, usability, and perceived training impacts of TACTICS VR Stroke Telehealth training across 20 rural NSW hospitals, including survey response data from a subset of 7 sites within a single local health district. The feedback indicated a high level of end user acceptability (including perceived usability and usefulness) among health care professionals involved in stroke management at telehealth spoke hospitals. Furthermore, the feasibility of deploying VR training in a real-world clinical setting outside of a formal clinical trial context was demonstrated, while noting that additional work is required to optimize training uptake and integration into existing training processes. TACTICS VR users provided positive feedback on application delivery and design. Survey respondents reported perceived improvements in key aspects of stroke telehealth management, including an increased understanding and awareness of telehealth workflow, knowledge around accessing stroke telehealth, an improved ability to optimally communicate with colleagues, and an increased ability to make improvements to stroke care.

Extensive participant feedback was very positive, and implementation was overall deemed feasible, but we believe that there is room for improvement in terms of overall training uptake. To encourage use and simplify deployment, we specifically developed training sessions that were relatively short (<20 minutes), included brief talking head videos emphasizing key learning objectives, and provided supporting documentation as well as a user-facing website so that training could be deployed on site without trainer support.

Although this study was not structured to objectively determine factors influencing site-specific implementation, the captured data and discussions did provide some useful insights to assess in future implementation interventions. Rural telestroke hospitals varied widely across a range of factors, including overall hospital size (from 30 to 520 beds), stroke team composition (eg, specific stroke teams vs emergency department–based or locum management, staffing numbers and positions, skill sets, and on-site vs off-site radiographers), resourcing and NSW Telestroke Service site coordinator demographics (eg, on site vs off site, preexisting members of the local team vs new appointments, clinical vs administrative background, and single site vs multisite coverage). Discussions with study investigators and site coordinators highlighted barriers relating to staffing (both trainer and trainee availability), existing attitudes and training frameworks, and competing priorities. Mapping these factors onto the theoretical domains framework highlights relevant aspects within the domains of knowledge, skills, social or professional role and identity, beliefs about capabilities, reinforcement, environmental context and resources, and social influences [48]. By applying the Behavior Change Wheel [49], we propose a range of strategies that could address these domains within local contexts, including education (eg, promoting awareness of, and practical skills in delivering, VR training; and tailored training documentation), persuasion (eg, making VR training a mandatory component of local staff orientation), incentivization, environmental restructuring (eg, local staffing and resourcing), enablement (eg, upskilling training facilitators and providing for dedicated training time), communication or marketing, and service provision (eg, facilitated training by an external service provider). In the long term, if VR training is demonstrated to be effective and sustainable in supporting clinical behavior change and improving patient outcomes, it may be appropriate to consider its integration into consensus guidelines and clinical pathways.

Future studies should seek to document enablers and barriers to VR training uptake and explore additional implementation approaches. To this end, we are currently assessing the effects of a range of approaches to TACTICS VR training uptake and sustainment, including making training mandatory, integrating training into existing continuing professional development credit systems, deploying VR headsets via roaming educators who travel among sites, providing time-limited access to hardware at individual sites on a rolling basis, delivering supported face-to-face education sessions or workshops where multiple staff members complete training in parallel (eg, 10 trainees/1-hour session), and embedding VR training within a broader staff training program with expert-supported debriefing. We anticipate that a combination of different implementation approaches and strategies, which applies a codevelopment approach to optimize training within each organization, will be useful to increase adoption across a range of rural sites with different needs.

As part of the development process, we also documented associated costs, which may be relevant to readers who are considering developing and implementing similar VR training in their specific context. Note that during the study period conversion rates ranged from approximately Aus $1 (US $0.6-$0.8). Direct costs associated with the development of TACTICS VR Stroke Telehealth training included VR application coding and updating of the existing automated analytics portal (approximately Aus $37,000; ie, ~US $24,200), expansion and redesign of the user-facing website (approximately Aus $4000; ie, ~US $2600), and hardware (VR headsets and Wi-Fi routers; approximately Aus $1800 [~US $1200] per site). Additional costs associated with project management, internal application testing, research assessment, ongoing support and maintenance, and implementation within the broader NSW Telestroke Service rollout were not specifically captured or reported.

Comparison With Prior Work

Telestroke services improve the rates of reperfusion treatment and functional patient outcomes without increasing the rates of treatment-induced hemorrhage, although it has been noted that evidence for impacts on resource use and cost-effectiveness is limited [50,51]. As a result, patients treated through telestroke networks achieve outcomes that are similar to those managed at comprehensive stroke centers [10,12,13]. Of note, in Australia, the importance of telehealth-supported stroke care was recently recognized through its inclusion in the Australia Stroke Foundation guidelines as best practice to improve outcomes in rural settings [52]. However, the effectiveness of stroke telehealth delivery depends upon a number of factors, including trained staff, infrastructure to support CT image transfer, videoconferencing capabilities, established protocols and processes, and funding. Furthermore, effective deployment requires the coordinated training of health care staff in telestroke workflows across diverse clinical settings. TACTICS VR Stroke Telehealth was developed to address this need.

VR technology is increasingly used to support training in a range of workplace settings, including health care. VR has advantages over traditional 2D training delivery approaches in terms of presence, privacy, and immersion [53], but the relative benefit of VR regarding training outcomes depends upon the specific application as well as the delivery context. Several recent systematic reviews have collated findings on mixed reality or VR and health care staff training, with specific focuses on head-mounted devices (HMDs) [37] or augmented reality in medical education [39] and VR-based training in nursing [38]. The majority of reported studies demonstrated the effectiveness of training (or noninferiority to traditional approaches), with greater trainee enthusiasm and enjoyment when using HMD-based technology in medical education [37]; improved performance time, confidence, and satisfaction using

AR for medical education [39]; and improved knowledge development using VR for nursing education [38]. However, the existing literature remains limited, with a low number of total studies (11-27 studies each across 3 systematic reviews), low total participant numbers (a total of 654-956 participants across all studies), and application to training in a limited range of medical fields (eg, 48% of HMD-based training studies in surgery and 15% in anatomy [37]). Notably, there has been limited application of VR technology for the continuing education of health care professionals, the target population in this study; for example, across all studies of HMD-based training in medical education, 60% of the study participants were medical students, and 30% were medical residents (ie, 90% combined) [37]. On the basis of the reported 956 total participants across all 27 studies, this indicates that only approximately 95 (approximately 10%) nontrainee participants were included [37]. Thus, the 177 VR sessions included in this study represent almost twice the total number of reported HMD-based VR training participants in the existing literature within a continuing medical education context. Across the 3 systematic reviews, the authors noted many limitations, including most of the studies being small-scale short-term pilot studies, often conducted in a single nonclinical setting with limited participant diversity in medical field or training stage and often poor-quality study design. Our study addressed several of these areas and provides insights into the application of VR training for the continuing education of health care professionals in a clinical context, which is a setting that is underrepresented—in terms of both population and training—in the existing literature. None of the studies identified in the systematic reviews specifically focused on the continuing education of health care professionals in stroke management. To our knowledge, the only VR applications that have been previously studied for stroke (other than our previous report of the first TACTICS VR module [24]) have targeted patient users to support poststroke rehabilitation (eg, limb motor function recovery) [35,36].

This study builds on our previous experience of developing the first TACTICS VR training module, which provided hyperacute stroke workflow training without telehealth integration [24]. The first TACTICS VR Hyperacute Stroke Management module continues to be assessed in a clustered stepped-wedge clinical trial across 3 Australian states, with data collection conducted through the end of 2022 [40]. This study differs from the previous work by upgrading content into a 6-degrees-of-freedom VR headset, developing training content specifically for stroke telehealth workflow, and assessing implementation outside of a formal structured clinical trial context. The specific elements incorporated into training include 3 telehealth consultation calls, a detailed voice-over walkthrough of CT imaging interpretation, the incorporation of an assessment support tool (termed the Acute Stroke Assessment Protocol Triage Tool), and a simulated workstation on wheels. Despite more limited infrastructure and support during implementation in this study, we noted very similar participant feedback on acceptability, feasibility, and utility, which was very encouraging. This study also builds on our previous work deploying VR training in workplaces outside of health care, which has highlighted the importance of considering broad institutional factors and developing frameworks that support training implementation, uptake, and ongoing sustainment [54-57]. Consistently across sectors (ie, in health, tertiary education [55,56], and defense [54]), these aspects must be considered and addressed at the organizational level to optimize training implementation and maximize effects.

Training programs for health care professionals in stroke management are typically delivered face-to-face by an experienced trainer or clinical expert with relevant expertise via traditional teaching modalities (eg, printed materials and slide-based presentations), informal mentor or mentee learning, and the passive distribution of guidelines and training materials. These approaches support the delivery of evidence-based clinically relevant educational content but are expensive to either deliver or scale across rural settings and are passive and limited in utility. Group education approaches contribute to relatively small improvements in professional practice (eg, <10%) [58] but are better than the passive delivery of clinical guidelines and recommendations. Limited studies have assessed simulation-based approaches to support stroke workflow training [59]. We propose that TACTICS VR training specifically and stand-alone VR-based training more broadly are a feasible and useful approach to supplement existing training modalities, particularly in rural contexts.

Limitations

We note several limitations, which should be considered when interpreting data from this study. First, study recruitment was led by on-site staff at spoke hospitals who were requested to target health care professionals involved in stroke management; as such, it was nonrandom. This was partially mitigated by encouraging site coordinators to recruit all staff involved in stroke management. Study participants primarily included physicians and nurses in emergency or acute stroke care. We note that the demographic mix captured from TACTICS VR users in the headset was similar to that of the survey respondents in terms of department, position title, and relative stroke experience. Although this was the intended target population for this training, their feedback on the utility of VR training to support workplace training more broadly may not be representative of all health care professional groups. It may be useful to specifically target additional training populations in future studies (eg, radiographers). Second, implementation was limited to hospitals in NSW, and detailed survey collection was limited to a subset of 7 sites, with corresponding ethics approvals. This was due to the complexities in obtaining specific ethics approvals for survey distribution across multiple local health districts and hospitals. Although it would be useful to collect additional data in specific local health districts or contexts to inform the location-specific integration of training in the future, we believe that the responses collected at the 4 sites are representative of the general feedback overall because the sites included are reflective of regional Australian spoke hospitals. Third, TACTICS VR Stroke Telehealth training was deployed as part of the NSW Telestroke Service, which included additional education materials, site visits, and follow-up support, as well as staffing and quality improvement activities. VR training was intended to complement these training approaches and resources as an add-on that can be deployed on site in rural settings. However, this approach does limit the ability to directly assess and attribute the effects of TACTICS VR training on clinical behavior or patient outcomes in isolation. Metrics on clinical behavior and patient outcomes are being captured as part of the NSW Telestroke Service implementation, which will provide insights into the effects of the overall program but will not allow an assessment of the direct effect of TACTICS VR Stroke Telehealth training specifically. Fourth, given the nature of this feasibility study, no control group was included; as such, we were unable to compare the effects of TACTICS VR Stroke Telehealth training with those of alternative approaches. Finally, the survey was intentionally kept short, noting the time constraints of study participants, and limited to study-specific questions. Additional assessments, including questions relating to the implementation approach as well as the application of validated instruments, may be useful in future studies (eg, assessing presence via the Presence Questionnaire [47], usability via the System Usability Scale [46], and engagement via the User Engagement Scale [60]).

Conclusions

User acceptance among those who used TACTICS VR Stroke Telehealth training was very high and included suggestions for future implementation and expansion. The feedback provided has directly led to the subsequent scoping and development of a dedicated stroke nursing module (TACTICS VR Stroke Nursing), and additional modules are in development to support paramedic-led stroke assessment and transport decision-making in a prehospital phase (TACTICS VR Stroke Paramedic). The platform is deemed feasible for deployment within a real-world clinical setting, supported by high ratings on perceived usability and usefulness. Further research is now required to document the effects of TACTICS VR training on clinical practice and patient outcomes as well as to assess cost-effectiveness. Further research will also be useful to optimize training uptake and identify approaches to support the integration of training into existing education pathways.

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Authors' Contributions

SM, CG-E, KJ, KB, JWE, WOB, MGK, AR, CLP, NJS, CRL, and FRW conceptualized the study. SM, MGK, and FRW conducted the formal analysis. SM, MGK, and FRW were responsible for funding acquisition. SM, CG-E, KJ, KB, CD, SR, NW, MGK, AR, NJS, CRL, and FRW conducted the investigation. SM, CG-E, KJ, MGK, AR, CLP, NJS, CRL, and FRW were responsible for the methodology. SM, CD, SR, NW, and FRW were responsible for project administration. KB, JWE, and WOB were responsible for resources. KB, NJS, CRL, and FRW supervised the study. SM, MGK, and FRW wrote the original draft, and all authors reviewed and edited the manuscript.

Conflicts of Interest

All authors were involved in the development of the TACTICS VR Stroke Telehealth application. KJ, CD, SR, and NW are employed by the New South Wales Agency for Clinical Innovation and work to support implementation of the New South Wales Telestroke Service, but they were not involved in funding decisions for this study.

Multimedia Appendix 1
Supplementary tables (pretraining survey questions and responses as well as posttraining survey questions and responses).
[DOCX File , 46 KB - games_v11i1e43416_app1.docx]

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Abbreviations

ACI: Agency for Clinical Innovation
ATS: Centre for Advanced Training Systems
CT: computed tomography
HMD: head-mounted device
NSW: New South Wales
SME: subject matter expert
VR: virtual reality

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Original Paper

Co-Design of a Virtual Reality Multiplayer Adventure Game for Adolescents With Autism Spectrum Disorder: Mixed Methods Study

Silvia Gabrielli[1], MSc, PhD; Melanie Cristofolini[2,3], MSc; Marco Dianti[1,3], MSc; Gianpaolo Alvari[2], MSc, PhD; Ersilia Vallefuoco[2], MSc; Arianna Bentenuto[2,4], MSc, PhD; Paola Venuti[2], MSc, PhD; Oscar Mayora Ibarra[1], MSc, PhD; Elio Salvadori[3], MSc, PhD

[1]Digital Health Research, Fondazione Bruno Kessler, Trento, Italy

[2]ODFLab - Observational, Diagnosis and Education Lab, Department of Psychology and Cognitive Science, University of Trento, Trento, Italy

[3]Meeva Srl, Trento, Italy

[4]Cooperativa Socio Sanitaria Albero Blu, Trento, Italy

Corresponding Author:
Silvia Gabrielli, MSc, PhD
Digital Health Research
Fondazione Bruno Kessler
Via Sommarive 18
Trento, 38123
Italy
Phone: 39 0461 312 477
Email: sgabrielli@fbk.eu

Abstract

Background: Virtual reality (VR) adventure games can offer ideal technological solutions for training social skills in adolescents with autism spectrum disorder (ASD), leveraging their support for multisensory and multiplayer interactions over distance, which may lower barriers to training access and increase user motivation. However, the design of VR-based game environments for social skills training is still understudied and deserves the deployment of an inclusive design approach to ensure its acceptability by target users.

Objective: We aimed to present the inclusive design process that we had followed to develop the Zentastic VR adventure game to foster social skills training in adolescents with ASD and to investigate its feasibility as a training environment for adolescents.

Methods: The VR game supports multiplayer training sessions involving small groups of adolescents and their therapists, who act as facilitators. Adolescents with ASD and their therapists were involved in the design and in an explorative acceptability study of an initial prototype of the gaming environment, as well as in a later feasibility multisession evaluation of the VR game final release.

Results: The feasibility study demonstrated good acceptability of the VR game by adolescents and an enhancement of their social skills from baseline to posttraining.

Conclusions: The findings provide preliminary evidence of the benefits that VR-based games can bring to the training of adolescents with ASD and, potentially, other neurodevelopmental disorders.

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KEYWORDS

co-design; virtual reality environments; autism; social skills interventions; multiplayer game design; serious games

Introduction

Background

Impairments in social skills represent a central feature of autism spectrum disorder (ASD), a neurodevelopmental disorder affecting verbal and nonverbal social communication in children [1]. Approximately 44% of children with ASD have IQ scores in the average and above-average range [2]. However, they may experience difficulties in social skills such as an absence of social reciprocity, a poor display of eye contact and facial expressions, a lack of nonverbal behaviors and gestures, and difficulty in acquiring and maintaining peer relationships. Individuals with ASD commonly have difficulties with exhibiting the appropriate social skills across contexts [3] and facing social tasks required by complex situations in community life, school, and work [4].

Different methods and interventions have been designed to facilitate the acquisition of social skills in adolescents with ASD, including video-based instruction, in vivo instruction, high-tech augmentative and alternative communication, low-tech augmentative and alternative communication, behavioral skills training, social skills training [5], and play-based interventions in virtual environments.

Virtual reality (VR) is a computer-generated 3D simulation of imaginary or real-life environments that is explored and interacted with by real-time users. VR can take variant forms, ranging from desktop computer rendering of a highly interactive virtual world to a fully immersive multisensory environment in laboratories [6]. VR has some intrinsic appeal as a training tool for children with ASD, who tend to learn using visual support [7,8]. A VR-based learning environment allows participants to practice social skills in a nonthreatening, synthetic, but realistic, motivating, controllable, and diversifiable environment during learning [9]. There is evidence that VR technologies can, and do, represent authentic and plausible scenarios and social encounters, thereby reflecting and supporting real-world conventions, understandings, and behaviors for a range of different user groups [10-13]. Supporting multisensory interactions for multiple users over distance is another salient feature of VR that makes social skills training accessible in diverse formal and informal learning settings [14].

Despite its promise, the VR-based learning environment is still understudied and warrants further development and testing. Early efforts on studying VR-based learning for individuals with ASD proceeded from embedding multimedia direct instruction in a virtual world [15] to emphasizing multiplayer simulation and scenario-based social role-play [7,16,17]. In a recent pretest-posttest study with 30 children with ASD [17], researchers examined the effects of desktop VR–based social cognition training that involved children in social role-play with 2 to 3 peer- and clinician-controlled, confederate avatars in daily life social scenarios. The study showed participants' improvements in measures of emotion recognition, social attribution, and executive function of analogical reasoning. Another explorative study [18] provided preliminary evidence on the positive effect of desktop VR–based play- and design-oriented social skills training for children with ASD. The study also indicated some main challenges in designing and implementing a comprehensive social skill intervention for learners with ASD, such as the need for a longer duration of practice and learning sessions for novel or demanding social tasks. Previous work has also observed that gamified therapeutic interventions may run the risk of having a reduced appeal for children, especially when marginal relevance is given to game design, neglecting children's interests and their experience with video games available in the market [19]. According to recent studies, such risk is particularly relevant because children with ASD tend to spend nearly twice the amount of time playing video games than typically developing children do [20]. In a recent study, the authors proposed an inclusive design model to guide the development of effective and enjoyable therapeutic games, stressing the need to integrate knowledge from different perspectives, typically those of clinical experts, designers, and children [19].

Objective

The purpose of this study was to present how we applied an inclusive co-design approach [21,22] to develop a VR adventure game named Zentastic, fostering social skills acquisition in adolescents with ASD.

Methods

Overview

We describe our work in eliciting requirements from therapists and adolescents and merging their contributions in an early prototype of the multiplayer game; preliminary testing of the game with adolescents was performed to uncover their acceptance of the game, feedback, and preferences with respect to the game scenarios and mechanics proposed. We also describe how we incorporated the results of this preliminary explorative phase into the final release of the VR game and how we further evaluated the feasibility of our intervention with 12 adolescents and their therapists over a period of 3 weeks. Finally, in the Discussion section, we report the promising results achieved in the study, suggesting VR-based gaming interventions as viable and motivating solutions for training social skills in adolescents with ASD.

Co-Design of the Zentastic VR Gaming Intervention

This section describes the inclusive co-design approach [19,21] applied to develop the Zentastic VR gaming intervention by leveraging on the ideas and suggestions of the designers, the neurodevelopmental psychologists, and the children with ASD.

The Game Design Context

The Zentastic VR adventure game was designed in the context of the European Project XR4A (extended reality–enabled social skills therapy for adolescents with autism and neurodevelopmental disorders), which aimed at experimenting the application of VR gaming technologies as potentially engaging and motivating environments for training of social skills in adolescents with ASD. The game was developed through a close collaboration with ASD experts at ODFLab (Observational, Diagnosis, and Education Lab, University of Trento), a specialized center for children and adolescents with

ASD and neurodevelopmental disorders (Cooperativa Albero Blu) in Italy.

The motivation for developing a VR game to engage and train social skills in adolescents with ASD started with the assumption that VR technology can be conceptualized as a mediator of social interaction [19]. It can be an instrument for scaffolding and facilitating interpersonal relationships between adolescents, their therapists, and their peers in a training and therapeutic context [23]. To achieve this, it is important to design game experiences that are sufficiently engaging and valuable, so that the adolescents would feel motivated to initiate social interaction and communication in the playing setting, as well as to generalize the social skills acquired in everyday settings.

Eliciting Requirements From Experts

Requirements from psychologists and therapists at the local autism center, Cooperativa Albero Blu, were aimed at defining the structure of the VR game, the objectives, and the roles of players. To define these aspects, 4 meetings involving both designers and experts were arranged during the initial stage of the design process [19,21]. Each meeting lasted for almost 2 hours and involved between 2 and 4 experts from the local autism center. The first meeting focused on (1) introducing the 2 teams, interaction, VR game designers and ASD experts, (2) explaining the project objectives, (3) presenting state-of-the-art and key examples of VR game solutions for adolescents with ASD, and (4) sharing ideas and previous experiences of the teams in co-design methodologies [19,21,22] to be deployed in the VR game design.

The following meetings were arranged as brainstorming sessions aimed at establishing the conditions for cocreation through a merging of design ideas and clinical requirements. For this purpose, after each meeting, the designer team produced a document summarizing the main ideas that emerged and the decisions taken and sketching some initial proposals for the game structure to be discussed in the following meeting.

During the subsequent phases of the VR game design and prototyping, additional meetings were organized to evaluate our progress. The analysis of the requirements collected from the ASD experts and the study of their current use of game-based approaches in the training of adolescents with ASD allowed us to properly frame the scope of the VR gaming intervention as well as our target user group.

As the main goal of the project was to support social skills training in adolescents with ASD as an important enhancement in their daily activity and future lives, the target users specified by experts were adolescents aged 13 to 18 years with level 1 ASD severity, according to the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition [1]. Children with level 1 ASD are those with higher cognitive development who have more chances of having an autonomous life if adequately assisted through their childhood and adolescence [1]. Therefore, we concentrated our efforts on this target user group, which might be more suitable and motivated to engage with multiplayer VR games and train their social skills by interacting with peers and therapists. The inclusion criteria defined by our experts were (1) a minimum IQ level of 70, which refers to the ability to understand the environment and hence, understand the VR game challenges presented; and (2) a diagnosis of autism with an Autism Diagnostic Observation Schedule module 3 with a minimum severity level of 4 (ie, having a fluent verbal capacity).

The game intervention plan recommended by the experts was characterized by a progressive scaffolding and elicitation of social interaction in the VR game, which is aligned with current practices in traditional treatment. This plan ensured that adolescents first familiarized themselves with the play environment, were introduced to the colocated play goals and challenges by their therapist, and then they shared the play experience with their peers (in groups of 2-4 players per session) to meet the game objectives. The VR game should enable social skills training over multiple sessions; therefore, the experts also expressed the need for having the possibility of tuning the level of difficulty of the game challenges to better adapt them to the players' needs and familiarity with the VR game.

The initial game structure was derived from the experts' requirements, defined around the Zentastic adventure game story. In the game, players were asked to enroll on a space journey to the Zentastic planet. The game mission consisted of overcoming different challenges in the attempt to find and retrieve the precious Zennite material, which was needed by the scientists on Earth to repair the ozone layer and thus ensure the survival of Earth.

The players' interaction patterns recommended by experts were based on a cooperative and collaborative model for the game experience, leveraging synergies between different user abilities, shared goals, and complementarities of player actions [24].

The experts also defined a set of core behavioral skills required in the game to foster social interaction and social skills training in adolescents with ASD. The required social skills were (1) turn taking; (2) social interaction and cooperation; and (3) executive functions such as sustained attention, selective attention, and inhibition that strengthen social skills.

These requirements led to the design of a basic structure of game mechanics, as reported in Table 1, to be implemented in the first VR game prototype and tested with adolescents for subsequent refinement according to their preferences and feedback.

Table 1. Core behavioral skills and game mechanics that were defined by experts in the design phase.

Game session and objectives	Game mechanics
Introduction	
Sustained attention	The player has to pay attention to the instruction provided by the facilitator.
First mission (Coin Hunt)	
Selective attention and inhibition	The player has to discriminate between the target objects and nontarget objects and avoid picking up nontarget objects.
Cooperation	The player has to collaborate with other players to collect as many target objects as possible.
Second mission (Space Station)	
Social interaction	The player has to interact with an agent to obtain a target object.
Turn taking	The player has to respect his turn to obtain a target object.
Third mission (Planet Battle)	
Sustained attention and inhibition	The player has to discriminate between the target objects and nontarget objects.
Cooperation	The player has to collaborate with other players to obtain the target objects as fast as possible.

The Zentastic Multiplayer VR Adventure Game

The Zentastic adventure game is an immersive multiplayer VR game (developed in Unity and deployed on Meta Oculus technology) aimed at promoting social skills training in adolescents with ASD. The game is designed to be played by small groups of adolescents (2-4 players per session) in the presence of a therapist who acts as a facilitator in the virtual environment. The overall objective of the adventure game is to go through different missions of the Zentastic journey, facing and overcoming the challenges presented to achieve the final goal of collecting the Zennite material and taking it back to Earth to save the planet. At the start of the game session, players gathered in front of the fire in a common room, where they were introduced to the game plot and objectives. The players were then presented with the first mission called the Coin Hunt, where each player needed to collect a target number of coins (level of difficulty set by the facilitator) of a certain color hidden in a park to proceed with the following mission. The targeted behaviors related to social interaction trained by this mission are sustained attention, selective attention, and inhibition required to collect only the right coins during their hunt. In the Space Station mission, the players were asked to interact with a ticket-office agent (role played by the facilitator) to buy a ticket for the space shuttle that would take them to the Zentastic planet. Here, the targeted behavior trained is mainly turn taking, as the players would have to respect their turn while queuing to buy the ticket and initiate social interaction with the ticket agent to purchase the ticket. In the Planet Battle mission, the players had to climb a hill where the Zennite material was stored, and they were assigned colored laser guns to shoot colored stones falling down the hill that prevented them from reaching the Zennite. The targeted behaviors trained here are not only sustained attention, selective attention, and inhibition (to shoot the right stones) but also collaboration to reach the hill's top as fast as possible as a team. At the end of the game, the players gathered again in the common room for a debriefing, congratulating on the experience and closing the session.

Each mission in Zentastic was designed to address a targeted behavior related to social interaction, with increasing complexity levels. A description of each mission and complexity level, corresponding to the intervention plan previously described, is provided in Textbox 1.

Textbox 1. Brief description of the Zentastic game missions and their challenges.

First mission (Coin Hunt)

- In this mission, the player has to collect a target number of coins that are each assigned a color and hidden in a park. The target number is set by the facilitator (the level of difficulty can vary), and players have to achieve the target number of coins as a team. The team score increases or decreases according to each right or wrong coin collected. An additional bonus score is added if the players accomplish their individual targets within certain time thresholds. Players can help each other during the game to find the coins. As soon as the challenge is completed, multimedia effects appear, and a gold coin is assigned to each player as a reward in the gazebo.

Second mission (Space Station)

- Here, the players have to buy the ticket to get into the shuttle that will take them to the Zentastic planet. Players need to interact with a ticket agent (played by the facilitator) who may have different conversational attitudes (supportive vs unsupportive) toward the player (to vary the level of difficulty). When reaching the ticket counter room, each player has to respect their turn to talk with the ticket agent by waiting in a colored spot (previously assigned). A happy meter will increase every 3 s if players stay within their spot and decrease if they leave their spot and buzz around.

Third mission (Planet Battle)

- Here, players are on the Zentastic planet, climbing a hill to obtain the Zennite material. To reach the hill's top, each player has to shoot at the rocks of assigned color that are challenging their climbing. Shooting at the wrong rock means losing 1 life. When all lives are lost, the player has to restart climbing from the bottom of the slope. The facilitator can vary the level of difficulty either by assigning the number of lives available to each player or by varying the speed of the falling rocks. Once the players have completed the challenge, the Zennite pile explodes, and each player gets a piece of Zennite to bring back to Earth.

Uncovering Adolescents' Expectations and Preferences

An initial evaluation of an early prototype of the Zentastic VR adventure game was conducted with children and adolescents with ASD who visited the autism center to investigate the acceptability and level of engagement of the target users with the game intervention designed. This explorative phase of co-design [21,22] was focused on collecting adolescents' expectations and preferences regarding the game experience to feed this information into a refinement and finalization of our VR prototype. The methods used to collect the users' feedback are as follows:

- Field observations of the behaviors exhibited by the participants during the VR game sessions to identify possible usability issues
- Short, structured postsession interviews aimed at understanding the level of satisfaction with the game experience and suggestions for improvements (Multimedia Appendix 1)

Overall, 31 participants with ASD were involved in this explorative study. This is justified in the literature review of studies using innovative solutions for adolescents with ASD by the difficulty of obtaining large samples when the aim of the study is related to psychopathology [25,26]. Participants included 25 (81%) adolescent boys and 6 (19%) adolescent girls; their average age was 13.2 (SD 3.41) years, their average Autism Diagnostic Observation Schedule score was 6.3 (SD 1), and their mean IQ was 96.6 (SD 20). All 31 participants performed at least 1 session of the VR game; 27 (87%) participants performed 2 sessions; 19 (61%) participants were involved in 3 sessions; and 3 (10%) participants performed 4 sessions.

Most participants (25/31, 81%) had an overall positive experience with the VR gaming environment, as evidenced by the high average scores (scale 1-5: 1=not at all; 5=very much) in the level of engagement and enjoyment with the VR experience (Table 2).

Table 2. Participants' appreciation of the virtual reality (VR) gaming environment on a scale of 1 to 5 (1=not at all; 5=very much) in the explorative study.

Factor measured	Score, mean (SD)
Clarity of VR game	4.1 (0.8)
Engagement	4.1 (0.9)
Interaction with objects	4.3 (0.7)
Movement in VR	4.1 (0.9)
Object grasping	4.1 (0.9)
Interaction with the environment	4.2 (0.8)
Focus on activity	3.8 (0.9)
Enjoyment	4.5 (0.9)
Willingness to play again	4.6 (0.9)

Regarding the interaction with the VR hardware required for playing, some difficulties were observed, especially with the use of the controllers, and a few participants (4/31, 13%) experienced nausea after prolonged activity in VR (Table 3).

Regarding the emotional feelings of the participants after interacting with the VR gaming environment, 81% (25/31) of the participants reported feeling happy or relaxed, and 19% (6/31) reported feeling frustrated or confused.

From the postsession interviews with participants, some suggestions for improving the VR gaming experience were collected, which are as follows:

- Improving movement in VR: some participants pointed out that moving in the VR game was somehow too slow, while they preferred the teleporting functions.
- Making the VR scenarios more coherent with the story: some participants asked for improvement in the coherence of the 3 VR missions' environments with the space adventure game plot by introducing relevant objects and characters in each of the game missions.
- Improving engagement and game dynamics in the VR game: most participants wanted to be provided with more engaging challenges in the game missions by including more interactive objects and characters, brighter colors, relevant music and sounds, and clear feedback to support progress toward the achievement of the game objectives.

Following stakeholders' indications (including both the facilitators and the adolescents involved in the explorative study), improvements were implemented in the final release of the Zentastic game; for example, the 3 game missions were enriched by improving their interactive quality and overall coherence to the space challenge. We also designed and integrated a clearer scoring system within the game missions to provide feedback to participants during the game and facilitate an easier functional assessment of the players' performance and targeted behavior by therapists during and after the game session.

We added specific controls for the facilitator in the VR game, allowing for a smoother personalization of the playing experience according to the level of complexity and ensuring the engagement of participants over multiple sessions in the VR game.

However, as the user sample used for this explorative study only partially fits the age of the target user group and the evaluation was based on an early prototype of the game, it was necessary to carry out an additional study with adolescents with ASD (aged 13-18 years) to evaluate the suitability of the experience. Nonetheless, such evaluation allowed us to ensure that our design was sufficiently usable and engaging for adolescents to support a multisession gaming intervention. This aspect is particularly relevant when designing for adolescents with ASD as VR game experiences not fitting their expectations and preferences may drastically reduce their motivation to engage with such experiences, as well as impair the overall effectiveness of such training interventions.

Table 3. Participants' difficulties experienced with the virtual reality gaming environment on a scale of 1 to 5 (1=not at all; 5=very much) in the explorative study.

Factor measured	Score, mean (SD)
Difficulty with Oculus headset	2.3 (1.2)
Difficulties with controllers	2.5 (1.4)
Nausea	1.7 (1.1)

Mixed Methods Study: Participants and Method

This section presents the study conducted to evaluate the feasibility of our VR game for training social skills in adolescents with ASD and the main results achieved.

We conducted an observational study on the interaction of 12 boys with ASD [20] (mean age 13.9, SD 3.1 years) with the final version of the Zentastic VR game. All participants could use the computer and internet and had prior experience of playing digital games (see Textbox 2 for inclusion criteria). The goals of the study were to evaluate the acceptance and enjoyment of the game [19,21] and to investigate whether it facilitated the targeted behaviors contributing to enhancing adolescents' social skills.

The study was carried out at the Cooperativa Albero Blu Center premises for >1 month.

Textbox 2. Inclusion criteria to select participants.

The participants must

- be aged between 13 and 18 years
- be diagnosed as having autism spectrum disorder (ASD; without intellectual impairment) using standard instruments from the Diagnostic and Statistical Manual of Mental Disorders-5 criteria, with Autism Diagnostic Observation Schedule module 3 having a severity level of at least 4 (within the ASD range spectrum)
- have a cognitive capacity of >70 as measured by the standard Wechsler Intelligence Scale for Children (fourth edition) [27]
- sign the consent form to participate in the study (applies to both the parent or tutor and the adolescent)

The participants played the VR game in groups of 2 to 4 players per session, assisted by the facilitator. Each adolescent participated in 3 sessions, scheduled weekly.

Each session lasted for 45 minutes, during which adolescents were first introduced to the game by the facilitator. Before the study launch, the researchers provided the facilitators with a dedicated training session on the use of the VR game controls and a prescripted document of guidelines to follow during the game sessions to ensure a consistent deployment of the game intervention among the different facilitators involved.

The methods used to assess the feasibility of the VR game were as follows:

- Participants' score on the Social Skills Questionnaire (SSQ [28]), Teacher form, filled out by their therapist before and after the intervention in VR
- Postsession observations on the targeted behaviors exhibited by adolescents during the VR game to assess the effect of the game on training social skills
- An ad hoc user experience questionnaire and semistructured interview administered to participants after each session to collect feedback on their satisfaction with the VR game and suggestions for improvements (Multimedia Appendix 1).

Each session involved the presence of an expert observer positioned in front of the users, whose task was to record the behaviors exhibited by the participants during the VR activity. At the end of each session, the observer and therapist would jointly fill out a specially prepared observation form, recording the observed behaviors.

In addition, each session was video recorded, which allowed for the review of the sessions and further coding of the participants' behavior.

Ethics Approval

The study was approved by the research ethics committee of Azienda Provinciale Servizi Sanitari, Trento on March 15, 2023 (report 4959).

Results

Social Skills Questionnaire

A comparative analysis of the pre- and postintervention SSQ responses (Teacher form) for matched participants was performed using the Wilcoxon signed rank test. This test was used to examine the statistical significance of the improvement in social and communication competence of the participants based on the aggregated data of the 12 participants. Wilcoxon signed rank tests determined that there was a statistically significant median increase (W=1, P=.008; critical value of W=1 at n=8) between pre- and postintervention scores, indicating that the participants showed significantly higher frequencies of positive social interaction and communication competence after the intervention.

Postsession Observations

Postsession observations by the therapist were mainly oriented toward understanding the behaviors exhibited by the participants during the VR game sessions to identify possible usability issues. Different behaviors were considered to gather information about the user experience with the VR game, including (1) qualitative measures of participants' adaptation and engagement with the game, (2) a systematic evaluation of participants' interactions and communication, and (3) an assessment of participants' emotional states during the activities.

Overall, all the participants displayed a natural curiosity and interest in the experience, which further grew over time. This observation was supported by various qualitative indicators, including positive and enthusiastic expressions (both verbal and nonverbal) during the tasks as well as during active engagement.

During the game sessions, most participants actively shared their improvements, difficulties, impressions, and questions with other players and, particularly, with their facilitators. The collaborative interactions among the participants increased as the game missions progressed (Figure 1; Table 4).

We observed a growth in self-confidence among the participants throughout the game missions, as suggested by a gradual increase in the level of engagement with the activities as well as a decrease in adaptive distress in VR scenarios and visuospatial difficulties when interacting with the virtual surroundings (Figure 1; Table 4). Initially, they primarily focused on following the game missions and did not fully explore the virtual environment. However, gradually, they started venturing into the game scenario, comprehending its dynamics and, most importantly, feeling increasingly capable and secure.

The first mission (Coin Hunt) emphasized collaboration and communication among the participants, whereas the third mission (Planet Battle) actively engaged the participants to a greater extent than other missions. It is possible that these results were influenced by the game dynamics. Coin Hunt offered a lesser challenging and emotionally impactful setting than other missions. Thus, this environment might have facilitated increased social interactions among participants as they worked together to complete the task. By contrast, according to participant reports, Planet Battle was the most enjoyable game mission, which increased participants' motivation and engagement.

Overall, the participants successfully completed all game sessions, consistently achieving high scores. Notably, their game scores showed a clear upward trend across the sessions, even if the difficulty level was progressively increased by the facilitators.

Figure 1. Participants' behavioral assessment (first part) during the virtual reality (VR) gaming missions, expressed on a scale of 1 to 5 (1=low; 5=high).

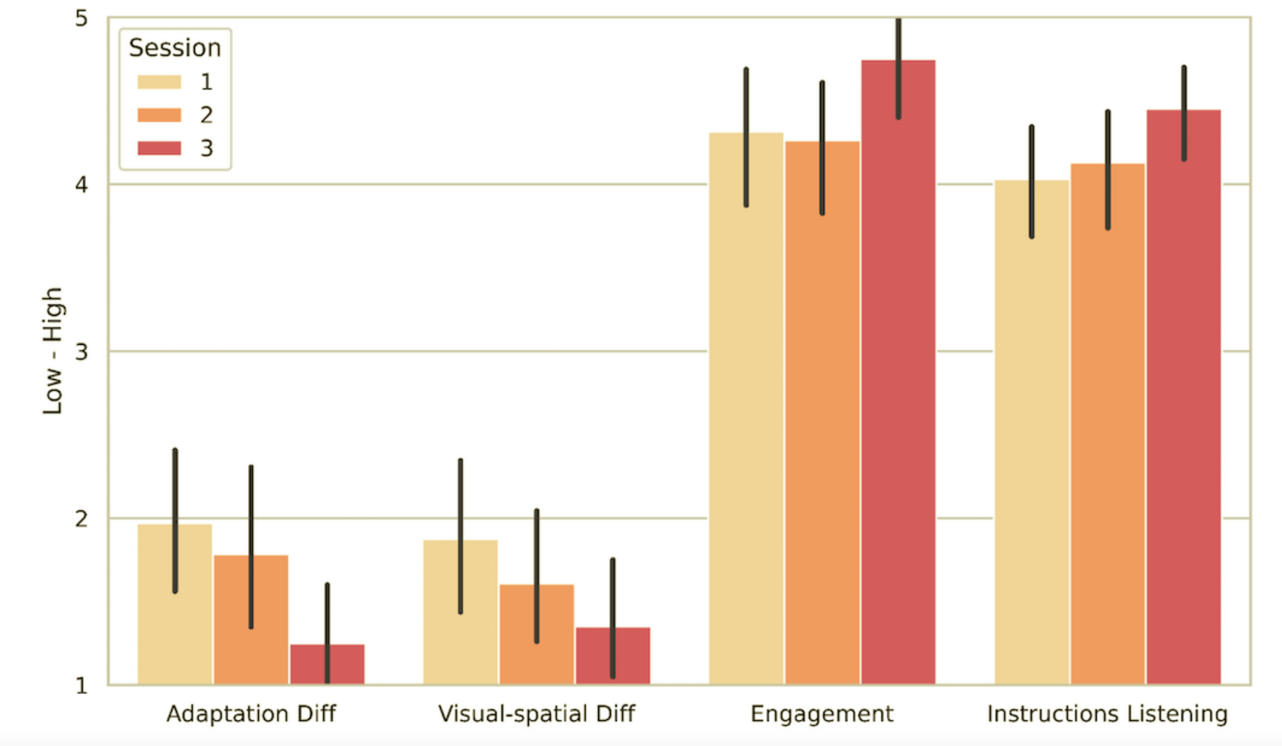

Table 4. Participants' behavioral assessment (first part) during the virtual reality (VR) gaming missions, expressed on a scale of 1 to 5 (1=low; 5=high).

Feature	First mission, mean score (SD)	Second mission, mean score (SD)	Third mission, mean score (SD)
Difficulties in adapting to VR	2.0 (1.3)	1.7 (1.2)	1.3 (0.7)
Visuo-motor difficulties	1.9 (1.3)	1.6 (1.0)	1.4 (0.8)
Listening to instructions	4.0 (1.0)	4.1 (0.9)	4.5 (0.6)
Engagement with the game	4.3 (1.2)	4.3 (1.0)	4.8 (0.7)

In addition, to obtain a more systematic measurement of the social patterns displayed during the VR activities, we quantified the number of social exchanges. The group social behaviors considered were social initiations and social responses to peers. Moreover, we differentiated between spontaneous social exchanges and prompted social exchanges. Spontaneous social exchanges included initiations and responses manifested spontaneously by the participant toward peers. By contrast, prompted exchanges included initiations or responses that were not spontaneously manifested by the participant but were solicited by the therapist through verbal cues. This differentiation allowed us to distinguish social exchanges based on spontaneity and to analyze any differences between activities. Furthermore, we noted the number of times each participant requested a break during the game. We quantitatively compared the distributions of these parameters among the 3 game missions using the Kruskal-Wallis test. Our results indicated a significant difference in both spontaneous (H_2=49.6, *P*<.001) and prompted (H_2=14.8, *P*<.001) social initiations and spontaneous (H_2=43.3, *P*<.001) and prompted (H_2=11.6, *P*=.003) social responses, with the first mission exhibiting higher scores than the subsequent ones. In addition, the number of requested breaks was significantly higher in the first mission, confirming that Coin Hunt is the most socially promoting activity. The collaborative and communicative nature of the gameplay is reflected in the higher number of social initiations and responses observed during this mission. Moreover, a higher need for breaks during this game mission by users corroborates this analysis, highlighting the critical role of appropriate social interaction modes for individuals with ASD. To gain a broader perspective on the nature of these results, we compared the ratio between spontaneous and prompted social exchanges. Our analysis of the distribution of spontaneous and prompted initiations and responses using the Mann-Whitney test revealed that the participants showed a significantly greater number of spontaneous social openings (mean 12.9, SD 11.4) than prompted social openings (mean 0.7, SD 1.2; *U*=76.0, *P*<.001) and a higher number of spontaneous social responses (mean 11.8, SD 0.6) than prompted social responses (mean 0.3, SD 0.6) to peers (*U*=74.5, *P*<.001), emphasizing the effectiveness of the game missions in promoting spontaneous group interactions.

To obtain a more systematic measurement regarding the participants' emotional state, we classified the gaming sessions by qualitatively indicating the nature of the activation state during the VR experience. The emotional state was encoded in agreement with 3 independent evaluators using 2 distinct parameters. The first parameter coded the level of activation and was characterized as calm, agitated, or dysregulated. The second parameter referred to the level of participation in the activity and was classified as active or passive. The results indicated that 75% (9/12) of the players approached the activity calmly, while only 25% (3/12) manifested episodes of agitation, and none of the participants became dysregulated during the activities. Moreover, >86% (10/12) of the players participated actively in the scenarios, whereas only 14% (2/12) showed a passive attitude. Overall, the participants maintained a positive attitude during the game sessions, demonstrating collaboration and maintaining a high level of attention and activity. Moreover, the analysis showed a low level of frustration experienced by most participants. We observed 9 episodes of frustration during the first mission (mean 1.6, SD 0.5), 2 episodes during the second mission (mean 1.5, SD 0.5), and 1 episode during the last mission. The observed results could indeed be attributed to increased participant familiarity and adaptation throughout the different missions, both in terms of knowledge of the VR game and the ability to use the controllers. As participants progressed through the game missions, they likely became more comfortable with the VR environment and developed better skills in using the controllers. This increased familiarity and skill level may have contributed to the decrease in frustration episodes during subsequent missions. These results confirmed that the VR game provides a controlled and safe environment that supports skills training.

Results of the Interviews With the Participants

The interviews with participants at the end of the VR gaming experience were mainly oriented toward evaluating whether the VR gaming experience met the participants' expectations and identifying possible usability issues. Different questions were used to gather information about user experience with the VR game. The results from the rating on a Likert scale (1=not at all; 5=very much) showed an overall appreciation of the VR game user experience by all participants (12/12, 100%), who found the VR game easy to use, clear, and engaging (Table 5), with no participants reporting interaction issues or discomfort with the VR game (Table 6).

To further confirm this positive experience of participants with the VR game, we asked them to express their willingness to play again with it after the end of the intervention (Table 4). All the participants (12/12, 100%) were willing to play again, and 92% (11/12) of them reported experiencing positive feelings, such as happiness and relaxation, during the VR gaming session and at the end of the intervention.

Table 5. Participants' appreciation of the virtual reality (VR) gaming environment on a scale of 1 to 5 (1=not at all; 5=very much) in the feasibility study.

Factor measured	Score, mean (SD)
Clarity of VR game	4.5 (0.5)
Engagement	4.8 (0.3)
Interaction with objects	4.3 (1.1)
Movement in VR	4.9 (0.2)
Object grasping	4.6 (0.4)
Interaction with the environment	4.7 (0.4)
Focus on activity	4.8 (0.3)
Enjoyment	4.7 (0.4)
Willingness to play again	4.8 (0.3)

Table 6. Participants' difficulties experienced with the virtual reality gaming environment on a scale of 1 to 5 (1=not at all; 5=very much) in the feasibility study.

Factor measured	Score, mean (SD)
Difficulty with Oculus headset	1.1 (1.5)
Difficulties with controllers	1.3 (0.6)
Nausea	1.0 (0.2)

Discussion

Principal Findings

The feasibility study with 12 adolescents with ASD showed a good level of acceptance of the VR game intervention, and several targeted behaviors related to social interaction were observed. Although the findings of this study have an exploratory nature, they can help guide the future design of VR game interventions that foster social skills training in adolescents with ASD. In particular, as shown in previous work [19] the design of a cooperative model for the game mechanics helped to sustain the motivation and engagement of players over the VR gaming sessions and to promote the triggering of social behaviors. This finding is also aligned with the recent studies highlighting the social motivation explanation of ASD [29], such as the importance of learners' motivation or agency in social engagement and interaction performance. An implication is that VR-based training activities differ in their social affordance and should be selected and designed in alignment with the learner and learning needs to promote a comprehensive set of social skills [16]. In accordance with previous studies [30-32], the findings from our observations during the game sessions highlight the significance of maintaining a balance between serious content and game elements in serious games designed for individuals with ASD. Moreover, our positive findings in terms of participants' success in completing the game missions and achieving their objectives suggest a potential alignment between the participants' skill levels and the challenges presented in the game; this indicates a promising match between their abilities and the game's demands [33]. Overall, we can confirm that the deployment of an inclusive co-design method during the Zentastic game development facilitated a successful merging of therapists' knowledge and expertise with adolescents' requirements and preferences for VR gameplay, ensuring their motivation to engage with the game over multiple sessions to train their social skills in a positive and safe VR environment.

Limitations

This study contributes new knowledge to the inclusive co-design of VR gaming solutions for the training of adolescents with special needs; this domain of design and research is still understudied, often omitting to include the views of the key stakeholders involved in the adoption of such solutions. However, some limitations are still present.

First, the sample of participants involved in the iterative design process was rather limited, which implies that the results of our feasibility study should be interpreted with caution. Future applied research to study the effectiveness of VR gaming environments for training social skills should involve a larger sample of target users and control groups with a systematic research design. In addition, the number of female participants involved was very small, and this might have affected our design, which better represented the preferences and interests of male adolescents.

Another limitation of the feasibility study conducted is the lack of control for history effects that might be coincidental with the intervention deployment, so we cannot derive final conclusions in terms of social skills training outcomes determined by our VR game intervention. However, our results can inform future research that is needed to further assess the transferability of the social skills trained in the VR game to everyday settings, as well as the long-term deployment of the VR game intervention in natural, formal, and informal learning environments, including, for example, remote access to the VR game from home. Another interesting question to be addressed by our own and future design-based research is regarding the effect of different design and implementation features of VR game interventions for training social skills of adolescents with ASD, so that we can support their long-term training in VR with a more diversified range of missions targeting additional behavioral skills.

Conclusions

Overall, the results of our feasibility study showed that playing the Zentastic multiplayer VR game had a positive effect on supporting the enhancement of social skills and competence in adolescents with ASD, as evidenced by the results of the SSQ scores before and after intervention. Data collected from the postsession observations by therapists and from the interviews with participants further confirmed the value of the VR game in terms of user engagement, safety, and well-being during the training activities in VR; this would encourage the future application of VR gaming solutions for the training of adolescents with ASD and, potentially, other neurodevelopmental disorders. Even if further research is necessary to validate these results, these initial findings could be considered as promising indications of the usefulness of adopting an inclusive co-design approach when developing VR gaming solutions for the training of skills in this target population.

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Authors' Contributions

SG, MC, and ES designed the study; ES and OMI acquired funding; MC and MD supervised the study recruitment and game implementation; and SG and ES coordinated the research activities. EV, GA, AB, and PV provided intellectual input to the game and study design. SG and AB led ethics approval. MC and EV led the study recruitment and data management. SG, MC, GA, and EV performed data analyses. SG drafted the manuscript and incorporated feedback from coauthors. All coauthors revised and approved the submitted manuscript.

Conflicts of Interest

ES, MC, and MD are cofounders of Meeva Srl. All other authors declare no conflicts of interest related to this study.

Multimedia Appendix 1
Zentastic virtual reality game interview.

[PDF File (Adobe PDF File), 22 KB - games_v11i1e51719_app1.pdf]

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Abbreviations

ASD: autism spectrum disorder
SSQ: Social Skills Questionnaire
VR: virtual reality

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Effectiveness of a Game-Based Mobile App for Educating Intensive Critical Care Specialist Nurses in Extracorporeal Membrane Oxygenation Pipeline Preflushing: Quasi-Experimental Trial

Zihan Wang[1,*], MSN; Ruting Gu[2,*], MSN; Jingyuan Wang[2], MSN; Yubiao Gai[2], MSN; Hui Lin[2], MSN; Yan Zhang[2], MSN; Qianqian Li[2], MSN; Tong Sun[3], MSN; Lili Wei[2], DScN

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*these authors contributed equally

Corresponding Author:
Lili Wei, DScN

Abstract

Background: In the context of training specialist nurses and nursing education, a game-based mobile app was used as a simulation to teach intensive critical care specialist nurses the knowledge and skills of extracorporeal membrane oxygenation (ECMO) pipeline preflushing.

Objective: This study aimed to evaluate the impact of a game-based mobile app on improving ECMO pipeline preflushing skills in intensive critical care specialist nurses.

Methods: A total of 86 intensive critical care specialist nurses who were learning ECMO for the first time were included in this study. The nurses were divided into 2 groups: a control group (n=43) and an experimental group (n=43). Participants in the experimental group used a game-based mobile app for simulation exercises; the control group received no additional intervention. All participants took a theoretical test and a skill operation test at the beginning of the study and 1 week later. The differences in scores between the 2 groups were compared, and the learning curve of the experimental group was observed.

Results: The final theoretical test scores (88.44 and 85.02) and skill operation test scores (89.42 and 86.33) of the experimental group and control group, respectively, were significantly higher than those of the initial tests (theoretical test scores: 75.88 and 74.42; skill operation test scores: 75.44 and 75.93; all $P<.001$). The scores of the final theoretical test (88.44) and the final skill operation test (89.42) in the experimental group were higher than the scores of the control group (85.02; $P<.001$ and 86.33; $P<.001$, respectively). Learning curve analysis showed that the experimental group needed an average of 17 operations to master the skill.

Conclusions: This study suggests that a game-based mobile app may be more effective for intensive critical care specialist nurses in ECMO pipeline preflushing education than traditional Chinese lecture-practice education.

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KEYWORDS

extracorporeal membrane oxygenation; mobile app; simulation training; specialist nurses; learning curve; ECMO; intensive care

Introduction

Extracorporeal membrane oxygenation (ECMO) is a treatment that uses an improved extracorporeal circulation system to provide temporary life support for patients with potentially reversible heart or respiratory failure [1]. ECMO achieves the purpose of lung or heart recovery from disease by providing a mechanism for gas exchange and heart support. With the continuous development of ECMO-related technologies, it has become a recognized treatment method for neonates, children, and adults who do not respond to conventional medications for respiratory failure and heart failure. According to statistics, among 1099 patients with COVID-19 in China diagnosed between December 2019 and January 29, 2020, a total of 55 patients entered the intensive care unit for treatment, 67 patients underwent invasive mechanical ventilation, and 5 patients received ECMO treatment [2]. During the new coronary pneumonia epidemic, the application of ECMO played an important role during the treatment of patients who are critically ill. Despite major advancements in technology, ECMO is still associated with high morbidity and mortality [3,4], with nosocomial infections being the leading causes, including ventilator-associated pneumonia (57.6%), tracheobronchitis (9.1%), bloodstream infections (9.1%), skin and soft tissue infections (9.1%), and cytomegalovirus reactivation (9.1%) [5]. Although the occurrence of these complications is not necessarily directly related to improper pipeline preflushing, if medical staff do not follow the correct sequence of steps and do not observe the principle of sterility, it may lead to an increased risk of complications. Therefore, it is necessary to train intensive critical care specialist nurses on ECMO.

In recent years, to compensate for the shortcomings of traditional education models, such as classroom teaching and group exercises, and to improve teaching quality, education in the field of medicine and health has continuously sought more innovative models and methods. More and more educators are applying game teaching to medical field teaching. For example, Tan et al [6] applied games to blood transfusion teaching and found that they had a positive effect in improving nursing students' knowledge and confidence in blood transfusion practice. Researchers used video games to simulate nursing and medical students' first visit to the operating room in hopes of improving perception and performance and reducing stress [7]. In addition, a serious game was used to supplement the teaching of cardiopulmonary resuscitation (CPR) [8]. This game could simulate emergencies in a 3D virtual environment. Participants must apply CPR to rescue an injured patient. The use of this game improved students' CPR knowledge and skills [8]. At present, there are few innovative education studies on ECMO and its pipeline preflushing; they mainly consist of the combination of education using high-fidelity simulation and augmented reality (AR) technology. Researchers have carried out high-fidelity simulation education and training courses for intensive critical care specialist nurses, improving their personal skills and the skill level of the whole team [1,9]. There was also great potential for improving the effect of ECMO intubation training based on AR instructions [10]. However, due to the high cost of training using the abovementioned teaching methods or techniques, and limited by the training venue and practice time, students usually do not have enough time to practice and cannot check the learning practice results in a timely manner.

The traditional ECMO training method mainly consists of students or nurses passively accepting theoretical explanations and technical operation demonstrations. The training method is simple and lacks innovation, and the training process does not evoke enthusiasm and participation from the trainees. In addition, the traditional ECMO training method, including high-fidelity simulation and AR technology education, limits the time and place for nurses to perform operational exercises [1,9]. To our knowledge, there have been no studies on the use of games in ECMO education or ECMO pipeline preflushing teaching. Therefore, this study integrated games into traditional clinical teaching methods and developed a game-based mobile app of ECMO pipeline preflushing, which enables intensive critical care specialist nurses to master the relevant technologies; at the same time, the app can become a tool for nurses to learn relevant knowledge and test learning results anytime and anywhere. We explored whether a game-based mobile app affected the practical knowledge and skill levels of intensive critical care specialist nurses. At the same time, combined with the learning curve, we analyzed the minimum number of operations intensive critical care specialist nurses needed to master this operation, to provide a reference for formulating more standardized training and guiding ECMO education in the future.

Methods

Participants

The study population included 86 nurses who were undergoing targeted training as intensive critical care specialist nurses at a university-affiliated hospital in China.

The inclusion criteria for this study consisted of the following:

- Having a mobile phone or computer
- Having internet access
- Having obtained the intensive critical care specialist nurse certificate but no previous experience in ECMO

The exclusion criteria for this study consisted of the following:

- Having participated in at least 1 theoretical lecture, demonstration, or group study on ECMO
- Have not undertaken the first or final theoretical and skill performance assessments of ECMO pipeline preflushing

Based on the experimental results, the researchers determined that the required number of nurses was at least 68 intensive critical care specialist nurses (34 in the experimental group and 34 in the control group). A total of 86 participants (43 in the experimental group and 43 in the control group) were included in the study due to an expected loss of 10% to 20% of the sample during follow-up.

We used convenience sampling methods to select intensive critical care specialist nurses from 2 districts (the eastern district and the western district) of a university-affiliated hospital in China as the research participants. Among them, those from the western district were used as the experimental group, and those from the eastern district were used as the control group. We registered the participants' details and kept the group information confidential. Before completing the training and evaluation, the trainers and participants were not informed of the group allocation.

Ethical Considerations

This study was approved by the Medical Ethics Committee of the Affiliated Hospital of Qingdao University, where the researchers are located. In this project, the rights and interests of the participants were fully protected, and the research protocol was approved in accordance with the requirements of the Medical Ethics Committee (approval number: QYFYWZLL26706). In this study, all participants provided informed consent, and participants reserved the right to withdraw at any time. During data collection and analysis, the data were anonymized, and only a number was used to match the results of each test. No other form of compensation was provided to the participants in this study.

Procedures

The study was conducted from March 8, 2021, to March 18, 2021. To prevent interaction between the 2 groups, intensive critical care specialist nurses from 2 different districts of the same general hospital were selected for the study. The 2 districts are located on opposite sides of Jiaozhou Bay, 40 km apart. The same management team was responsible for the management and training of the 2 groups.

On March 8, 2021, all intensive critical care specialist nurses conducted a 1-day theoretical training in the Shinan district of this general hospital. The training content referred to the *ECMO Manual* (2nd edition; Chinese version) [11] and *ELSO Guidelines for Training and Continuing Education of ECMO Specialists* [12], including the principles and indications of ECMO, contraindications, equipment and consumables, pipeline preflushing, etc. Subsequently, all intensive critical care specialist nurses underwent 2 days of skill training and practice. The skill training corresponded to the content of theoretical training. After the 3 days of on-site intensive training, the first theoretical and skill tests were immediately carried out. The intensive critical care specialist nurses who participated in the tests were not known to the examiners; they knew only that all participants had received training on ECMO.

Next, we downloaded the game-based ECMO pipeline preflushing mobile app onto the mobile phones of the intensive critical care specialist nurses of the experimental group, explained that they could play the game anytime and anywhere in the next 7 days, and asked them to use and complete the program more than 30 times. Within 7 days after the first evaluation, the control group received no additional intervention measures. Seven days after the intervention measures were implemented, the 2 groups of participants were again assessed on theoretical knowledge and skills.

Preparation of the Game-Based Mobile App

The game-based mobile app was designed and developed by a team of authors, including 6 nursing administrators with more than 10 years of clinical teaching experience, 10 clinical teachers, 1 software engineer, 1 technical support staff, 1 artist, and 1 graduate nurse. The software research and development team made reference to previous literature—based on the training of applied skills in nursing and combined with clinical teaching experience, gamification teaching theory, and the use of virtual clinical resources as the carrier—and simulated a clinical operation with high adaptability [13]. The researchers designed an “ECMO Pipe Preflushing Skill List” based on the *ECMO Manual* (2nd Edition; Chinese version) [11] and used it to create a game scene including pictures and animations. The researchers used the C++ programming language, which can be used to write a working system language or application programming languages [14], and the Cocos2D game engine to develop the game-based mobile phone app [15]. During software development, the team was responsible for overall coordination, supervision, management, and quality control, and they recorded, summarized, and organized the data for the entire process. This app was reviewed by professionals with a medical background. Since the software works with any Android operating system, the app can be played anywhere without an internet connection. Nurses start the game by registering with their phone number, but at first, they need to be connected to the internet to download the game.

According to the sequence of operations, the game was divided into 7 stages with a total of 61 steps:

- Stage 1: Preparing items and materials according to the detailed list (13 steps)
- Stage 2: Checking supplies (5 steps)
- Stage 3: Connecting and installing pipelines (12 steps)
- Stage 4: Using gravity to preflush the front membrane pipeline (4 steps)
- Stage 5: Using the machine to exhaust the gas after the membrane (17 steps)
- Stage 6: Stopping the pump, clamping the pipeline, and removing the pipeline (7 steps)
- Stage 7: Connecting the air-water cycle (3 steps)

The steps for users to use the game-based mobile app are as follows. The user logs in using the registered mobile number and password; the log-in screen is shown in Figure 1. After entering the game interface, the user first needs to select the “steps” box at the bottom left of the game interface. At each step, the user need to place the cards at the bottom right of the game screen into the green boxes at the top right of the screen in the correct order. An example of the game-based mobile app is shown in Figure 2. If the user places a card in the correct position, the card remains in the box, and when the positions of all the cards and green boxes are correctly aligned, then the next step can be entered. If the card is placed in the wrong position, it will bounce back to its original position, and the flower in the lower left corner will drop a petal. The flower has 9 petals; when all the petals have dropped, the game results in failure, and the “game failure” interface is shown (Figure 3). If the user completes all the steps before all the petals fall off, the game is successful, and the “game success” interface is shown (Figure 4).

Figure 1. User log-in screen. ECMO: extracorporeal membrane oxygenation.

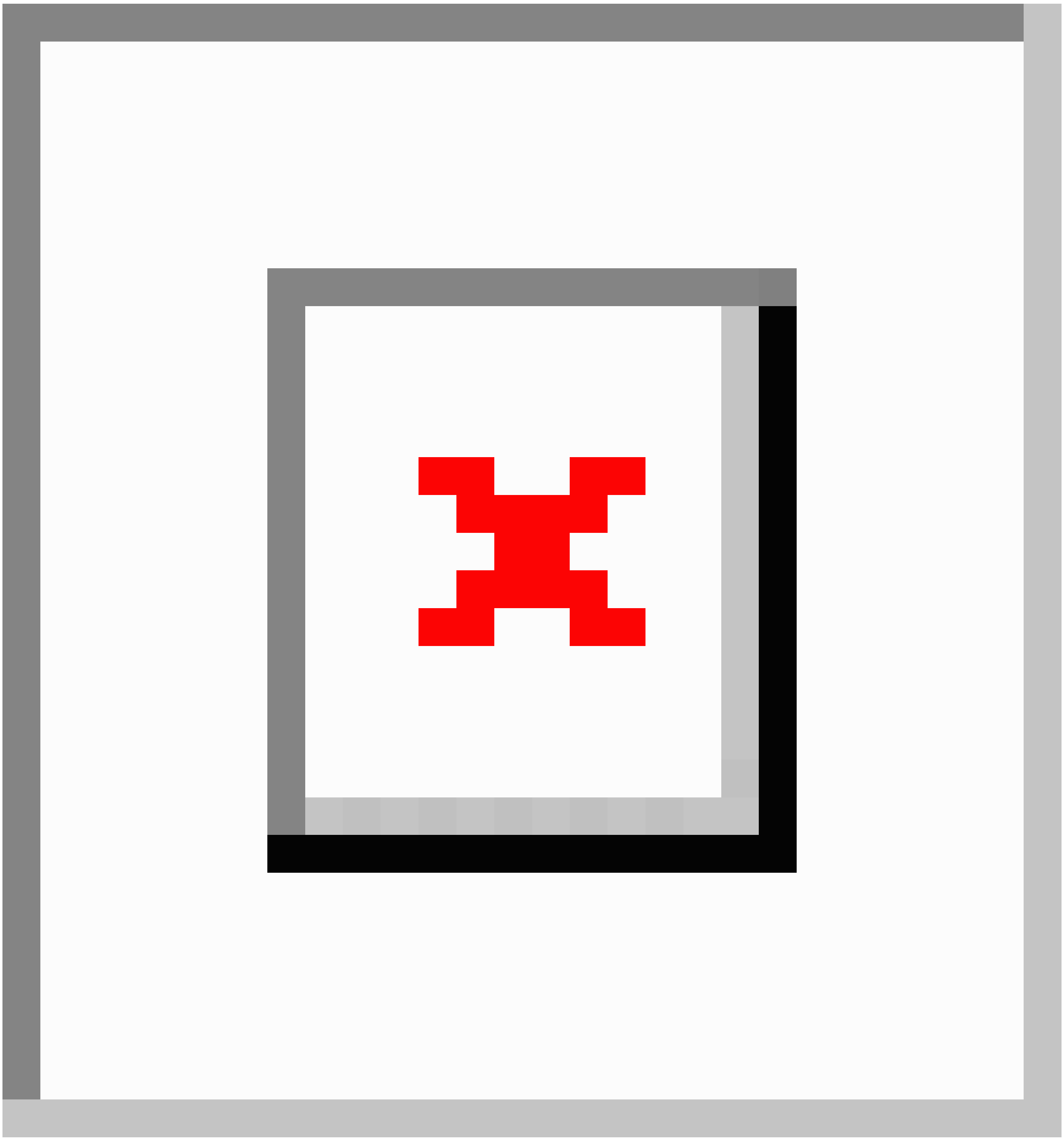


Figure 2. An example of the game-based mobile app. ECMO: extracorporeal membrane oxygenation.

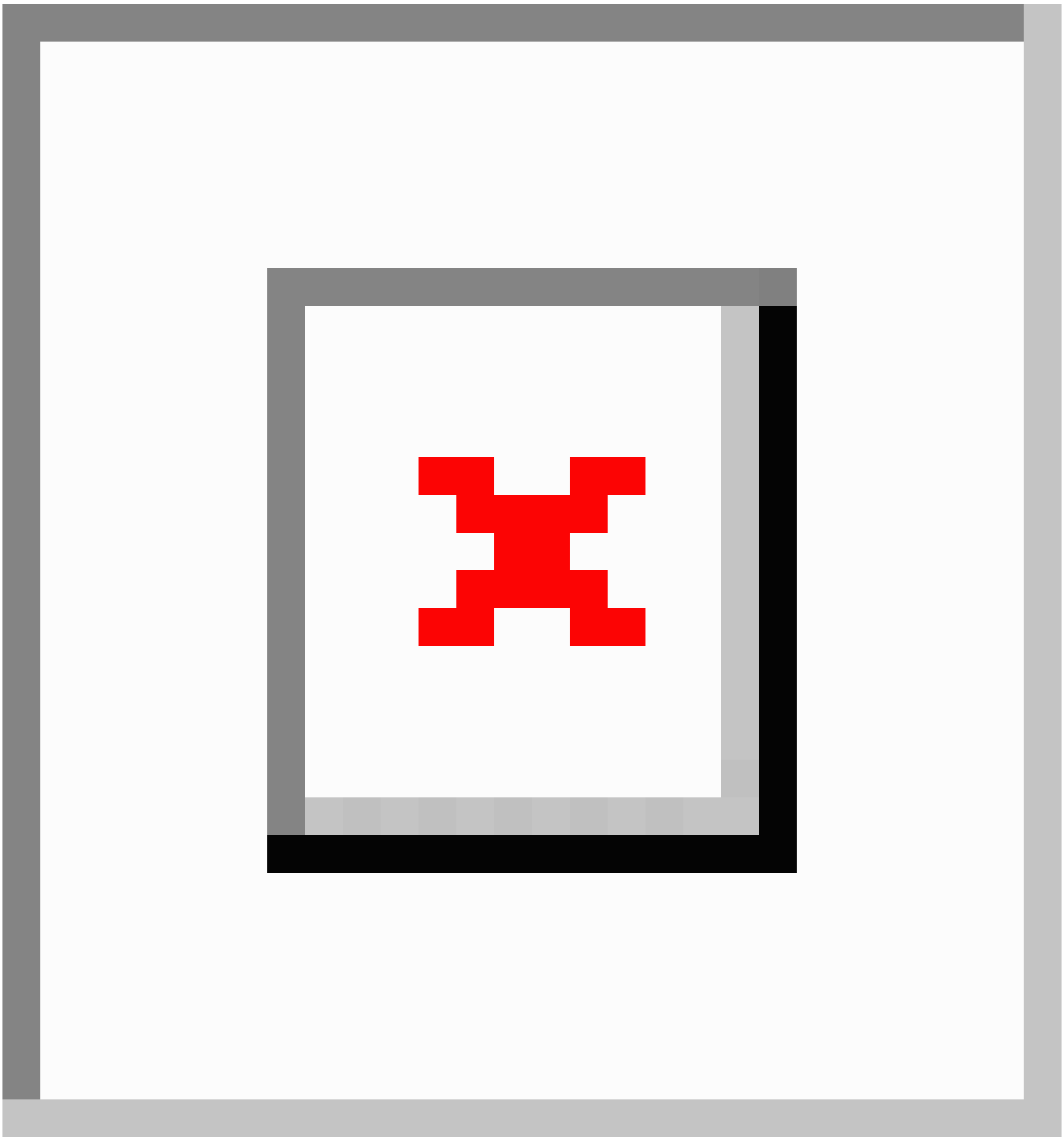


Figure 3. Screenshot of the interface at the end of the game when the user fails.

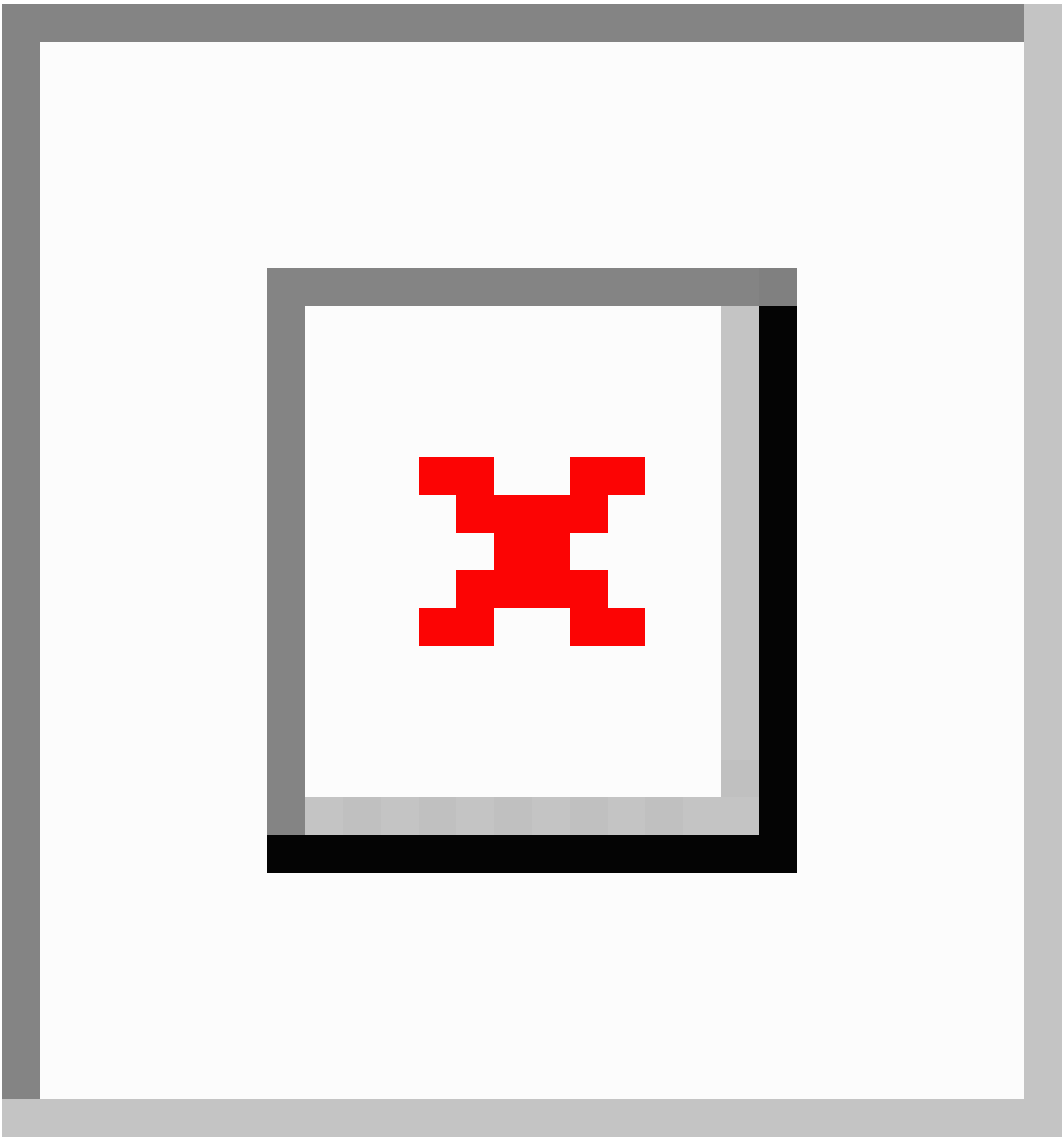
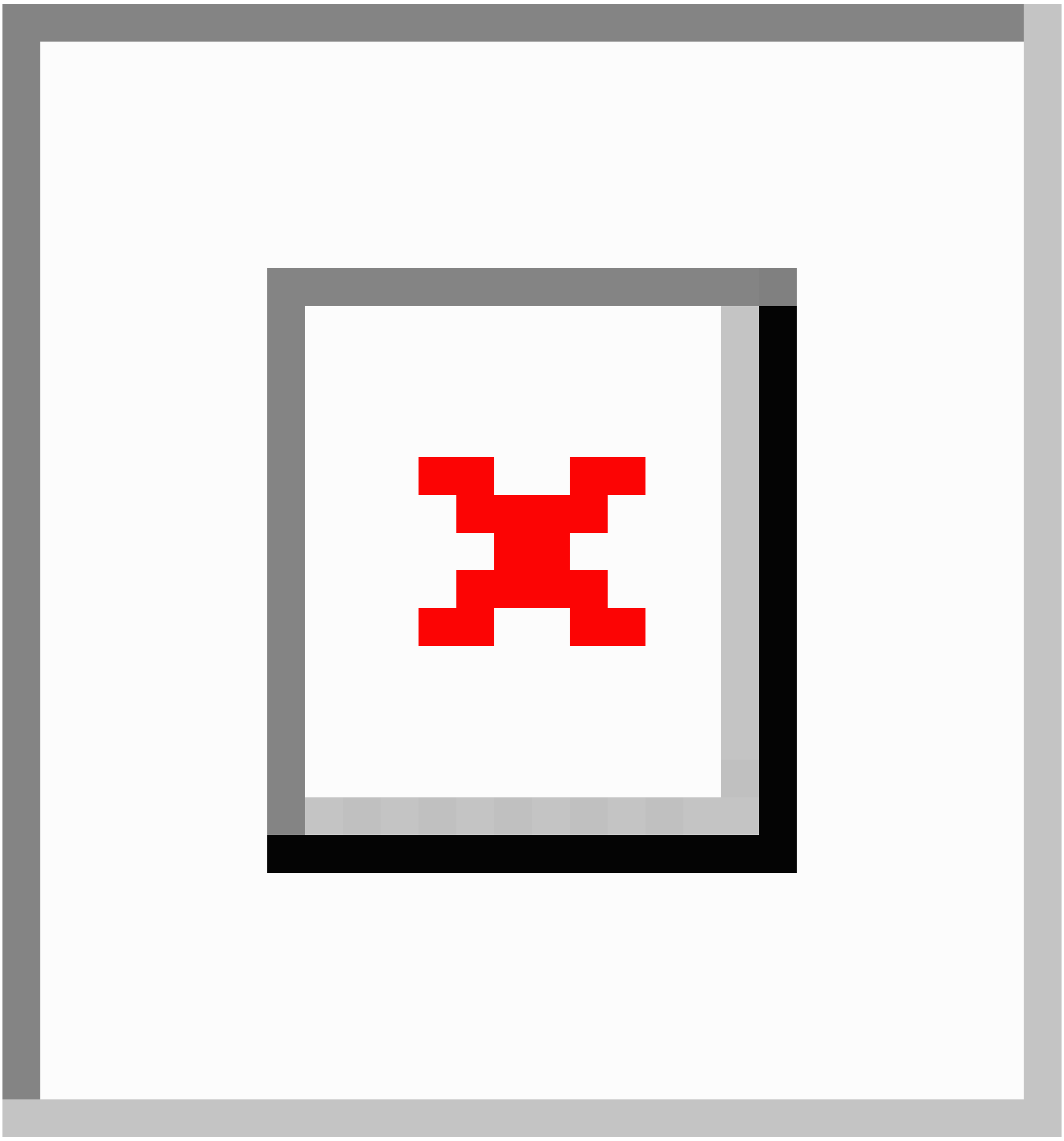


Figure 4. Screenshot of the interface at the end of the game when the user succeeds.



Data Collection Tools

Demographic Questionnaire

A descriptive characteristics questionnaire with 5 questions was used to collect data, including sex, age, education, job title, and the number of working years.

Skills Evaluation Tool

The ECMO Pipeline Preflushing Theoretical Scale and ECMO Pipeline Preflushing Skills Scale were used to assess the participants' mastery of theoretical knowledge and practical ability. We referenced the *ECMO Manual* (Chinese version; 2nd edition) [11] and *ELSO Guidelines for Training and Continuing Education of ECMO Specialists* [12] when designing these scales. The 2 scales were evaluated by 12 specialists in the field of acute and critical care and nursing education with a title of deputy senior or higher and with at least 15 years of work experience. When the content validity index–individual items (I-CVI) of a scale is >0.78 and the content validity index–overall scale (S-CVI) is >0.9, the content validity of the scale is considered good [16]. The I-CVI of the ECMO Pipeline Preflushing Theoretical Scale was 0.83, and the S-CVI was 0.91. The I-CVI of the ECMO Pipeline Preflushing Skills Scale was 0.83, and the S-CVI was 0.94.

ECMO Pipeline Preflushing Theoretical Scale

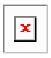
The ECMO Pipeline Preflushing Theoretical Scale has 58 items and consists of 3 parts: single-choice questions (40 items), multiple-choice questions (15 items), and short answers (3 items). The scale’s score ranges from 0 to 100.

ECMO Pipeline Preflushing Skills Scale

The ECMO Pipeline Preflushing Skills Scale has 61 items and consists of 3 parts: preparing items and materials according to the detailed list (13 item), preoperation preparation (5 items), and operation process (43 items). The scale’s score ranges from 0 to 100.

Data Analysis Tool

Based on the results of the pre-experimental study, the researchers referred to the average number of the ECMO pipeline preflushing needed to master the skill as 25 times. Therefore, this study counted the data of 30 operations used by each participant in the experimental group. Cumulative summation analysis (CUSUM) is a sequence analysis method first proposed by Page [17] to map the learning method of operation [18]. This study used CUSUM to draw the learning curve of the experimental group using a game-based mobile app to practice ECMO pipeline preflushing operation skills. The CUSUM was calculated as follows:



X_0 indicates the failure rate, and X_i represents the procedural success or failure of each practice. If it succeeds, then X_i=0, and if it fails, then X_i=1. In this study, we regarded the completion of the game before all the petals fell (within 9 mistakes) as a success, and the termination of the game as a result of all the petals falling was regarded as a failure. According to previous studies [19], the operation success rate was 94.4%, so the failure rate was X_0 = 1 – 94.4% = 5.6%.

The difference between the score of each operation of the participant and the set target value was sequentially accumulated. A learning curve was drawn, where the abscissa (*x* value) represents the number of intubation operations and the ordinate (*y* value) represents the sum of the previous cumulative sums. The curve fitting effect was evaluated by the curve fitting coefficient of determination (R^2), where $0 \le R^2 \le 1$. An R^2 value ≥0.95 indicates that the curve fit is satisfactory. The curve derivative function formula was obtained according to the curve function formula; the curve slope value corresponding to each operation was calculated; and the corresponding abscissa (*x* value) and the curve function value when the slope *k*=0 were calculated, that is, the curve peak value. The first integer value of *x* is the minimum number of operations the research participant needed to master the skill.

Data Analysis

The data obtained from the study were analyzed using the SPSS (version 24.0; IBM Corp) software package. The percentage, number, mean, and SD values were used in the descriptive statistical evaluation of the data. The normal or nonnormal distribution of the data was evaluated using the 1-sample Kolmogorov-Smirnov test. Nonparametric tests showed that the distribution of skill scores was nonnormal (*df*=86; *P*=.04). The skill scores between the 2 independent groups were compared using the Mann-Whitney *U* test. The χ^2 test was used to analyze the relation between the grouped variants. The Wilcoxon test was used in matching groups to determine the difference in scores between the first and final operation assessments and between the first and final skill performances. The data were evaluated at a *P*<.05 significance level.

Results

There was no significant difference in the distribution of descriptive characteristics between the control group and the experimental group (all *P*>.05; Table 1).

Table . Participant demographics between the control and experimental groups.

Demographics		Experimental group (n=43)	Control group (n=43)	*Z* score or χ^2 (*df*)	*P* value
Age (y), mean (SD)		30.51 (2.520)	30.44 (3.275)	−0.327[a]	.74
Number of working years, mean (SD)		6.93 (2.414)	6.84 (2.886)	−0.435[a]	.66
Sex, n (%)				0.231 (1)[b]	.63
	Female	32 (74)	30 (70)		
	Male	11 (26)	13 (30)		
Education, n (%)				0.311 (2)[b]	.86
	Postgraduate	4 (9)	5 (12)		
	Undergraduate	36 (84)	36 (84)		
	Junior college	3 (7)	2 (4)		
Job title, n (%)				3.817 (2)[b]	.15
	Senior	1 (2)	2 (4)		
	Intermediate	26 (60)	17 (40)		
	Junior	16 (38)	24 (56)		

[a]*Z* score.
[b]χ^2 value.

In the first ECMO pipeline preflushing theoretical test and skill operation test scores, no statistically significant differences were observed between the control group and the experimental group (*P*=.10 and *P*=.63). The experimental group's final theoretical test and skill operation test scores were significantly higher than those of the control group (*P*<.001). The final theoretical test and skill operation test scores of the experimental group were significantly higher than the first test scores of the experimental group (*P*<.001). The final theoretical test and skill operation test scores of the control group were also significantly higher than the first scores of the control group (*P*<.001; Tables 2 and 3).

Table . Difference in theoretical test scores between the control and experimental groups.

Score	Experimental group, median (range)	Control group, median (range)	*Z* score	*P* value
First theoretical test scores	75.88 (66-87)	74.42 (65-90)	−1.672	.10
Final theoretical test scores	88.44 (79-95)	85.02 (78-91)	−3.972	<.001[a]
Z score	−5.782	−5.715		
P value	<.001[b]	<.001[c]		

[a]Difference in theoretical test scores between the control and experimental groups at the final skill performance (*P*<.05).
[b]Difference in theoretical test scores between the first and final skill performance in the experimental group (*P*<.05).
[c]Difference in theoretical test scores between the first and final skill performance in the control group (*P*<.05).

Table . Difference in skill performance scores between the control and experimental groups.

Score	Experimental group, median (range)	Control group, median (range)	*Z* score	*P* value
First skill performance scores	75.44 (67-86)	75.93 (67-88)	−0.486	.63
Final skill performance scores	89.42 (82-94)	86.33 (76-94)	−4.145	<.001[a]
Z score	−5.783	−5.717		
P value	<.001[b]	<.001[c]		

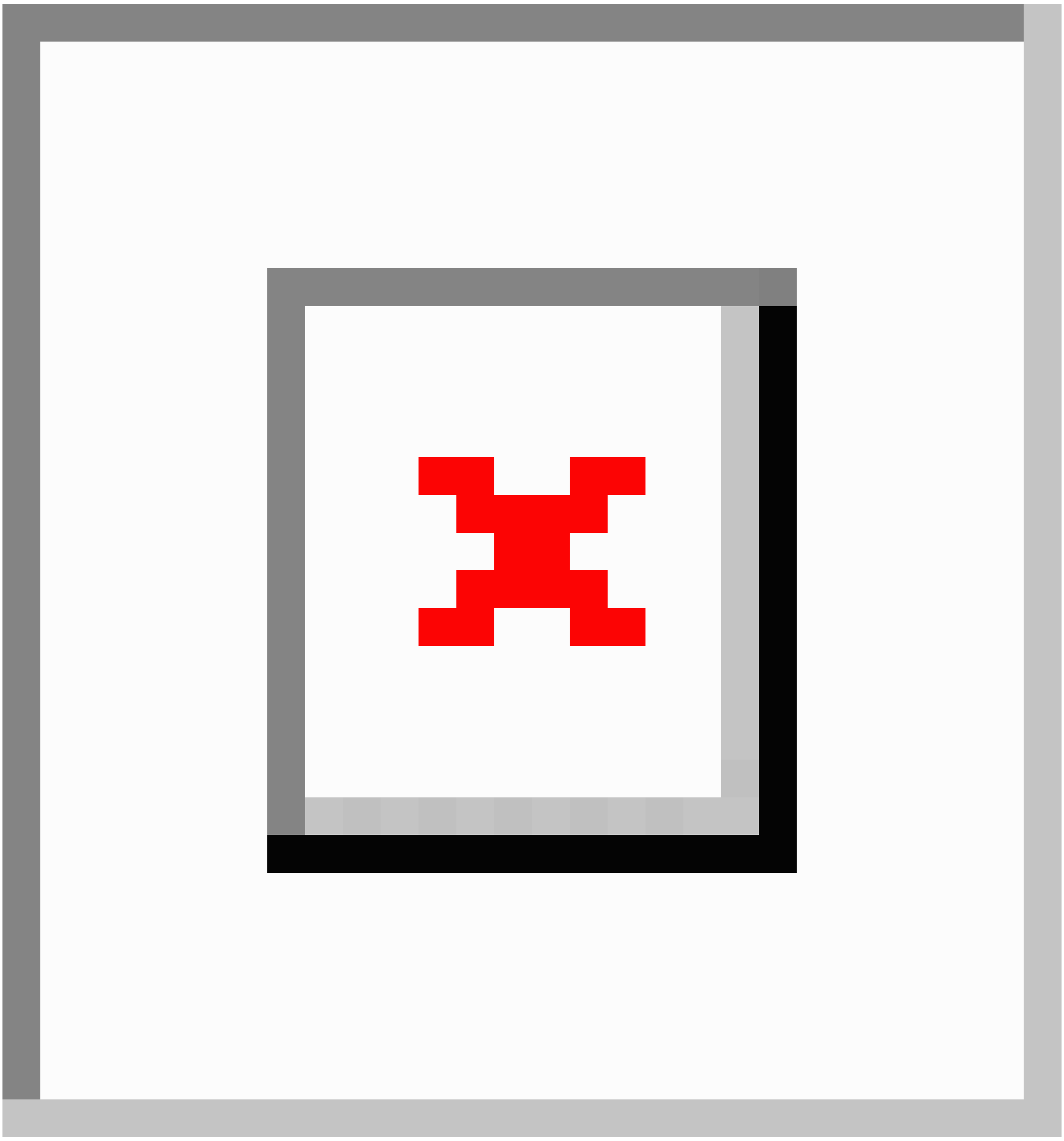
[a]Difference in skill test scores between the control and experimental groups at the final skill performance ($P<.05$).

[b]Difference in skill test scores between the first and final skill performance in the experimental group ($P<.05$).

[c]Difference in skill test scores between the first and final skill performance in the control group ($P<.05$).

The fitting curve model tests of the quadratic curve, compound function curve, exponential curve, and cubic curve showed that the *P* values were all <.05, and the R^2 values were 0.954, 0.498, 0.498, and 0.985, respectively. As $R^2>0.95$ for the quadratic curve and the cubic curve, the best fitting model curve was the cubic curve (Figure 5), and the fitting equation was $\sum i(\text{CUSUM value}) = 0.04x^3 - 3.17x^2 + 71.99x - 61.83$ (x=the number of operations). When the slope of the curve is 0, the corresponding abscissa (*x* value) represents the average number of operations for the group of students to master this skill. Calculated by the curve function formula, the first integer value of *x* after the peak of the curve of the experimental group was 17. Therefore, the minimum number of operations required for the experimental group to master this skill was 17.

Figure 5. The average learning curve of the experimental group. CUSUM: cumulative summation analysis.



Discussion

Principal Findings

In this study, the final averages of the ECMO pipeline preflushing theory and skill scores of the control group and the experimental group increased. The final theory and skill performance scores of the experimental group were significantly higher than those of the control group (*P*<.001). Both the game-based mobile app simulation training method and the conventional training method improved the theoretical knowledge and skill level of intensive critical care specialist nurses, but the game-based mobile app simulation training method was more effective than the conventional training method, which was consistent with the results of Gu et al [20]. In addition, the study used learning curve analysis to find that the experimental group of nurses needed 17 operations to master this skill.

Learning curves are increasingly used for health care education and formative assessment [21,22]. Every operation in the medical field requires a process from being unfamiliar to skilled. By establishing an operational learning curve, students' mastery can be assessed [23]. It could be seen from the learning curve that in the initial stage of learning, the curve showed an upward trend and the growth rate was large. This might be because at this stage, the participants were not familiar with the operation process and the rules of the game, and the researchers set the number of mistakes to only 9 in the game. Once the number of mistakes was too high, the game was terminated. In this period, the number of successful completions of the game was relatively small, so the CUSUM value increased greatly. After the first stage of grouping and learning, as participants became familiar with the operating process, although the learning curve continued to rise, the growth rate began to decrease. We called this period the plateau period. During this period, the slope of the curve was still positive but gradually approached 0. When the learning curve began to show a downward trend, the slope of the curve began to be negative, indicating that the number of successful players in the game was gradually increasing. The reason for these results might be that after studying and gaining experience, the participants were very familiar with the operation process of ECMO pipeline preflushing and could complete the game according to the correct steps within the specified number of 9 mistakes. Therefore, the learning curve analysis showed that the nurses in the experimental group needed 17 operations to master the skill.

Contributions and Implications

Game-based mobile apps can simulate real-life situations, and nurses or students can enter the clinical situation from the virtual world and improve practical skills and confidence before actual operations [24]. The results of this study were similar to the results of Bayram and Caliskan [25], which showed that the average score of nursing skills for pneumatic tube ostomy after using the game-based virtual reality application method was significantly improved. This app is suitable for Windows, Android, Mac, and other platforms and can be installed on computers, mobile phones, tablets, etc, thus achieving platform and network diversity. Most importantly, the game-based app provides participants with the opportunity and environment to practice and test learning outcomes anytime, anywhere, and with an unlimited number of attempts. This is different from traditional operation practices, where there is limited space, only a small number of participants can practice at a time, and the practice room is only open for a short time, along with other complicating factors. Overall, the integration of game-based mobile apps into ECMO pipeline preflushing education in China is effective in improving the learning time, knowledge, and skill level of intensive critical care specialist nurses compared to traditional training methods.

Significance for Clinical Education

This study confirms that a game-based mobile app can help intensive critical care specialist nurses better learn and master ECMO pipeline preflushing skills. The app can help nurses translate the theoretical knowledge of nursing into practice, stimulate learners' interest in learning, optimize the learning process, improve the learning effect, and cultivate clinical critical thinking. This app enables intensive critical care specialist nurses to learn the correct ECMO pipeline preflushing procedure for error-free operation in future clinical work while being a tool for nurses to learn and test learning outcomes anytime and anywhere. In addition, by establishing a learning curve, we understood how nurses learn a certain clinical operation for the first time and the amount of operational training required to master this operation, which has guiding significance for the development of clinical skills.

Limitations

First, in the early stages of learning, both groups of nurses made mistakes, leading to failure, but we could not identify which steps had a high error rate. Therefore, we could not explain the reason for the high failure rate of the early operations. Second, we could not monitor the scores of the nurses in the control group during each operation practice. Therefore, we could not draw the learning curve of the control group at this time, and there was no way to compare the learning curves of the 2 groups. Third, we will use more comprehensive sampling and randomized controlled trials in future investigations. According to the follow-up feedback of the research participants, we will add related knowledge questions, related knowledge teaching videos, and scene simulation modules in the follow-up study to improve the mobile app and its attractiveness and effectiveness.

Conclusions

This study suggests that a game-based mobile app may be more effective for intensive critical care specialist nurses in ECMO pipeline preflushing education than traditional Chinese lecture-practice education. In addition, the ECMO pipeline preflushing skill can be mastered by playing the game 17 times.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AR: augmented reality
CPR: cardiopulmonary resuscitation
CUSUM: cumulative summation analysis
ECMO: extracorporeal membrane oxygenation
I-CVI: content validity index–individual items
S-CVI: content validity index–overall scale

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Effects of a Preventive Mental Health Curriculum Embedded Into a Scholarly Gaming Course on Adolescent Self-Esteem: Prospective Matched Pairs Experiment

Christopher Jenson[1,*], MD; Sharon Fitzgerald Wolff[2,*], PhD; Libby Matile Milkovich[3,4,*], MD

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*all authors contributed equally

Corresponding Author:
Libby Matile Milkovich, MD

Abstract

Background: Positive self-esteem predicts happiness and well-being and serves as a protective factor for favorable mental health. Scholarly gaming within the school setting may serve as a channel to deliver a mental health curriculum designed to improve self-esteem.

Objective: This study aims to evaluate the impact of a scholarly gaming curriculum with and without an embedded preventive mental health curriculum, Mental Health Moments (MHM), on adolescents' self-esteem.

Methods: The scholarly gaming curriculum and MHM were developed by 3 educators and a school-based health intervention expert. The scholarly gaming curriculum aligned with academic guidelines from the International Society for Technology Education, teaching technology-based career skills and video game business development. The curriculum consisted of 40 lessons, delivered over 14 weeks for a minimum of 120 minutes per week. A total of 83 schools with previous gaming engagement were invited to participate and 34 agreed. Schools were allocated to +MHM or –MHM arms through a matched pairs experimental design. The –MHM group received the scholarly gaming curriculum alone, whereas the +MHM group received the scholarly gaming curriculum plus MHM embedded into 27 lessons. MHM integrated concepts from the PERMA framework in positive psychology as well as the Collaborative for Academic, Social, and Emotional Learning (CASEL) standards in education, which emphasize self-awareness, self-management, social awareness, relationship skills, and responsible decision-making. Participants in the study were students at schools offering scholarly gaming curricula and were enrolled at recruitment sites. Participants completed a baseline and postintervention survey quantifying self-esteem with the Rosenberg Self-Esteem Scale (score range 0-30). A score <15 characterizes low self-esteem. Participants who completed both baseline and postintervention surveys were included in the analysis.

Results: Of the 471 participants included in the analysis, 235 received the –MHM intervention, and 236 received the +MHM intervention. Around 74.9% (n=353) of participants were in high school, and most (n=429, 91.1%) reported this was their first year participating in scholarly gaming. Most participants were male (n=387, 82.2%). Only 58% (n=273) reported their race as White. The average self-esteem score at baseline was 17.9 (SD 5.1). Low self-esteem was reported in 22.1% (n=104) of participants. About 57.7% (n=60) of participants with low self-esteem at baseline rated themselves within the average level of self-esteem post intervention. When looking at the two groups, self-esteem scores improved by 8.3% among the +MHM group compared to no change among the –MHM group (P=.002). Subgroup analyses revealed that improvements in self-esteem attributed to the +MHM intervention differed by race, gender, and sexual orientation.

Conclusions: Adolescents enrolled in a scholarly gaming curriculum with +MHM had improved self-esteem, shifting some participants from abnormally low self-esteem scores into normal ranges. Adolescent advocates, including health care providers, need to be aware of nontraditional educational instruction to improve students' well-being.

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KEYWORDS

mental health; adolescent; scholastic gaming; self-esteem; school mental health; school; youth; student; students; adolescents; gaming; serious game; serious games

Introduction

Self-esteem is an important marker of overall adolescent well-being. Positive self-esteem predicts happiness, academic performance, and resiliency among other favorable outcomes, whereas low self-esteem contributes to anxiety and depression [1,2]. Because self-esteem can be either a risk factor or a protective factor for mental health challenges, it is critically important to target with supportive initiatives.

Adolescence is a pivotal time to develop positive self-esteem. A strong sense of self-worth propels adolescents to explore new opportunities and may help navigate feelings of inadequacy when experiencing common challenges at this age, such as friend group transitions, feelings of awkwardness, and unexpected emotional lability [3]. The benefits of self-esteem have been especially relevant since 2000 when the prevalence of anxiety, depression, and suicidal ideations began to increase in adolescents, worsening during the COVID-19 pandemic, and remaining slow to improve despite the end of COVID-19 restrictions [4-7].

One cohort of adolescents, high-volume technology users, are at increased risk for low self-esteem [8-10]. Multiple hypotheses exist for this relationship, including comparing self to social media standards and the social isolation that can occur with excessive video gaming [11,12]. In contrast, several research inquiries suggest that interactive technology use can be helpful [13,14]. One primary reason is that technology can serve as a motivator for behavioral intervention and contribute to the promotion or reduction of certain behaviors [15]. For example, in the educational space, interactive websites and captivating software apps can ignite student engagement, improve academic performance, and serve as a reward for completed learning objectives [16].

A more extensive example of using technology to positively shape behavior is scholarly gaming. Scholarly gaming is an academic course in secondary schools that leverages student excitement around video gaming to teach technology-based career skills, project-driven teamwork, and accountability for adolescents. However, there appears to be a gap that scholarly gaming has yet to fill—supporting the self-esteem of student participants. Many of the students who enroll in scholarly gaming classes may not be well connected to school life outside of their interest in technology and gaming, putting them at risk for feelings of isolation [17].

Our intervention offered a scholarly gaming curriculum that embedded opportunities to develop positive self-esteem within the academic instruction, serving as a vessel to deliver a mental health curriculum; offered schools an opportunity to improve the emotional well-being of adolescents at baseline; and promoted an inclusive extracurricular activity for interested students, boosting feelings of self-worth and confidence [18]. With these design elements, scholarly gaming could offer a practical and affordable approach to student mental health support, which many experts in education desire [19,20].

The purpose of this study is to evaluate the impact of scholarly gaming with and without an embedded mental health curriculum, known as Mental Health Moments (MHM), on the self-esteem of adolescents. We hypothesized that students participating in a scholarly gaming curriculum with embedded MHM (+MHM) would show greater improvement in self-esteem compared to the same scholarly gaming curriculum without the MHM (−MHM). To evaluate the hypothesis, we quantitatively assessed the self-esteem of adolescents at baseline and post intervention (+MHM or –MHM).

Methods

This prospective study compared baseline and postintervention self-reported self-esteem scores from adolescents participating in +MHM and –MHM. This study occurred from December 2021 through May 2022.

Setting and Participants

Recruitment for this study occurred at secondary schools in Canada and the United States. Eligible schools were identified by reviewing prior enrollment in school-sponsored gaming events, demonstrating that the school had the tech resources to support a scholarly gaming course. All schools that had participated in school-sponsored gaming events (N=83 middle and high schools in North America) were invited via email to participate in the study. A total of 34 schools agreed to participate, representing more than 30 independent districts across the United States (11 states) and Canada (1 province). There was no statistical difference between the schools that enrolled versus those that declined when comparing student body size, public versus private, Title 1 status, and poverty rates (Multimedia Appendix 1). There was a slight geographic difference between schools who agreed and declined to participate, with schools in the Midwest (55%) and West (55%) being more likely to enroll than schools in the Southwest (33%), Northeast (20%), or Southeast (7%; $P<.001$; Table S1 in Multimedia Appendix 1).

The most common reason for declining enrollment in the study was faculty preference, as some teachers did not want to deviate from pre-existing lesson plans. A total of 17 schools each were allocated to the intervention (+MHM) and control (–MHM) arms.

Participant eligibility included enrollment in a course that provided the –MHM or +MHM scholarly gaming curriculum at a participating school, aged 12-18 years, and a class schedule that allowed engagement with the study-approved curriculum for 120 minutes each week. No student was required to participate, and students could withdraw at any time from the survey process. There was no compensation or benefits in kind for participation.

Ethical Considerations

Participating schools considered their local legislation and institutional requirements before joining the study. Additionally, scholarly gaming teachers provided all eligible participants with a written informed assent/consent form to share with their guardians. The institutional review board at Children's Mercy Hospital and Clinics (Kansas City, MO) approved the secondary analysis of data (STUDY00002344) collected by the study investigators who designed the +MHM and −MHM programs.

Study Design and Allocation

In this prospective study, participating schools were allocated to +MHM and –MHM arms through a matched pairs experimental design, balancing the number of students enrolled in the school, Title 1 status, public versus private, and geography.

Interventions

Teacher Training

All teachers received the following resources at no cost: access to either the +MHM or −MHM curriculum guides on the web, depending on their study allocation; paper versions of the curriculum guides as a backup; student handouts for applicable lessons; and three video tutorials. The curriculum guides included scripted lessons, along with standardized presentation materials and supplements for each lesson. The video tutorials explained how to use the scholarly gaming curriculum consistently and follow the data collection process, and emphasized the need for a standardized experience throughout the study. Finally, teachers were informed that the study sought to measure the impact of a new curriculum on self-esteem over time but were blinded as to whether they were providing +MHM or –MHM.

Standard Curriculum (–MHM)

The scholastic gaming curriculum included 40 lessons over 14 weeks for a minimum of 120 minutes per week. The goal of the curriculum was to teach students meaningful skills and knowledge needed to work in the digital gaming industry. Examples include project management, graphic design, basic coding, marketing, maximizing team performance, and career opportunities linked to gaming. The curriculum, designed by multiple educators and a school-based health intervention expert, was organized into units, daily lessons, and timed projects. The –MHM curriculum content aligned with the International Society for Technology in Education (ISTE) benchmarks. Lessons were led by the teacher and provided a standardized experience through prewritten lesson plans (within the curriculum) for teachers to follow. Each lesson plan engaged study participants with prescriptive teacher dialogue and premade resources (eg, worksheet or infographic) created by the curriculum writers. The research team verified with the participating schools that the scholastic gaming teacher held the appropriate professional licensure and certification to teach secondary school in that state/province.

Standard Curriculum With Embedded Mental Health Moments (+MHM)

Participants allocated to the +MHM group received the same scholastic gaming curriculum and teacher training as those in the –MHM group but with the addition of +MHM embedded into 27 of the 40 scholarly gaming curriculum lessons. To make room for the embedded +MHM, 10 minutes of student work time was removed from the lesson plan. There were no other changes made. +MHM was designed by the same team of professionals as –MHM and aligned with the previously mentioned ISTE standards and validated frameworks in education and psychology that support favorable mental health [21,22]. Additionally, all scholarly gaming teachers who provided +MHM met the same credentialing standards as the –MHM faculty.

The primary goal of +MHM was to promote positive self-esteem in participants, growing confidence in their worth and abilities. +MHM accomplished this goal by linking elements of the tech-based academic lesson to one of three premade student experiences (discussion, activity, or personal reflection) that provided insight into one or more of the following: self-awareness, self-management, social awareness, relationship skills, responsible decision-making, positive emotions, engagement, sense of meaning, and achievements. All +MHM experiences were led by the teacher in a standardized way, using prescriptive teacher dialogue and premade resources from the curriculum. +MHM experiences were designed to be delivered in 10 minutes, as this was the time allotment created for them.

To illustrate an example of +MHM, an academic lesson that explored harsh feedback for a game design linked itself to a discussion regarding the "purpose of emotions" and offered scripted strategies for controlling emotions calmly and professionally. An expanded example of an MHM lesson can be found in Multimedia Appendix 2.

Measures

At baseline and post intervention (14 weeks), each school's scholastic gaming teacher was emailed a link to the electronic study surveys. Upon receipt of the link, teachers distributed the surveys to each student enrolled in the study to complete within a standardized window of 5 days. All survey responses were deidentified through a school code plus a number that was selected by each student. Supervising teachers were directed to ensure no duplicate student numbers.

Demographic Characteristics

Students were asked to report their age; grade in school; number of years participating in scholastic gaming; race; gender; and if they identified as lesbian, gay, bisexual, transgender, queer (LGBTQ+). Grade in school was categorized into middle (grades 6 through 8) or high school (grades 9 through 12). Years of participation in scholastic gaming was categorized as "first year" versus "two or more years." Race was asked by "Which do you identify with?" allowing participants to select one or more options. Race was classified as American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian/Pacific Islander, White, more than one race, or prefer not to say or unknown. Gender was asked similarly to race, allowing participants to select male, female, or nonbinary. Students could also identify as LGBTQ+ or not LGBTQ+.

Self-Esteem

The Rosenberg Self-Esteem Scale (RSES), a validated scale consisting of 10 questions on a four-point Likert scale measured participant self-esteem at baseline and week 14 [23]. The total RSES score was calculated by summing responses to each question and reverse coding five questions that use negative phrases. Scores range from 0 to 30, with lower scores indicating lower levels of self-esteem. A score of less than 15 is considered low self-esteem [23,24]. A binary variable indicating if a student had low self-esteem (defined as RSES <15) was created.

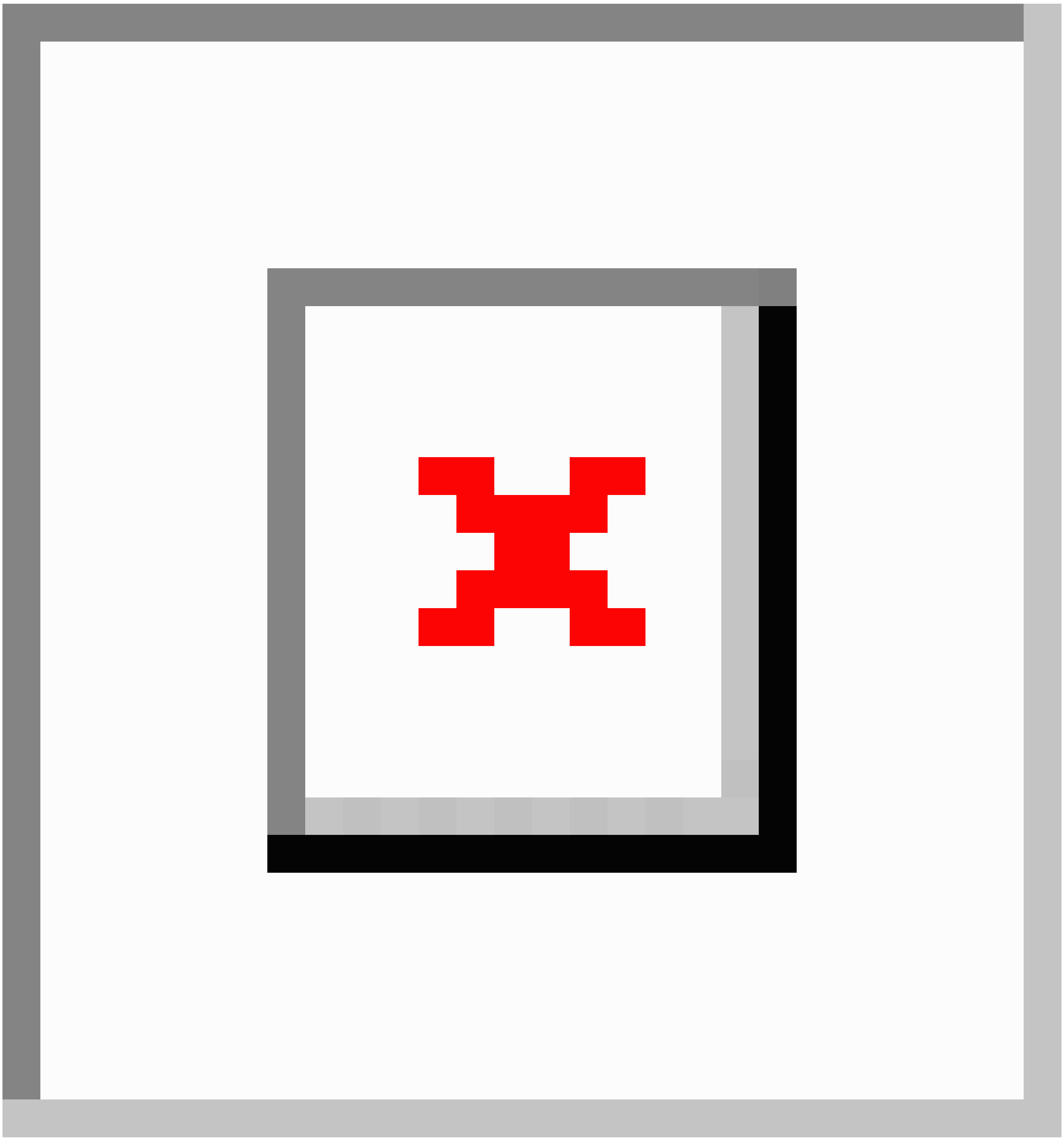
Data Analysis

Basic descriptive statistics (frequencies, means) were used to describe the study sample. Baseline demographic differences between the +MHM and –MHM groups were assessed using χ^2/Fisher exact and *t* tests for categorical and continuous data, respectively. Changes in the RSES score from baseline to postintervention as a continuous variable were assessed via multivariable repeated measures linear regression, controlling for baseline imbalances between the study arms. A multilevel model was implemented to account for the clustering of individuals within each school. Subgroup analyses were conducted using multivariable repeated measures linear regression to examine if there was a differential impact on the MHM curriculum by race, gender, and sexual orientation. Subgroup analyses collapsed the following racial categories into an "additional races" category due to small sample sizes: American Indian and Alaska Native, Asian, Native Hawaiian or Pacific Islander, more than one race, or prefer not to say or unknown. Students who chose not to self-report their gender were excluded from the subgroup analyses related to gender. The association between the MHM curriculum and improvement of low self-esteem (RSES score <15) was assessed using multivariable logistic regression controlling for baseline imbalances between the study groups. All analyses were completed using SAS Version 9.4 (SAS Institute, Inc).

Results

Among the 34 participating schools, 710 students enrolled in the study. Of those, 471 students completed all surveys (+MHM: n=236; –MHM: n=235) and were included in the analyses (Figure 1).

Figure 1. Study participation.



Demographic Characteristics

The majority (n=353, 74.9%) of the 471 participants were enrolled in grades 9-12 at the time of the study, were male (n=387, 82.2%), and reported that this was their first year participating in scholastic gaming (n=429, 91.1%). About half (n=273, 58%) reported their race as White. The characteristics of students in each study group were balanced at baseline, except for age and race. The mean age of students in the +MHM arm was slightly less than that of the –MHM arm (14.9, SD 1.5 years vs 15.2, SD 1.8 years; *P*=.04). The distribution of self-reported race was even between the study groups, except for the +MHM group that included more students who reported their race as Asian than the –MHM group (19/236, 8.1% vs 9/235, 3.8%), and the +MHM group also had fewer students who reported their race as White than the –MHM group (125/236, 53% vs 148/235, 63%; Table 1).

Table . Baseline characteristics of study participants.

Characteristic		Total (n=471)	+MHM[a] (n=236)	–MHM (n=235)	*P* value[b]
Years of participation, n (%)					.99
	First year	429 (91.1)	215 (91.1)	214 (91.1)	
	Two or more years	42 (8.9)	21 (8.9)	21 (8.9)	
Grade level, n (%)					.38
	Middle school	118 (25.1)	55 (23.3)	63 (26.8)	
	High school	353 (75.0)	181 (76.7)	172 (73.2)	
Age (years), mean (SD)		15.0 (1.6)	14.9 (1.5)	15.2 (1.8)	*.04* [c]
Race, n (%)					*.047* [d]
	American Indian or Alaska Native	16 (3.4)	5 (2.1)	11 (4.7)	
	Asian	28 (5.9)	19 (8.0)	9 (3.8)	
	Black or African American	49 (10.4)	25 (10.6)	24 (10.2)	
	Hispanic or Latino	76 (16.1)	43 (18.2)	33 (14.0)	
	Native Hawaiian/Pacific Islander	5 (1.1)	2 (0.9)	3 (1.3)	
	White	273 (58.0)	125 (53.0)	148 (63.0)	
	More than one race	19 (4.0)	14 (5.9)	5 (2.1)	
	Prefer not to say/unknown	5 (1.1)	3 (1.3)	2 (0.9)	
Gender identification, n (%)					.96[d]
	Female	59 (12.5)	31 (13.1)	28 (11.9)	
	Male	387 (82.2)	192 (81.4)	195 (83.0)	
	Nonbinary	21 (4.5)	11 (4.7)	10 (4.3)	
	Prefer not to say/unknown	4 (0.9)	2 (0.9)	2 (0.9)	
LGBTQ+[e], n (%)					.53
	Yes	48 (10.1)	22 (9.3)	26 (11.1)	
	No	423 (89.8)	214 (90.7)	209 (88.9)	
Rosenberg Self-Esteem Scale score[f], mean (SD)		17.9 (5.1)	18.0 (5.4)	17.9 (4.9)	.80
Low Rosenberg Self-Esteem Scale score [g], n (%)					.98
	Yes	104 (22.1)	52 (22.1)	52 (22.0)	
	No	367 (77.9)	183 (77.9)	184 (78.0)	

[a]MHM: Mental Health Moments.

[b]*P* value from χ^2 or *t* test.

[c]Italics indicate statistically significant differences between study groups at baseline.

[d]Fisher exact test.

[e]LGBTQ+: lesbian, gay, bisexual, transgender, queer.

[f]Rosenberg Self-Esteem Scale scores range from 0 to 30, with lower scores indicating lower levels of self-esteem.

[g]A Rosenberg Self-Esteem Scale score <15 indicates low self-esteem.

There were statistically significant differences in the study group, race, and gender identification between those who were included in the analyses versus those excluded due to not completing the follow-up assessment. Students enrolled in the +MHM group were more likely to be included in the analyses than those in the –MHM group, students who declined to report their race at baseline and those who reported their race as Black or African American were less likely to be included than other races, and students reporting their gender identity as male or nonbinary were more likely to be included than those who reported their gender as female or declined to report (Multimedia Appendix 3).

Self-Esteem

Baseline

The mean RSES score among the entire study sample at baseline was 17.9 (SD 5.1), with 22.1% (104/471) falling into the low self-esteem category (RSES <15). +MHM and –MHM had similar mean self-esteem scores at baseline (18.0, SD 5.4 and 17.9, SD 4.9, respectively; *P*=.80), with 52 participants in each group having low self-esteem (Table 1).

Postintervention –MHM

Among –MHM participants who had low self-esteem at baseline (RSES <15), 54% (28/52) had self-esteem scores in the normal range (15 or greater) by the end of the study (Table 2). RSES as a continuous variable did not change over time in the –MHM group (baseline RSES 17.9, SD 4.9; postintervention RSES 17.9, SD 5.5; Table 3). Self-esteem scores increased slightly among –MHM students reporting their race as White, Hispanic/Latino, and the races collapsed into the additional races category. Among –MHM students reporting their race as Black or African American, self-esteem decreased from baseline to the end of the study. Self-esteem scores also decreased among –MHM students reporting their gender as male, female, and nonbinary (Table 4).

Table . Odds of low self-esteem improving to normal by the end of the study period. Results of logistic regression controlling for age and race. The analysis includes 104 students with Rosenberg Self-Esteem Scale score <15 at baseline.

	Low self-esteem[a] improved[b], n (%)		aOR[c] (95% CI)
	Yes (n=60)	No (n=44)	
+MHM[d] (n=52)	32 (61.5)	20 (38.5)	1.17 (0.68-2.01)
–MHM (n=52; reference)	28 (53.9)	24 (46.2)	1.0

[a]Abnormally low self-esteem defined as Rosenberg Self-Esteem Scale score <15.

[b]Improvement measured as a score ≥15 by the end of the study.

[c]aOR: adjusted odds ratio.

[d]MHM: Mental Health Moments.

Table . Changes in self-esteem scores over time. Results of repeated measures linear regression controlling for age and race.

		Rosenberg Self-Esteem Scale score[a], mean (SD)[b]		*P* values[c]		
		Baseline	Week 14	Group[d]	Time[e]	Group × time[f]
Study group				.14	*<.001* [g]	*.002*
	+MHM[h]	18.0 (5.4)	19.5 (5.6)			
	−MHM	17.9 (4.9)	17.9 (5.5)			

[a]Rosenberg Self-Esteem Scale scores range from 0 to 30, with lower scores indicating lower levels of self-esteem.

[b]Raw means for respondents at each time point.

[c]*P* values are based on model-based means for repeated measure analyses controlling for age.

[d]*P* value group: differences in self-esteem scores at baseline between study groups.

[e]*P* value time: differences in self-esteem scores between baseline and week 14.

[f]*P* value group × time: differences in change in self-esteem score over time by study group.

[g]Italics indicate statistically significant results.

[h]MHM: Mental Health Moments.

Table . Subgroup analyses of changes in Rosenberg Self-Esteem Scale scores over time by race, gender, and sexual orientation. Results of repeated measures linear regression controlling for age and race.

Subgroup and study group			Rosenberg Self-Esteem Scale scores[a], mean (SD)[b]		*P* values[c]		
			Baseline	Week 14	Group[d]	Time[e]	Group × time[f]
Race[g]							
	Black				.51	.11	*.004*[h]
		+MHM[i] (n=25)	17.7 (5.9)	20.3 (6.0)			
		–MHM (n=24)	20.6 (5.3)	17.6 (5.1)			
	Hispanic/Latino				.12	*.01*	.19
		+MHM (n=43)	16.6 (5.8)	18.1 (5.0)			
		–MHM (n=33)	18.4 (3.6)	18.7 (5.1)			
	White				*.04*	*.002*	*.046*
		+MHM (n=125)	18.1 (5.4)	20.0 (5.8)			
		–MHM (n=148)	17.5 (5.1)	17.9 (5.9)			
	Additional races [j]				.08	.74	.50
		+MHM (n=43)	19.3 (4.6)	18.9 (5.2)			
		–MHM (n=30)	17.1 (3.3)	17.6 (3.6)			
Gender[k]							
	Male				*.046*	*.002*	*.03*
		+MHM (n=192)	18.5 (5.4)	18.0 (4.8)			
		–MHM (n=195)	19.8 (5.7)	18.2 (5.5)			
	Female				.79	.79	*.006*
		+MHM (n=31)	16.6 (5.1)	18.7 (5.0)			
		–MHM (n=28)	17.7 (5.4)	16.8 (5.4)			
	Nonbinary				.81	*.008*	.71
		+MHM (n=11)	13.9 (4.2)	14.5 (3.6)			
		–MHM (n=10)	16.9 (6.4)	16.5 (5.8)			
Orientation							
	LGBTQ+ [l]				.52	*.001*	.10
		+MHM (n=22)	13.5 (4.7)	18.8 (6.4)			
		–MHM (n=26)	14.3 (3.8)	15.7 (4.3)			
	Not LGBTQ+				.21	*.03*	*.006*
		+MHM (n=214)	18.5 (5.3)	19.6 (5.5)			
		–MHM (n=209)	18.3 (4.8)	18.2 (5.5)			

[a]Rosenberg Self-Esteem Scale scores range from 0 to 30, with lower scores indicating lower levels of self-esteem.

[b]Displays raw means for actual respondents at each time point.

[c]*P* values are based on model-based means for repeated measure analyses controlling for age.

[d]*P* value group: differences in self-esteem scores at baseline between study groups.

[e]*P* value time: differences in self-esteem scores between baseline and week 14.

[f]*P* value group × time: differences in change in self-esteem score over time by study group.

[g]Race subgroup analyses did not control for race.

[h]Italics indicate statistically significant results.

[i]MHM: Mental Health Moments.

[j]Additional races collapsed due to small sample sizes. Includes American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, more than one race, and prefer not to say/unknown.

[k]Four students who did not wish to disclose their gender were excluded from these analyses.

[l]LGBTQ+: lesbian, gay, bisexual, transgender, queer.

Postintervention +MHM

Among +MHM students who had low self-esteem at baseline (RSES <15), 62% (32/52) had self-esteem scores in the normal range (15 or greater) by the end of the study (Table 2). Self-esteem improved by about 8.3 percentage points from baseline to postintervention for the +MHM group (baseline RSES mean 18.0, SD 5.4; postintervention RSES mean 19.5, SD 5.6; Table 3). Among racial subgroups, self-esteem improved among +MHM students reporting their race as Black or African American, Hispanic/Latino, and White. Self-esteem decreased slightly among those falling into the additional races category. Results also displayed improvements in self-esteem among +MHM students reporting their gender as female and nonbinary. The largest improvement in self-esteem was among the LGBTQ+ subgroup, whose mean RSES score improved from 13.5 (SD 4.7) at baseline to 18.8 (SD 6.4) by the end of the study (Table 4).

Postintervention –MHM Versus +MHM

Results from the multilevel multivariable linear regression found that mean RSES score improvement over time was greater among the +MHM group (baseline: 18.0, SD 5.4; week 14: 19.5, SD 5.6) compared to the –MHM group (baseline: 17.9, SD 4.9; week 14: 17.9, SD 5.5; group × time; P=.002; Table 3). Additional subgroup analyses found that the +MHM intervention improved self-esteem more than the –MHM intervention among students identifying as African American or Black, White, male, female, and non-LGBTQ+ (see P values for group × time in Table 4).

Results of the multivariable logistic regression found that, among students with low self-esteem at baseline, the odds of reaching normal levels of self-esteem by week 14 were greater among students who were enrolled in +MHM compared to those in the –MHM group (adjusted odds ratio 1.17, 95% CI 0.68-2.01), although this finding was not statistically significant (Table 2).

Discussion

Principal Results

Our study found that the scholarly gaming curriculum produced a clinically relevant migration of participants from abnormally low self-esteem baselines to a normal range, and the +MHM group had greater self-esteem score improvement than the –MHM group. This suggests that the insertion of embedded preventive mental health (+MHM) into the scholarly gaming curriculum may amplify the well-being benefit of the scholarly gaming curriculum. Furthermore, the large sample size over one semester suggests delivering an embedded mental health curriculum within an academic course is feasible.

Independent of the macroscopic changes that embedded preventive mental health might offer, it's equally important to discuss the impact this intervention made on higher-risk cohorts of adolescents, as mental health burdens are not carried equally.

Implications for Adolescents at Higher Risk for Mental Health Threats

The Centers for Disease Control and Prevention reports that females; students of color; and individuals who identify as lesbian, gay, or bisexual are often at higher risk for mental health challenges throughout adolescence [25,26]. Subgroup analyses within our study revealed differences in the impact of the scholarly gaming curriculum (with or without MHM) between races, genders, and LGBTQ+ identification. These changes were magnified in the +MHM group, suggesting that embedded preventive mental health might offer some valuable improvements in self-esteem for several of the CDC-defined "higher risk" cohorts.

Female Adolescents

Participants who identified as female and received +MHM experienced an increased trend in self-esteem from baseline to the end of the study when compared to those who identified as female and received –MHM. This positive impact linked to embedded preventive mental health (+MHM) is worth noting for adolescent advocates—something they might consider sharing with schools in their community, given that adolescent females displayed a 53% increase in emergency department visits for suicidal ideations in 2021 compared to 2019 [27].

Students of Color

Racism can serve as a structural and social determinant of health that increases stress and negatively impacts mental health, making protective factors for mental health critically important to minoritized cohorts [28,29]. It is worth noting that Black and Hispanic/Latino participants who engaged with +MHM demonstrated increases in perceived self-esteem when compared to baseline values and the –MHM cohort for their race. It is possible that a curriculum that emphasizes student self-worth and provides an opportunity for peer connection as much as academic content may be beneficial for people of minoritized groups.

LGBTQ+ Identification

Adolescents who identify as LGBTQ+ sometimes have trouble finding a supportive niche and friend groups in school [30]. This can be a detriment to mental health, as prior research demonstrates how inclusion in extracurricular activities boosts students' perceptions of self-worth and confidence [31]. Enter scholarly gaming, an activity with no historical precedents and a nonthreatening environment for LGBTQ+ students potentially seeking a sense of belonging and friendship. The results demonstrated an increase in self-esteem scores for all LGBTQ+ participants post intervention. Furthermore, although not statistically significant due to sample size, students in the +MHM group who identified as LGBTQ+ had the lowest self-esteem scores at baseline and saw the largest improvement in self-esteem by the end of the study when compared to all other cohorts in the study. These findings may be related to benefits provided by the inclusive design of scholastic gaming and the impact of +MHM, suggesting that other school activities with a similar inclusive nature and embedded preventive mental health may benefit students who identify as LGBTQ+.

Comparison With Prior Work

To the best of our knowledge, this study is one of the first to quantify the impact of embedded preventive mental health within standard curricula, as compared to traditional social-emotional learning, which is often taught independent of academic content. Equally important, this study made a deliberate choice to use scholarly gaming, a class arguably centered around technology and video gaming, as the conduit to +MHM. The intent was to demonstrate that if +MHM could offer benefits in a scholarly gaming curriculum, it might offer benefits in another academic curriculum. Future implementations of the +MHM curriculum will need to be scalable for non–scholarly gaming classes, perhaps through universal instructional strategies, to see if they offer benefits for participants.

Limitations

The strengths of this study include its use of a longitudinal design, large sample size, and an intervention that was practical and affordable for schools to implement. Nevertheless, several limitations of this study should be considered. First, although the curriculum was prescriptive and standardized, we could not guarantee implementation validity, even with teacher training. Second, although the attrition rate was similar between both the +MHM and –MHM study groups, we could not definitively determine the causes of participant dropout. Third, the allocation of schools to the +MHM and –MHM groups used a matched pairs experimental design with the following key variables: student number, school number, Title 1 status, public versus private, and geographic distribution. While the nonrandom allocation pattern has the potential to introduce bias, we accounted for this by controlling for imbalances between the study groups at baseline and using multilevel modeling. Additionally, the LGBTQ+ categorization in our study was only able to classify a student as identifying as LGBTQ+ or not; we were unable to determine specific gender identities or sexual orientation. Further studies should consider more detailed identification. Finally, these findings may not be generalizable beyond students participating in a scholarly gaming curriculum. Future studies should evaluate the impact of the integration of +MHM into other curricula on student self-esteem.

Conclusions

Scholarly gaming with +MHM, a tech-based course that seems to capture the interest of many students, might serve as a successful conduit for embedded preventive mental health curriculum, improving the self-esteem of participants. This is particularly relevant, as scholarly gaming curricula often reach some of the most vulnerable youth through school-based interventions. Furthermore, if an embedded preventive mental health curriculum offers benefits in a scholarly gaming course, it might offer benefits in other academic settings [32,33]. Adolescent advocates and researchers should be aware of this potential opportunity for rapidly expanding school-based interventions to support self-esteem.

Acknowledgments

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

CJ led the conceptualization, investigation, resources, and supervision, and helped design the data curation. SFW generated all formal analyses and methodology. LMM led the reviewing and editing. Validation, visualization, and writing the original draft were shared equally by all three authors.

Conflicts of Interest

CJ was compensated for cowriting the scholarly gaming curriculum with +MHM.

Multimedia Appendix 1

Baseline school characteristics by inclusion in the study.

[DOC File, 44 KB - games_v11i1e48401_app1.doc]

Multimedia Appendix 2

Example of a Mental Health Moments (+MHM) lesson.
[PNG File, 210 KB - games_v11i1e48401_app2.png]

Multimedia Appendix 3
Baseline student characteristics by inclusion in analyses.
[DOC File, 45 KB - games_v11i1e48401_app3.doc]

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Abbreviations

CASEL: Collaborative for Academic, Social, and Emotional Learning
ISTE: International Society for Technology in Education
LGBTQ+: lesbian, gay, bisexual, transgender, queer
MHM: Mental Health Moments
RSES: Rosenberg Self-Esteem Scale

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Original Paper

Exploring Key Factors Influencing Nursing Students' Cognitive Load and Willingness to Serve Older Adults: Cross-sectional Descriptive Correlational Study

Pei-Lun Hsieh[1], PhD; Yu-Rung Wang[2], PhD; Tien-Chi Huang[3], PhD

[1]Department of Nursing, National Taichung University of Science and Technology, Taichung, Taiwan
[2]Department of Nursing, Chang Gung University of Science and Technology, Chiayi, Taiwan
[3]Department of Information Management, National Taichung University of Science and Technology, Taichung, Taiwan

Corresponding Author:
Pei-Lun Hsieh, PhD
Department of Nursing
National Taichung University of Science and Technology
No. 193, Sec. 1, San-Min Rd
Taichung, 40343
Taiwan
Phone: 886 422196854
Email: peilun@nutc.edu.tw

Abstract

Background: Virtual learning environments (VLEs) use a virtual environment to support learning activities. VLEs are commonly used to overcome the temporal and spatial restrictions of learning activities held in conventional face-to-face classrooms. In VLEs, students can participate in learning activities using the internet, and teachers can provide assistive learning tools during the process.

Objective: The purpose of this study was to investigate the relationships among nursing students' mental load, cognitive load, and affective learning outcomes in terms of their willingness to serve older adults in an interaction-based educational virtual reality (VR) learning environment.

Methods: This study used a cross-sectional method. A total of 130 students participated in interaction-based VR learning and completed related questionnaires. Descriptive and inferential statistics and stepwise regression for data analysis were used.

Results: The research results revealed that in the dimension of willingness to use VR learning materials, perceived usefulness received the highest score (mean 4.42, SD 0.45). In the dimension of nursing ability, students scored the highest in information management and application ability to care for case patients (mean 4.35, SD 0.54). Correlation analysis revealed that cognitive load during learning and willingness to serve older adults were negatively correlated, whereas willingness to use VR learning materials was positively correlated with nursing ability and willingness to serve older adults. Analyzing the regression coefficients of predictor variables revealed that willingness to use VR learning materials (β=.23; t_2=2.89, *P*=.005) and cognitive load during learning (β=–.35; t_2=–.4.30, *P*<.001) were predictive factors of nursing students' willingness to serve older adults.

Conclusions: This study demonstrated that students' willingness to use VR learning materials and their cognitive load during learning affected their willingness to care for older adults. Therefore, the components of mental or cognitive load generate inconsistent predictive effects on affective variables and willingness to serve older adults.

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KEYWORDS

immersive virtual reality learning; VR learning; mental effort; mental load; service willingness; older adult; virtual reality; nursing student; professional education; digital learning; older adult population

Introduction

As a consequence of population aging in many countries, nurses must be equipped with the ability to care for older adults, perform early assessments, and establish care demands. In nurse cultivation and education, technology learning elements are incorporated. Virtual learning environments (VLEs) use a virtual environment to support learning activities. VLEs are commonly used to overcome the temporal and spatial restrictions of learning activities held in conventional face-to-face classrooms. VLEs are learning environments free from temporal and spatial constraints that use a web-based virtual space to ensure representational fidelity and facilitate learner interactions. VLEs are typically established on servers.

In a VLE scenario, learners can perceive a construction of identity and a sense of presence and copresence. VLEs provide learners with multimedia materials and can be paired with teaching strategies. According to teaching goals, models can be designed to provide learning activities that assist learners in completing learning tasks [1,2]. VLEs have the following characteristics. (1) VLEs are planned information spaces. (2) VLEs are social spaces in which teachers and students can interact through teaching and learning processes. (3) Information and social spaces can be presented using text and 2D or 3D virtual reality (VR) modes. (4) In a VLE, students can participate in learning activities and discuss the content of the virtual learning space with teachers. (5) VLEs can integrate various techniques and teaching methods to innovate teaching. (6) VLEs can be used in distance teaching or in reinforcing classroom-based learning activities [1-5].

With advancing technology, content that cannot be presented using conventional teaching methods has gradually been converted using VR capabilities to enhance student learning. VR offer students the virtual experience of being in an actual environment and is suitable for assisting learning for scholars, students, nursing personnel, and patients [6]. In VLEs, students can participate in learning activities using the internet. During the process, teachers can provide assistive learning tools, such as web-based exchange and discussion, web-based tests, uploaded files, assignment submission, peer discussion, peer assessment, grading, questionnaires, and learning-history tracking, thereby generating rich interactive learning experiences [1,2,7].

Hodgson et al [8] used interactive VR lesson plans to support discussion and teaching, discovering that 65% of study participants reported that using VR for case discussion could increase their learning interests and assist them in preparing for future clinical internship scenarios. For the field of nursing, Chiou et al [9] established a VR learning platform to simulate the clinical scenario medication administration. They stated that students exhibited interest in the learning process and improved self-learning efficacy. Ball [10] applied the VR 360 Photosphere environmental platform experimentally, determining its ability to reduce students' anxiety about actual clinical environments. Herault et al [11] used 360-degree VR videos to simulate patients with trauma for the teaching of nursing students. The videos were divided into topics such as introducing the medical team, admitting patients into the emergency department, inspecting patients, and monitoring patients' conditions after they have been stabilized. These 4 scenarios supported the learning of students and medical and nursing personnel. Using the number of interactions noted during video coding, the duration of viewing a video, and the questions and answers raised on the basis of a video, the researchers discovered that the students exhibited significant differences in their cognition and learning processes. Hodgson et al [8] developed VR videos on the basis of real-world cases in hospital settings. The VR scenarios involved the interaction between patients and the medical team. Students were immersed in an environment to which they did not usually have access, enabling learning ahead of time. The research results indicated that 65% of the participants reported that discussing VR-based cases increased their learning interests and prepared them for clinical work.

Through a scoping review, Fealy et al [12] explored the effect of using immersive VR in nursing and midwifery education and discovered that using VR for simulated scenario learning provided students with the opportunity for repeated learning, which enhanced students' care ability and confidence. Foronda et al [6] and Shorey and Ng [13] conducted systematic reviews to investigate the effect of virtual simulation teaching on nursing students, nurses, and nursing education. The results revealed that VR for simulated scenario learning could replace or supplement traditional nursing education, with the VR-based method effectively increasing students' cognition and knowledge, skills and performance, critical thinking, self-confidence, and learner satisfaction.

Students can learn from VR simulation scenarios that enable interaction. In this study, we conducted a literature review of domestic and foreign studies and discovered that few studies have explored the use of interactive VR learning and its effect on nursing students' nursing ability and willingness to serve older adults. This study explored self-evaluated nursing ability and willingness to care for older adults in nursing students after they used interactive VR to learn; the influencing factors were also examined. The results can be used to enhance nursing students' nursing ability in terms of older adult care.

The research questions (RQs) of the study are as follows. RQ1: What are nursing students' perceptions of their adoption of interaction-based VR learning? RQ2: What are the nursing students' perceptions of factors (eg, willingness to use VR learning materials for older adult assessment, cognitive load, and willingness to serve for older adult care) that affect the adoption of VR educational technologies?

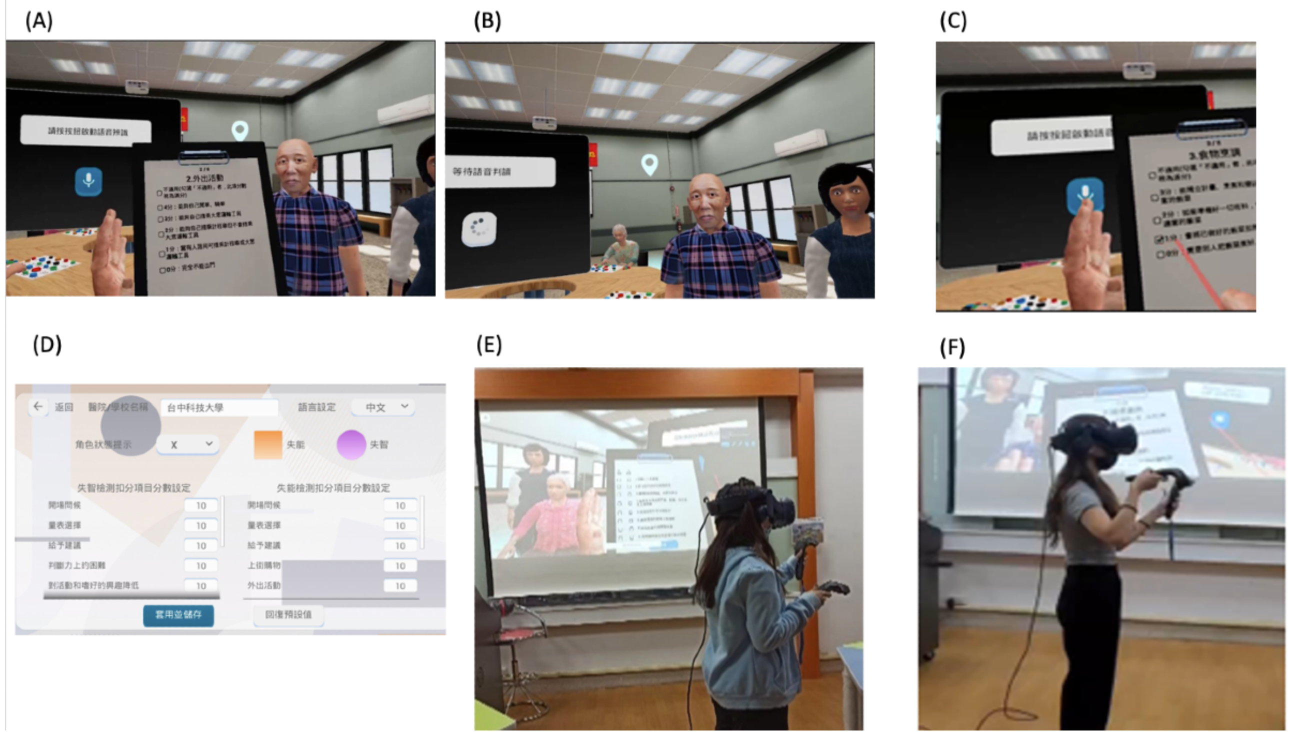
Methods

Research Design and Research Participants

This study adopted a cross-sectional correlation research design. A science and technology university in Taiwan acted as the recruitment site. Purposive sampling was used, and fourth-year students in the nursing department of a 5-year program were recruited as research participants, with those who had suspended their studies excluded. After the participants interacted with the VR-based older adult care assessment system, they completed a questionnaire survey. G*Power software (version 3.1.9.2; Heinrich-Heine-Universität Düsseldorf) was used to estimate the number of research samples. We set the statistical power as .8, type I error (α) as .05, and effect size as .3 (moderate effect). We identified 8 independent variables in this study. The calculation results indicated that the study required a sample size of 121; a total of 130 nursing students were recruited.

The research participants were enrolled in an older adult nursing course. In addition to classroom learning, they were instructed to use interactive VR lessons to experience older adult care. The VR lesson plan consisted of 2 units, namely the Ascertain Dementia-8 assessment and Instrumental Activities of Daily Living scale (IADLs). In the VR scenario, the students could interact with several older adults. The students could choose suitable assessment scales according to the older adults' conditions. For example, if an older adult or primary caregiver reported a decline in the older adult's memory function, then the student could select the Ascertain Dementia-8 assessment to assess the presence of early-onset dementia. If an older adult had reduced activity functions, then the IADLs could be selected. Using voice recognition and a VR images scale, the students could check the correct answers to scenario-based questions. A full test score of 100 was possible, with 60 representing the passing score. The detailed VR operation process is illustrated in Figure 1.

Figure 1. Virtual reality (VR) scenario. (A) Selecting a seated male or female older adult. (B) A caregiver was seated at the older adult's side. The caregiver could assist in answering questions that the older adult could not answer. (C) The assessment checklist was displayed as a virtual image; users could check the assessment items. (D) Backstage scoring system. Each assessment item (eg, Instrumental Activities of Daily Living scale items including ability to use telephone, shopping, food preparation, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances) was scored; the full score was 100. (E) and (F) Nursing students engaging in VR learning.



Research Instruments

An anonymous structured questionnaire was used for data collection. All research instruments were applied under the developer's consent. The scales were described as follows.

Personal Attributes and Demographic Information

We composed this part of the questionnaire through referencing the literature. Personal attributes consisted of age, sex, education level, and experiences with using VR to learn.

Willingness to Use VR Learning Materials for Older Adult Care and Assessment

We referenced the scale based on the technology acceptance model developed by Davis and Venkatesh [14], revising this scale to consist of perceived usefulness (6 items), perceived ease of use (3 items), attitude intention to use technologies (3 items), and perceived flexibility (3 items) regarding self-assessed VR-based older adult care learning materials. A 5-point Likert scale was used for assessment, comprising the options of *strongly disagree*, *disagree*, *neutral*, *agree*, and *strongly agree*.

Cognitive Load Scale for Using VR-Based Learning Materials for Older Adult Care and Assessment

Referencing Hwang et al [15] and Paas et al [16], we developed a cognitive load scale consisting of 2 dimensions, namely mental load and mental effort. Mental load was used to assess the perceived burden generated for nursing students when they complete the VR-based older adult care learning tasks. Mental effort was applied to evaluate the degree of cognition and amount of resources required by the nursing students when they complete the VR-based older adult care learning tasks, thereby facilitating the measurement of the perceived difficulty of the learning materials and tasks, the formats in which learning materials were presented, and the students' feelings about the explanation methods. A 5-point Likert scale was used for assessment, comprising the options of *strongly disagree*, *disagree*, *neutral*, *agree*, and *strongly agree*.

Nursing Students' Service Willingness Scale Regarding Older Adult Care

For the nursing students who used the VR lesson to learn to assess older adults, we used a scale to assess their willingness to serve older adults. The questionnaire design referenced that developed by Hsieh et al [17]. This willingness to serve older adults scale comprised 15 items rated on a 5-point Likert scale, ranging from *strongly disagree* to *strongly agree*; the higher the score, the greater the student's willingness to serve older adults. All questionnaire items were direct items. Experts were invited to modify the items to ensure construct validity.

Questionnaire Reliability and Validity

Validity

To ensure the content validity and expert validity of the questionnaire, we invited 3 nursing professors in departments related to older adult care and 2 industry experts to review the adequacy of the content of each scale in the questionnaire. We referenced Polit and Beck [18], who suggested a calculation method for content validity indicators in which items scored higher than 3 by experts are retained. After calculating the percentage, we determined that the content validity index of the willingness to use VR learning materials for older adult care and assessment was .98, that of the cognitive load scale for using VR-based older adult care learning materials was .96, and that of the nursing students' willingness to serve older adults scale was .99. Each scale exhibited favorable content validity.

Reliability

Cronbach α coefficient analysis was applied. The Cronbach α of the willingness to use VR learning materials for older adult care and assessment was .96, that of the cognitive load scale was .98, and that of the willingness to serve scale was .97. All scales exhibited favorable internal consistency.

Ethics Approval

Ethical approval for the study was obtained from the Human Research Ethics Council (CRREC-110-088). The researcher explained the research purpose and process to the participants. To ensure the protection of their personal rights, written informed consent was obtained prior to data collection.

Data Processing and Analysis

This study used the SPSS statistical software (version 23.0; IBM Corp) for data entry and statistical analysis. A P value of <.05 indicated statistical significance. Descriptive statistics involved using the percentage, mean, and SD to present distributions. The independent sample 2-tailed t test, one-way ANOVA, Pearson correlation coefficient, and stepwise regression were used for inferential statistics and analysis.

Results

Descriptive Variables of Research Participants

Of the 130 participants of this study, most (n=126, 96.9%) were women. Most of the participants were aged 19 years (n=66, 50.8%), followed by those aged 18 (n=62, 47.7%) and 20 (n=2, 1.5%) years. A total of 93.9% (n=122) of the participants had previously used VR, but none had used VR learning materials related to the care of older adults.

Participants' Use of VR-Based Learning Materials for Older Adult Care and Assessment and Their Nursing Ability

Regarding the overall research variables, the total mean score of cognitive load during learning was 2.49, that of willingness to use VR learning materials was 4.23, that of nursing ability was 4.25, that of willingness to serve older adults was 3.66, and that of the satisfaction toward the VR learning model was 4.14. The detailed data are presented in Table 1.

Table 1. Participants' use of virtual reality (VR) learning materials to assess older adult care and their nursing ability (N=130).

Research variable, secondary dimension	Secondary dimension, mean (SD)	Total, mean (SD)
Cognitive load during learning		2.49 (0.73)
Mental load	2.45 (0.74)	N/A[a]
Mental effort	2.52 (0.78)	N/A
Willingness to use VR learning materials		4.23 (0.47)
Perceived usefulness	4.42 (0.45)	N/A
Perceived ease of use	4.25 (0.61)	N/A
Willingness to use	3.96 (0.74)	N/A
Flexibility	4.29 (0.49)	N/A
Nursing ability		4.25 (0.48)
Basic and general educational competencies	4.32 (0.50)	N/A
Information management and application ability of nursing care case scenario	4.35 (0.54)	N/A
Health care policies, finance, and environmental capability	4.28 (0.62)	N/A
Care quality, case content safety, and leadership ability	4.18 (0.70)	N/A
Nursing practice ability	4.26 (0.49)	N/A
Preventive health care ability	4.22 (0.54)	N/A
Teamwork ability	4.09 (0.72)	N/A
Risk and quality management ability	3.26 (0.75)	N/A
Ethical ability	3.38 (0.65)	N/A
Willingness to serve older adults	N/A	3.66 (0.40)
Satisfaction toward the VR learning model	N/A	4.14 (0.52)

[a]N/A: not applicable.

Difference Analysis of Demographic Data and Research Variables

The independent sample 2-tailed *t* test was used to explore whether sex-based differences were present among the 4 variables of cognitive load during learning, willingness to use VR learning materials, nursing ability, and willingness to serve older adults; Levene test with equal variance was used to obtain the *F* test values of the 4 aforementioned variables, which were 4.13, .01, .34, and 5.07, respectively. Among them, cognitive load during learning and willingness to serve older adults had *P* values of <.05. Next, the *t* value and significance were used for data analysis. The *t* values of the 4 variables of cognitive load during learning, willingness to use VR learning materials, nursing ability, and willingness to serve older adults were .92, 1.52, 1.23, and –14.53, respectively. Only the *t* value of willingness to serve older adults exhibited a significant difference (*P*<.001). According to the mean values listed in Table 2, women's willingness to serve older adults was significantly higher than that of men (*P*<.001).

Table 2. Sex-based differences in research variables (N=130).

Dimension	Participants, n		Research variable, mean (SD)			*F* test		*t* test	
	Male	Female	Male	Female	*P* value	Value	*P* value	Value (*df*)	*P* value
Cognitive load during learning	4	126	3.00 (1.15)	2.47 (0.71)	.43	4.13	.04	.92 (128,3)	.43
Willingness to use VR[a] learning materials	4	126	4.58 (0.48)	4.22 (0.47)	.13	.01	.91	1.52 (128,3)	.13
Nursing ability	4	126	4.53 (0.54)	4.24 (0.47)	.22	.34	.56	1.23 (128,3)	.22
Willingness to serve older adults	4	126	3.10 (0.04)	3.68 (0.39)	<.001	5.07	.03	–14.53 (128,43)	<.001

[a]VR: virtual reality.

Correlation Analysis of Cognitive Load During Learning, Willingness to Use VR Learning Material, Nursing Ability, and Willingness to Serve Older Adults

According to the analysis results summarized in Table 3, the correlation coefficient of cognitive load during learning and willingness to serve older adults was –.374 (*P*<.001), indicating that these 2 variables were significantly and negatively correlated. The correlation coefficient of willingness to use VR learning materials and nursing ability was .693 (*P*<.001), indicating that these 2 variables were significantly and positively correlated. The correlation coefficient of willingness to use VR learning materials and willingness to serve older adults was .274 (*P*<.001), indicating that these 2 variables were significantly and positively correlated.

Table 3. Correlation analysis.

Research variable	Cognitive load during learning	Willingness to use VR[a] learning materials	Nursing ability	Willingness to serve older adults
Cognitive load during learning				
r	1	—[b]	—	—
P value	—	—	—	—
Willingness to use VR learning materials				
r	–.122	1	—	—
P value	>.05	—	—	—
Nursing ability				
r	–.006	.693	1	—
P value	.94	<.001	—	—
Willingness to serve older adults				
r	–.374	.274	.138	1
P value	<.001	<.001	>.05	—

[a]VR: virtual reality.

[b]Not applicable.

Regression Analysis of Willingness to Use VR Learning Materials and Cognitive Load During Learning on Willingness to Serve Older Adults

We applied regression analysis, and the model variance analysis results in Table 4 indicated that the overall regression model reached a significant level (F_2=15.133, *P*<.001), indicating that the overall regression model was statistically meaningful. After adjustment, the coefficient of determination was .180. Following the *F* test, we conducted an analysis of the regression coefficients of the predictor variables. The results revealed that the standardized regression coefficient (β) of willingness to use VR learning materials was .23 (t_2=2.89, *P*=.005), reaching a significant level; the β of cognitive load during learning was −.35 (t_2=–4.30, *P*<.001), also reaching a significant level. The standardized regression coefficient represented the amount of variance explained by the individual predictor variables for the dependent variables.

Table 4. Regression analysis of willingness to use virtual reality (VR) learning materials and cognitive load during learning on willingness to serve older adults. The adjusted R^2 was 0.18 (F_2=15.13, *P*<.001).

Model	Unstandardized coefficient, B estimation value (SE)	Standardized coefficient beta distribution	*t* test (*df*)	*P* value
Constant	3.30 (.32)	.32	10.36 (2,127)	<.001
Willingness to use VR learning materials	.19 (.07)	.23	2.89 (2,127)	.005
Cognitive load during learning	–.19 (.04)	–.35	–4.30 (2,127)	<.001

Discussion

Participants' Use of VR Learning Materials for Assessing Older Adult Care and Nursing Ability Under Personal Attributes

Among the research participants, 96.9% were women, 50.8% were aged 19 years, and 93.9% had previously used VR but not VR learning materials related to the care of older adults. This result indicates that VR has been widely applied in daily life but little older adult care learning materials had incorporated VR, resulting in few opportunities for students to learn and experience this immersive technology. The overall learning satisfaction of the students using VR learning materials to assess older adult care was high, a result that is in line with those of the systematic literature review of Gasteiger et al [19].

Under the dimension of willingness to use VR learning materials, perceived usefulness scored the highest among all aspects. This result is similar to that of related studies [20-22], indicating that using VR to assist learning reinforced the cognitive level of learners and assisted them in their learning. Regarding the nursing ability dimension, information management and application ability to care for case patients scored the highest among all aspects, indicating that through engaging with the interactive VR scenario, learners' ability to perceive and respond to scenario-based problems was enhanced. The participants could use voice recognition to respond and select the correct care method. The learning process was valuable for the participants' future case management ability, a result echoing those of other studies [22,23].

Significant Correlation Factors of Cognitive Load During Learning, Willingness to Use VR Learning Materials, Nursing Ability, and Willingness to Serve Older Adults

This study revealed sex-based differences in the participants' willingness to serve older adults, with women being significantly more willing to do so than did men. This result may be attributable to the nursing department being composed largely of women, and thus their willingness to care was higher than that of men. This result is in line with that of Guo et al [24].

The mean score of cognitive load during learning in this study was low, reflecting that during the research process, the older adult care assessment learning materials were not perceived as difficult or burdensome by the learners. If participants can be equipped with relevant older adult care knowledge in the classroom before experiencing VR, their cognitive load during learning can be reduced. Notably, cognitive load during learning and willingness to serve older adults were negatively correlated. This result indicated that when teachers choose learning materials, in addition to making selections according to the teaching objectives and content of the professional course, they must also consider the difficulty and appropriateness of the content. During the students' learning process, teachers must adjust the course content according to the learners' cognitive load, thereby increasing learners' learning effectiveness and their willingness to care for older adults. This finding is consistent with those of other studies [17,25,26].

Willingness to use VR learning materials and nursing ability were positively correlated, demonstrating the essentiality of the vividness of the learning environment. Through the use of VR to present a vivid scenario of caring for older adults, the nursing students' ability to provide professional nursing care to older adults was enhanced. From the positive feedback scenario of interactive VR, the opportunities for nursing students to interact with older adults were increased, which reinforced the students' willingness to serve older adults. This research result is in line with those of related studies [21,27-30].

Critical Factors Influencing Willingness to Serve Older Adults

This study discovered that willingness to use VR learning materials and cognitive load during learning were critical factors influencing willingness to serve older adults. This result indicated that engaging in the interactive VR scenario increased the students' willingness to use such materials. Additionally, with VR supporting conventional classroom teaching, students may repeatedly practice older adult care scenarios, allowing them to become familiar with the relevant knowledge on a cognitive level. They can engage in learning without worrying about making mistakes and harming older adults. Thus, students' learning load was reduced, and their problem-solving ability and self-confidence increased. These results are consistent with those of other studies [17,21,27,29-31].

Studies of willingness to serve older adults [10,13,17,24,32,33] have reported that through learning to interact with older adults, nursing students can observe older adults' verbal and nonverbal cues, with such interaction increasing their willingness to serve and care for older adults. This study used VR learning materials, and the results revealed that through the VR simulation scenario, the opportunities for students to interact with older adults were increased. Learning through VR scenarios can reduce students' anxiety when communicating with older adults in a real-world context, thereby increasing students' willingness to serve older adults.

Limitations

This study had some limitations. The respondents provided subjective responses, which could sometimes obscure their actual intention, and more male participants should have been included in the study. Moreover, this study was a quantitative study, which increased the difficulty of understanding the nursing students' willingness to serve older adults.

Conclusions

This survey of 130 preregistered nurses explored factors affecting their willingness to serve older adults. The most influential factors were willingness to use VR learning materials and cognitive load during learning, both of which can be enhanced through older adult care–related courses and practical experience. Nurses play a critical role in the care of older adults, and courses on older adult care are thus crucial for developing sufficient professional human resource capacity. We recommend that VR case scenarios about older adult nursing assessment be incorporated into in-service education. Through repeated practice using these scenarios, nurses' willingness and ability to care for and serve older adults can increase. Longitudinal follow-up studies of recent nursing graduates (preregistered nurses) who had engaged in VR-based older adult care courses must be conducted to elucidate these courses' effects on nurses' older adult care competence and willingness to serve older adults.

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Authors' Contributions

PLH and YRW was responsible for the study idea and design. PLH were responsible for the drafting of the manuscript. TCH supported the technical detail problems of the virtual learning system. PLH performed the data collection. YRW and PLH performed the data analysis. PLH made critical revisions to the paper for important intellectual content. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

IADLs: Instrumental Activities of Daily Living scale
RQ: research question
VLE: virtual learning environment
VR: virtual reality

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Original Paper

Case-Based Serious Gaming for Complication Management in Colorectal and Pancreatic Surgery: Prospective Observational Study

Sophie-Caroline Schwarzkopf[1], BA, MD; Marius Distler[1,2], MHBA, MD; Thilo Welsch[1,3], MBA, MD; Grit Krause-Jüttler[1,4], PhD; Jürgen Weitz[1,2], MSc, MD; Fiona R Kolbinger[1,2,4], MD

[1]Department of Visceral, Thoracic and Vascular Surgery, University Hospital and Faculty of Medicine Carl Gustav Carus, TUD Dresden University of Technology, Dresden, Germany

[2]National Center for Tumor Diseases (NCT/UCC), Dresden, Germany; German Cancer Research Center (DKFZ), Heidelberg, Germany; Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology, Dresden, Germany; Helmholtz-Zen, Dresden, Germany

[3]Department of General, Visceral, and Thoracic Surgery, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

[4]Centre for Tactile Internet with Human-in-the-Loop (CeTI), TUD Dresden University of Technology, Dresden, Germany

Corresponding Author:
Fiona R Kolbinger, MD
Department of Visceral, Thoracic and Vascular Surgery, University Hospital and Faculty of Medicine Carl Gustav Carus, TUD Dresden University of Technology
Fetscherstrasse 74
Dresden, 01307
Germany
Phone: 49 351 458 ext 19624
Email: fiona.kolbinger@uniklinikum-dresden.de

Abstract

Background: The potential risk and subsequent impact of serious complications after pancreatic and colorectal surgery can be significantly reduced through early recognition, correct assessment, and timely initiation of appropriate therapy. Serious gaming (SG) is an innovative teaching method that combines play with knowledge acquisition, increased concentration, and quick decision-making and could therefore be used for clinically oriented education.

Objective: This study aims to develop a case-based SG platform for complication management in pancreatic and colorectal surgery, validate the application by comparing game courses of various professional groups in the health care sector, and test the acceptance of the developed platform in the context of clinical education by measuring levels of usability and applicability within the framework of a validity and usefulness analysis.

Methods: In this observational trial, a novel SG for management of postoperative complications was developed and prospectively validated in a cohort of 131 human caregivers with varying experience in abdominal surgery. A total of 6 realistic patient cases were implemented, representing common complications after pancreatic and colorectal surgery. Cases were developed and illustrated using anonymized images, data, and histories of postoperative patients. In the prospective section of this study, following a brief case presentation, participants were asked to triage the virtual patient, make an initial suspected diagnosis, and design a 3-step management plan, throughout which the results of selected diagnostic and therapeutic actions were presented. Participants' proposed case management was compared to ideal case management according to clinical guidelines. Usability, applicability, validity, and acceptance of the application were assessed using the Trier Teaching Evaluation Inventory as part of a noncomparative analysis. In addition, a comparative analysis of conventional teaching and learning formats was carried out.

Results: A total of 131 cases were answered. Physicians selected more appropriate therapeutic measures than nonphysicians. In the Trier Teaching Evaluation Inventory, design, structure, relevance, timeliness, and interest promotion were predominantly rated positively. Most participants perceived the application to be superior to conventional lecture-based formats (training courses, lectures, and seminars) in terms of problem-solving skills (102/131, 77.9%), self-reflection (102/131, 77.9%), and usability and applicability (104/131, 79.4%).

Conclusions: Case-based SG has educational potential for complication management in surgery and could thereby contribute to improvements in postoperative patient care.

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KEYWORDS

Serious game; surgical education; clinical reasoning; medical education; postoperative complications; educational games; computer-based learning; colorectal surgery; decision-making; pancreatic surgery

Introduction

Advanced inflammatory [1] or malignant [2,3] diseases of the pancreas or colorectum usually require surgical intervention. Unpreventable postoperative complications occur in up to every second abdominal surgery due to the severity and complexity of the procedure and patients' general frailty [4,5]. Correct and rapid classification of symptoms is essential for the recognition and treatment of postoperative complications [6] such as postpancreatectomy hemorrhage [7], a potentially life-threatening complication after pancreatic surgery [8]. In such situations, misjudgments are directly associated with increased morbidity and mortality [2]. As the risk, severity, and subsequent impact of postoperative complications could be significantly reduced through early recognition, correct assessment, and timely initiation of appropriate therapy, the training of situation awareness and decision-making processes has the potential to translate into manifest clinical benefit [9].

In clinical practice, physicians face challenges related to rapidly changing health care systems and the need to constantly keep up with scientific advances [10]. Outdated doctrines can result in suboptimal care and medical errors [11]. Therefore, the establishment of new didactic formats can contribute to the maintenance of high standards, prove the effectiveness of innovative methods, and gain user acceptance [12,13]. Clinically oriented education aims to strengthen the theoretical, practical, and communication skills of medical staff and to prepare and motivate them for lifelong continuing training [14]. Various teaching methods with distinct characteristics can be combined to best achieve these goals [13,15]. Serious gaming (SG) is an innovative teaching method that combines play with knowledge acquisition, increased concentration, and quick decision-making [16,17]. The strengths of SG lie in the acquisition and subsequent transfer of procedural skills as well as declarative knowledge [18]. In addition, SG is suitable for teaching the peculiarities of individual cases, such as gender- or ethnicity-specific disease patterns, thus increasing awareness and raising consciousness. Recent evidence suggests that by implementing these aspects, both student education per se and the quality of patient care can be improved [19]. Traditionally, medical teaching takes place in person and offers relatively little interaction between students and teachers. During the COVID-19 pandemic, the need to digitize and restructure established formats has grown substantially, and both educators and students have realized that web-based teaching is not only feasible but also offers many advantages and opportunities, including independence in place and time and the promotion of cooperative learning [20]. Digital education options offer the potential to integrate recent evidence, contributing to lifelong learning and lasting knowledge. Considering the necessity not only to generate and make knowledge available but also to manage it, the potential of digital education has not yet been exhausted [21].

This project aims to develop and validate a scalable, case-based SG platform for clinical education of postoperative management targeting health care professionals throughout different stages of training. Ultimately, the aim is to improve the quality of care for hospitalized patients by increasing health care professionals' capability to transfer knowledge to specific disease contexts and thus provide sensitized care.

Methods

Structure and Development of the SG

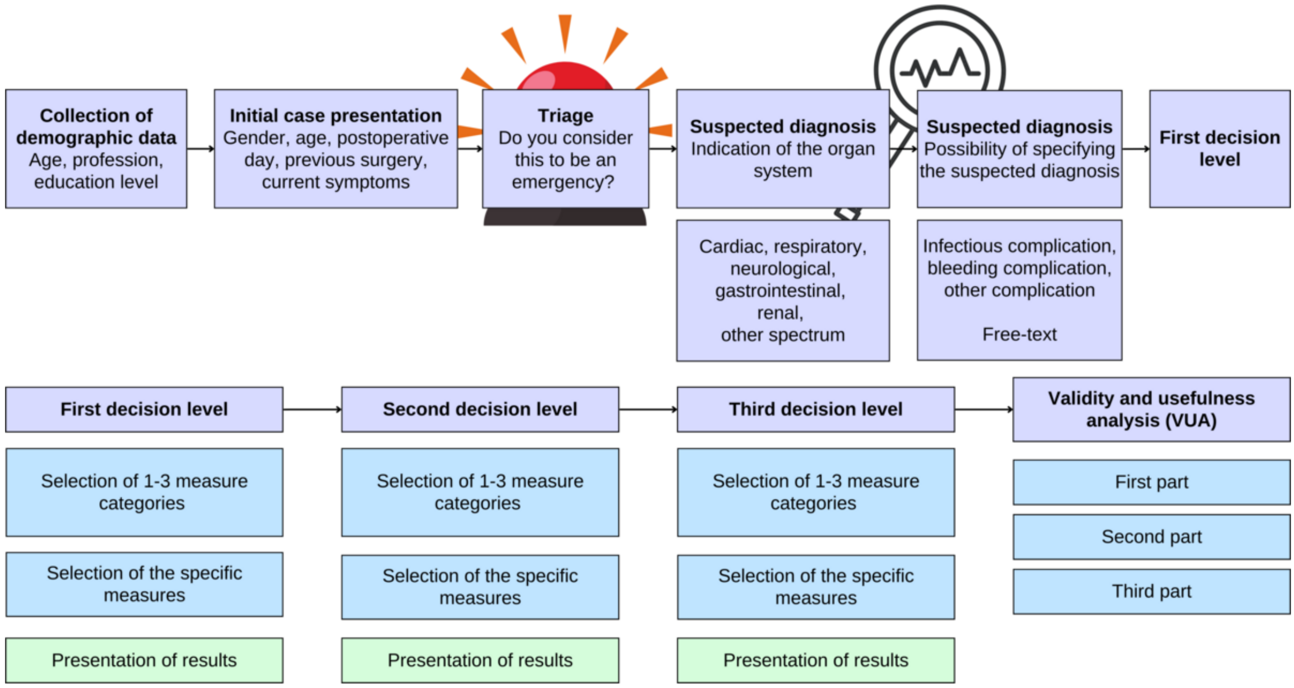
The SG was designed as an anonymized, prospective, open, observational study based on a voluntary web-based survey constructed with REDCap (Research Electronic Data Capture; Vanderbilt University) [22]. Participants included hospital staff with patient contact and medical students in German-speaking countries, and the study was carried out in German. A total of 6 independent SG cases were implemented. The cases represented complications after pancreatic surgery (postpancreatectomy hemorrhage or postoperative pancreatic fistula [POPF]), colorectal surgery (anastomotic leakage or mechanical ileus), and general postoperative complications (eg, stroke, wound infection, and COVID-19 infection). These 6 cases of postoperative complications were selected based on their rate of occurrence [23] and severity, as well as their potential to identify and respond to early clinical symptoms. Initial case selection took place with a drop-down menu that included brief case descriptions (ie, "4th postoperative day after ileostomy reversal, muscular defense" for the case on anastomotic leakage).

The SG platform allowed participants to plan and carry out diagnostic and therapeutic measures for fictitious postoperative patients who presented with new symptoms. After selecting 1 or more measures, participants were presented with the results of the respective diagnostic or therapeutic actions and could adjust their further actions accordingly. A total of 108 diagnostic and therapeutic measures, grouped into 16 measure categories, were available per selection level and case. Multimedia Appendix 1 gives an overview of measures and measure categories.

For case illustration, completely anonymized photographic images of visible disease symptoms or signs, laboratory parameters, imaging data, or other diagnostic tests of patients from the Department of Visceral, Thoracic, and Vascular Surgery at the University Hospital Carl Gustav Carus Dresden who underwent pancreatic or colorectal surgery between 2015 and 2021 were used.

For general statistical evaluations, demographic data were collected at the beginning of each game case. The following initial case presentation provided patient information. Subsequently, participants were asked to make a suspected diagnosis and select initial diagnostic and therapeutic measures from a list. The measure results were presented directly after selection. This was followed by 2 more decision levels, with the first level representing the acute, the second the definitive, and the third the long-term management of the suspected complication (Figure 1).

Figure 1. Serious gaming case structure. Introductory part: from the collection of demographic data of the participant to the first decision level. Main part includes 3-step case management and validity and usefulness analysis.



Between levels, participants were asked to change or narrow down their current suspected diagnosis, mandatorily indicating a suspected affected organ system and offering further specification of the complication mechanism and the complication itself. Furthermore, it was recorded whether the participants considered the case at hand to be an emergency (binary question). Each case was concluded with a validity and usefulness analysis (VUA).

VUA Framework

The first part of the VUA was based on the Trier Teaching Evaluation Inventory (Figure 1). The second part allowed a comparison of the application to existing lecture-based teaching and learning. The third part enabled an evaluation of the expected knowledge gain in comparison with common theoretical or practical learning formats. Finally, the case was to be evaluated with a grade (1=best to 6=worst grade).

All answers were given by means of a fully verbalized, 5-point, balanced scale (eg, scale end points of the first part: "agree," "rather agree," "undecided," "rather disagree," and "disagree"; second and third part: "SG is superior," "SG is rather superior," "undecided," "SG is rather inferior," and "SG is inferior").

Participant Recruitment

Pilot-testing and evaluation of the SG took place from December 2021 to February 2022. We aimed to recruit a diverse cohort of health care professionals as potential users of our application. To this end, the SG was advertised through various channels, including direct email advertisements to medical and nursing staff of the University Hospital Carl Gustav Carus Dresden and students of the Medical Faculty Carl Gustav Carus Dresden, web-based portals of the Technical University Dresden, and direct information events. Participants not affiliated with the University Hospital Dresden were reached by email through appropriate mailing lists (eg, mail distribution lists of German clinics). Participants were recruited from the entire German-speaking area, and the study was carried out in German.

The prerequisite for participation was the ability to give informed consent and the informed consent itself. Only fully answered cases were included in the final analysis.

Ethical Considerations

This study was carried out in accordance with the Declaration of Helsinki and its later amendments. The Ethics Committee of the Technical University Dresden reviewed and approved this study (BO-EK-378072021). Before participation, all participants consented to anonymized data acquisition, data analysis, and publication of the results.

Game Process Evaluation and Statistical Analysis

The SG case itself and the subsequent VUA were evaluated separately. The general statistical evaluation comprised a descriptive evaluation of the participant cohort, an evaluation of processing times, and a comparative evaluation of differences in case duration and duration of processing time of individual management levels between occupational and educational groups using ANOVA. Initial and final suspected diagnoses were evaluated using descriptive statistics, with free-text statements classified as "correct," "incorrect," and "not specified." The results were displayed using frequency distributions by case and occupational group.

In order to analyze the appropriateness of management decisions, an ideal solution path was elaborated for each case, corresponding to a specific sequence of diagnostic and therapeutic measures. Besides this ideal solution path, 1 measure was defined as crucial for each SG case, that is, essential for the recovery of the fictitious patient, by 2 surgical experts with over 15 years of clinical experience in general and abdominal surgery (TW and MD). This therapeutic action was used to assess appropriate, exaggerated, and understated therapy escalation. The appropriateness of the selected therapeutic pathway was rated based on all clinical decisions made throughout the course of the SG case. These evaluations were based on valid German or European guidelines [7,24-26], expert opinions, and publications, as well as existing evidence on complication management in abdominal surgery, to ensure medical correctness and contextual coherence as well as a straightforward and realistic initial presentation. The ideal paths with the appropriate therapeutic measures for all cases as well as initial case presentations are presented in Multimedia Appendix 2, and measure categories and individual measures are presented in Multimedia Appendix 1. Final diagnoses had to be given in free-text format.

VUA results were summarized using descriptive statistics. Raw data were exported directly from REDCap [22] and are provided in Multimedia Appendix 3. The subsequent statistical analysis and illustration were performed using R software (R Foundation for Statistical Computing) [27], GraphPad Prism (version 9; Dotmatics) [28], and Canva (Canva Inc) [29]. Significance in groupwise comparisons was assessed using ANOVA (for numerical variables) and the Fisher exact test (for categorical variables), with $P<.05$ considered statistically significant.

Results

Participant Cohort and Processing Time

A total of 131 SG cases were completed in the desktop-based SG application (Multimedia Appendix 4). Overall, the participant cohort reflected the entire spectrum of health care professionals with the largest proportions; 57% (74/131), 15% (20/131), and 14% (18/131) of cases were completed by medical students, nursing and other clinical staff with patient contact, and experts, respectively (Multimedia Appendix 5). The age group of 21-25 years was most frequently represented (45/131, 34%), and the average age of the participants was 30.8 (SD 10.4) years (Multimedia Appendix 4). On average, a single SG session took 11 minutes and 46 seconds. No significant differences regarding the duration were found between cases (P=.68; Multimedia Appendix 6), age (P=.46; Multimedia Appendix 4), or occupational groups (P=.33; Multimedia Appendix 5).

In addition, a cross-case analysis was performed comparing the time needed per measure stage, which was defined from the beginning of the selection of the measure top categories per stage until the presentation of the results of the respective stage. The analysis showed a significant difference in processing time. On average, participants needed 1 minute and 25 seconds for the first stage, 53 seconds for the second stage, and 30 seconds for the third stage (all $P<.001$; Table 1).

Table 1. Average duration of serious gaming cases with respect to management level.

3-step case management	Average duration	*P* value
Acute management	1 min 25 s	<.001
Definitive management	53 s	<.001
Long-term management	30 s	<.001

SG Cases Discriminate Between Professions and Surgical Expertise

The implemented SG cases were of varying difficulty and were capable of discriminating between varying surgical expertise. A total of 121 (92.4%) out of 131 participants selected the correct organ system at the initial assessment (Figure 2). When other optional specification levels were used, the result was predominantly correct (correct specification of complication mechanism: 77/88, 88%; Figure 3; correct specification of exact complication: 29/33, 88%; Figure 4).

All participating experts and board-certified surgeons correctly selected the suspected organ system after the initial patient presentation (Figure 2), demonstrating that case presentations provided sufficient information for surgical experts to conclude relevant details about the virtual case. In contrast, medical students and nonphysician caregivers selected incorrect organ systems more frequently. This demonstrates that varying surgical expertise was mirrored by the differences in correct case interpretation. The final diagnoses given at the end of the game also correlated with the participants' level of training. In the final step of each case, physicians gave the correct diagnosis in all cases (Multimedia Appendices 7-12).

Based on the results of medical students and other staff, the cases varied in difficulty. The COVID-19 and wound infection (Multimedia Appendix 11) case was ultimately correctly interpreted by all participants, and most participants correctly diagnosed the virtual patients with stroke (16/19, 84%; Multimedia Appendix 8) and ileus (9/10, 90%; Multimedia Appendix 10). In contrast, sentinel hemorrhage (Multimedia Appendix 12), POPF (Multimedia Appendix 9), and 2 pancreatic surgery-specific complications were misspecified by 67% (12/18) and 43% (6/14) participants, respectively, with marked differences between physicians and other participant groups.

Figure 5 summarizes the case-specific therapy escalation. Overall, the assessment of therapy escalation led to particular difficulties in case 3 (POPF) and 4 (mechanical ileus). Case 5 (COVID-19 and wound infection), on the other hand, was correctly assessed by the great majority (17/19, 89%) of participants.

Figure 2. Interprofessional evaluation of the initially specified suspected diagnosis by suspected organ system across all serious gaming cases. Specification of the organ system was mandatory, while specification of complication mechanism and exact complication were voluntary.

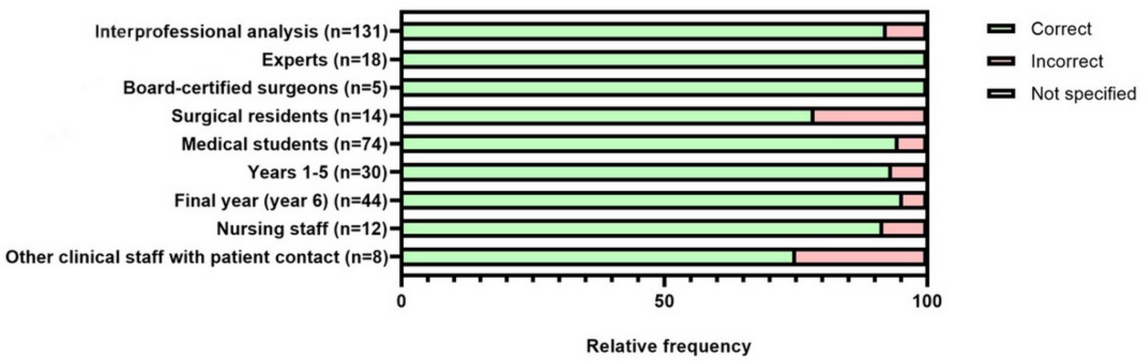


Figure 3. Interprofessional evaluation of the initially specified suspected diagnosis by suspected complication mechanism across all serious gaming cases. Specification of the organ system was mandatory, while specification of complication mechanism and exact complication were voluntary.

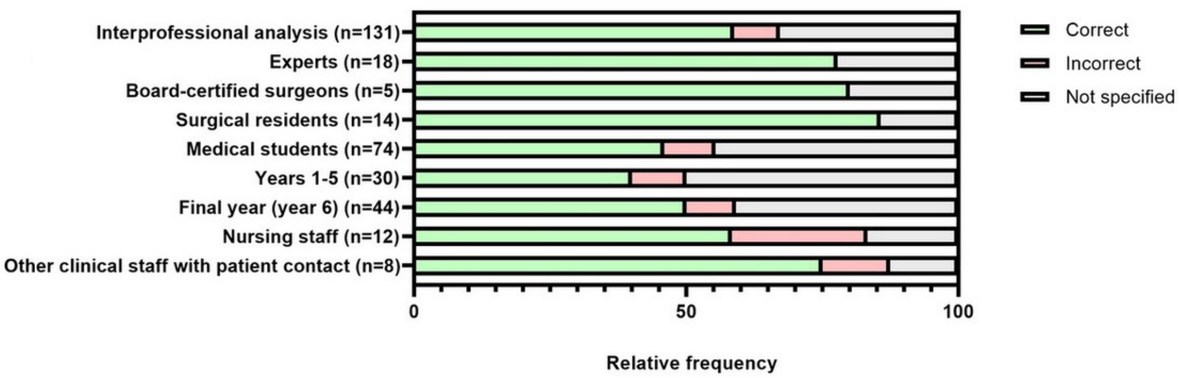


Figure 4. Interprofessional evaluation of the initially specified suspected diagnosis by suspected exact complication across all serious gaming cases. Specification of the organ system was mandatory, while specification of complication mechanism and exact complication were voluntary.

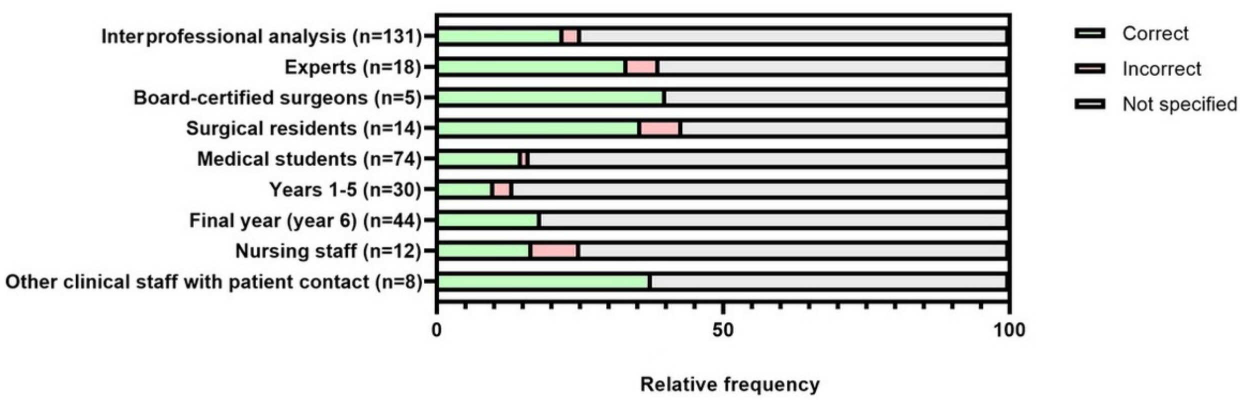
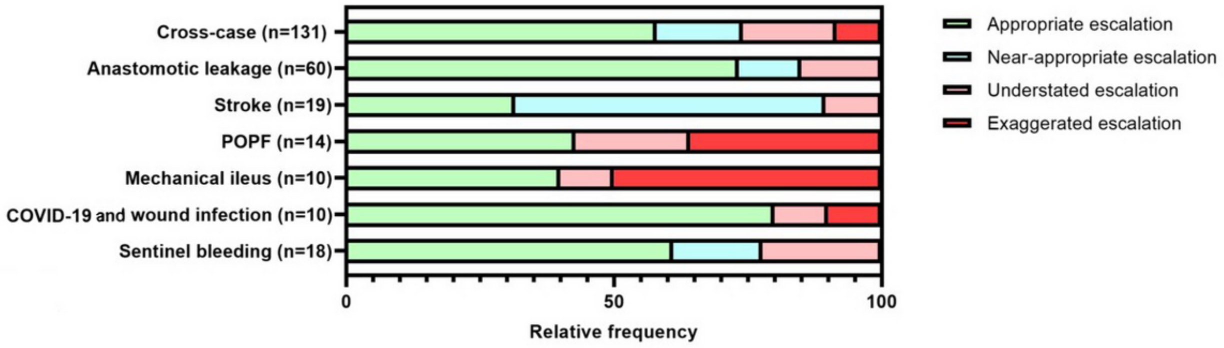


Figure 5. Case-specific evaluation of therapy escalation. In order to analyze the appropriateness of management, 1 therapeutic measure was defined as crucial for each serious gaming case based on valid guidelines. POPF: postoperative pancreatic fistula.



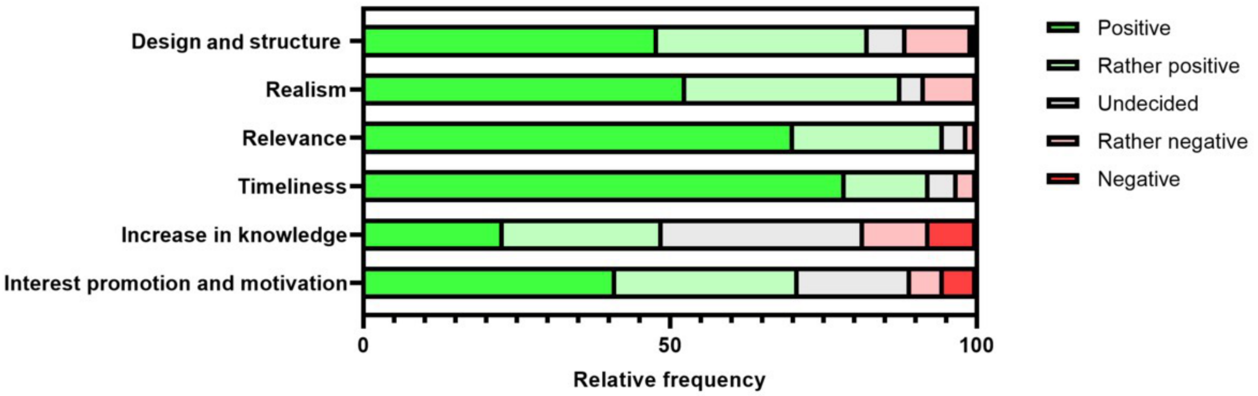
Multimedia Appendices 13-18 display the case-specific therapy escalation stratified by occupational and educational group.

SG Is Accepted by Health Care Professionals

The goal of the VUA was to determine how instructive and user-friendly participants perceived the case-based SG application to be. Overall, design, structure, realism, relevance, and timeliness were predominantly rated positively (Figure 6). Interest promotion and motivation for autodidactic workup and estimated increase in knowledge were rated lower compared to the aforementioned dimensions. The detailed results of the VUA are summarized in Multimedia Appendix 19.

Most participants perceived case-based SG to be superior to conventional lecture-based learning and teaching formats (training courses, lectures, and seminars) in terms of increasing problem-solving skills (53/131, 41% perceived it superior; 49/131, 37% perceived it rather superior), self-reflection (50/131, 38% perceived it superior; 52/131, 40% perceived it rather superior), and usability and applicability (55/131, 42% perceived it superior; 49/131, 37% perceived it rather superior). Overall, 74 (57%) out of 131 participants perceived the SG application to be superior (26/131, 20% perceived it superior; 48/131, 37% perceived it rather superior) to these conventional teaching formats with regard to the gain of theoretical competencies, while 26 (20%) out of 131 participants did not see any difference. Overall, the case-based SG was rated "good" ("2") or better in 78% (102/131) of cases (Multimedia Appendix 19).

Figure 6. Results of the noncomparative validity and usefulness analysis. After completing a serious gaming case, participants were asked to rate it across several dimensions using a 5-point scale.



Discussion

Principal Findings

This study presents a new didactic implementation of case-based learning (CBL) as a SG for medical education in the field of identification of surgical complications and validates this implementation in a representative cohort of participants with varying medical experience and expertise. Overall, the case-based SG format was well-accepted, and the majority of participants rated the platform as superior to traditional formats in terms of problem-solving skills, self-reflection, usability and applicability.

Comparison to Previous Work

Postoperative complications are a part of the perioperative process that can only be prevented to a limited extent [9]. Timely recognition and straightforward treatment initiation are crucial to optimizing patient outcomes [2]. One limitation of conventional didactic methods lies in the poor transfer of theory into practice [30]. SG has the potential to markedly improve this transfer by teaching medical decision-making, training a systematic and complete approach, building up automatisms, and transferring these into a virtual action [31].

Complications after surgical interventions are common and closely linked to higher morbidity and mortality [2,3]. Despite knowledge about predisposing factors and early warning signs, clinical management guidelines generally leave room for individualized decisions that take clinical circumstances into consideration. In terms of such diagnostic and therapeutic decisions (ie, diagnostic computer tomography scan or application of antibiotics), a recent large-scale study [32] has compared a decision-making algorithm to standard care in the context of postoperative complications after pancreatic resection. Here, the algorithm-directed initiation of diagnostic and therapeutic measures resulted in a significantly reduced 90-day mortality rate, indicating that logic-triggered decision-making has the potential to improve clinical outcomes in postoperative care. The presented case-based SG platform could contribute to an integration of such knowledge and "quasi-algorithmic" decision-making into medical education, which could result in improved identification of early warning signs of serious complications after major abdominal surgery.

In aviation and military training, simulations (ie, flight simulators) have been an integral part of training curricula for over a century [33]. Adapted to the growing demand for digital and combined teaching concepts [34], the interest in SGs is currently growing in the field of medicine too [12]. Cases present a combination of theory and practice and can prepare users for clinically acute and challenging situations, with growing evidence suggesting the effectiveness of CBL [35,36]. Medical SGs address different specialties (surgery [37], internal medicine [38], etc) and target groups (patients [39], physicians [40], nurses [41], and students [18]) and vary regarding the type of application (web-based [42], virtual, or augmented reality [43]). To date, no comparable case-based SG for complication management in surgery is available. Existing works in the field of surgery mostly aim at training laparoscopy or other specific practical skills [37] and focus less on cases requiring complex multilevel management.

SG facilitates training under near-realistic conditions without the risk of harming patients [44]. Moreover, it has the potential to raise awareness about medical errors and, therefore, ultimately, reduce health care use and costs. Specific and rare medical scenarios are reproducible, which is challenging to teach in theoretical curricula. The strengths of SG lay in building up strategic and analytical skills and to train decision-making. As such, better attitudes toward learning and increased enthusiasm for learning were reported in individuals taught with SG in comparison to those taught with a written script [36,45].

The proposed platform does not impose any requirements for the end device, facilitating mobile, time- and place-independent, and inexpensive usage. In contrast, existing SG applications often rely on equipment that is prone to failure, expensive to develop and implement, and has limited scalability and availability [46]. Our overall results add to the growing body of evidence that CBL and SG have the potential to increase learning fun, which are important precursors for motivation and success [47,48]. Upscaling of the platform through transfer into other medical specialties or inclusion of other professional contexts of patient care, as well as an adaptation to rapidly updating medical evidence, are possible extensions of this work that are being investigated in follow-up trials.

In line with these findings, participants perceived the proposed SG application to be superior to traditional learning formats such as lectures with regard to gaining clinical and problem-solving skills and empowerment for self-reflection as well as higher joy in learning.

Strengths and Limitations

The study results suggest that case-based digital SG could be a relevant addition to existing learning formats in the context of multimodal learning in medical education. The major strengths of the proposed SG application are its realism, topicality, and uncomplicated applicability and handling. The only dimensions of the VUA in which the SG platform was rated positive or superior in less than 50% of the cases were those of estimated increase in knowledge gain. These lower ratings in terms of subjectively perceived learning gains present a weakness of the SG format, which may be partially inherent to the methodology used. Rather than assessing concrete knowledge acquisition, we explored the subjective impact on learning. Future studies may gauge SGs' impact on learning through diverse methods, such as multiarm interventions comparing SG with traditional approaches and long-term assessments including multiple-choice questions, clinical scenarios, simulator-based performance, practical exams, and Objective Structured Clinical Examinations. Still, learning is characterized by an interplay of different modalities that complement each other.

The limitations of this study are mostly related to the study design. First, the generalizability of the results is limited since participation was voluntary. As a consequence, the validation of the presented case-based SG platform primarily included interested individuals. Due to the voluntary participation, the subgroup sizes were variable and, in some cases, small, rendering subgroup analyses impossible. These sources of bias could be eliminated through other modes of inclusion, that is, cohort inclusion in the context of mandatory classes or a cross-sectional study with mandatory participation, improving the representativity and homogeneity of subgroups. Second, the representation of selectable diagnostic and therapeutic measures in the form of a finite list could have introduced bias, as participants could be guided in both a favorable (ie, toward correct measures) and an unfavorable direction (ie, toward wrong measures). In the future, enhancement could be achieved by substituting drop-down menus with free-text fields. These would facilitate more individual responses without the risk of influencing participants' decision-making process. The results would therefore be more likely to mirror the unbiased thought process, but this process would make evaluation substantially more challenging. To provide quick and reliable feedback for free-text fields within a game, artificial intelligence–based language processing methods could be integrated to filter and categorize the free-text responses in terms of content [49,50], providing respective feedback. Additionally, a human expert review process could be connected with such automated feedback, which could be used in the case of difficulty classifying certain answers. Third, realistic conceptualization of cases was time- and labor-intensive and required an expert review process to guarantee case quality. Simplifying this procedure could be accomplished by implementing a standardized and user-friendly input interface for health care professionals, coupled with a structured and straightforward review process to guarantee medical accuracy and relevance. Third, our platform, similar to most other SGs in medical education, primarily analyzes knowledge gain, skill enhancement, attitudes, and satisfaction within a testing scope [12]. Future studies should venture an implementation attempt into real teaching with the aim to prove the effectiveness and clinical impact of the format and to map a learning curve after a longer period of participation.

Despite these limitations, this study introduces an innovative, scalable combination of case-based learning and SG with high educational potential, particularly in the context of clinical decision-making in the context of complication management in pancreatic and colorectal surgery.

Future Directions

Until now, medical SGs, including our platform, primarily analyze knowledge gain, skill enhancement, attitudes, and satisfaction within a testing scope [12]. Future studies should venture an implementation attempt into real teaching with the aim to prove the effectiveness and clinical impact of the format and to map a learning curve after a longer period of participation. To boost knowledge gained through SG, various extensions, like stronger game characteristics, could potentially be integrated into these continuing studies, such as a coaching simulated senior physician to request advice from during the game.

Conclusion

This study explores the use of SG in medical education, particularly for teaching surgical complication management. Using a desktop-based SG application, we assessed its effectiveness and acceptance among health care professionals. The findings reveal various strengths of the proposed case-based SG platform. The application presents real postoperative complications, allowing users to enhance their decision-making skills without risk. This approach enhances early complication identification, which could ultimately contribute to the sensitization of caregivers and better patient care and outcomes after abdominal surgery.

Acknowledgments

The authors would like to thank all the study participants who took part in the validation trial. This work has been funded by the German Research Foundation DFG within the Cluster of Excellence EXC 2050: “Center for Tactile Internet with Human-in-the-Loop (CeTI)” (project number 390696704). Furthermore, FRK received funding from the Medical Faculty of the Technical University Dresden within the MedDrive Start program (grant 60487) and from the Joachim Herz Foundation (Add-on Fellowship for Interdisciplinary Life Science).

Data Availability

The case descriptions and ideal clinical pathways are available in Multimedia Appendix 2. Participant data gathered in the context of this work are available in Multimedia Appendix 3.

Authors' Contributions

S-CS contributed to conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, software, validation, visualization, writing the original draft. MD and TW were involved in conceptualization, funding acquisition, investigation, resources, supervision, validation, writing, reviewing, and editing. GK-J contributed to funding acquisition, project administration, writing, reviewing, and editing. JW was involved in funding acquisition, resources, supervision, writing, reviewing, and editing. FRK contributed to conceptualization, formal analysis, funding acquisition, investigation, methodology, project administration, software, supervision, validation, visualization, writing the original draft.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Measure categories and individual measures did not differ between cases and stages.
[DOCX File , 17 KB - games_v11i1e44708_app1.docx]

Multimedia Appendix 2
Initial serious gaming case presentations and ideal serious gaming case pathways with appropriate therapy escalation in bold face and near-appropriate therapy escalation in last row.
[DOCX File , 17 KB - games_v11i1e44708_app2.docx]

Multimedia Appendix 3

Anonymized participant data.
[XLSX File (Microsoft Excel File), 490 KB - games_v11i1e44708_app3.xlsx]

Multimedia Appendix 4
Average duration of serious gaming cases about age group.
[DOCX File , 23 KB - games_v11i1e44708_app4.docx]

Multimedia Appendix 5
Average duration of serious gaming cases about professional group or educational level.
[DOCX File , 23 KB - games_v11i1e44708_app5.docx]

Multimedia Appendix 6
Average duration of serious gaming cases about selected case.
[DOCX File , 23 KB - games_v11i1e44708_app6.docx]

Multimedia Appendix 7
Interprofessional evaluation of the final suspected diagnosis. Case: anastomotic leakage.
[PNG File , 84 KB - games_v11i1e44708_app7.png]

Multimedia Appendix 8
Interprofessional evaluation of the final suspected diagnosis. Case: stroke.
[PNG File , 79 KB - games_v11i1e44708_app8.png]

Multimedia Appendix 9
Interprofessional evaluation of the final suspected diagnosis. Case: postoperative pancreatic fistula (POPF).
[PNG File , 81 KB - games_v11i1e44708_app9.png]

Multimedia Appendix 10
Interprofessional evaluation of the final suspected diagnosis. Case: mechanical ileus.
[PNG File , 80 KB - games_v11i1e44708_app10.png]

Multimedia Appendix 11
Interprofessional evaluation of the final suspected diagnosis. Case: COVID-19 or wound infection.
[PNG File , 85 KB - games_v11i1e44708_app11.png]

Multimedia Appendix 12
Interprofessional evaluation of the final suspected diagnosis. Case: sentinel bleeding.
[PNG File , 86 KB - games_v11i1e44708_app12.png]

Multimedia Appendix 13
Evaluation of correct therapy escalation (in brackets) by occupational group. Case: anastomotic leakage (laparotomy).
[PNG File , 92 KB - games_v11i1e44708_app13.png]

Multimedia Appendix 14
Evaluation of correct therapy escalation (in brackets) by occupational group. Case: stroke (lysis therapy [thrombolytics, eg, alteplase]).
[PNG File , 87 KB - games_v11i1e44708_app14.png]

Multimedia Appendix 15
Evaluation of correct therapy escalation (in brackets) by occupational group. Case: POPF (Computed tomography + intervention: drainage system). POPF: postoperative pancreatic fistula.
[PNG File , 87 KB - games_v11i1e44708_app15.png]

Multimedia Appendix 16

Evaluation of correct therapy escalation (in brackets) by occupational group. Case: mechanical ileus (stoma extension on fascia level).
[PNG File , 89 KB - games_v11i1e44708_app16.png]

Multimedia Appendix 17
Evaluation of correct therapy escalation (in brackets) by occupational group. Case: COVID-19 or wound infection (medical history and clinical examination).
[PNG File , 91 KB - games_v11i1e44708_app17.png]

Multimedia Appendix 18
Evaluation of correct therapy escalation (in brackets) by occupational group. Case: sentinel bleeding (laparotomy).
[PNG File , 94 KB - games_v11i1e44708_app18.png]

Multimedia Appendix 19
Complete validity and usefulness analysis.
[DOCX File , 16 KB - games_v11i1e44708_app19.docx]

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Abbreviations

CBL: case-based learning
POPF: postoperative pancreatic fistula
REDCap: Research Electronic Data Capture
SG: serious gaming (or serious game)
VUA: validity and usefulness analysis

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Original Paper

The Multidomain Metaverse Cancer Care Digital Platform: Development and Usability Study

Sunghak Kim[1], PhD; Timothy Jung[2], PhD; Dae Kyung Sohn[3], MD, PhD; Yoon Chae[1], MPH; Young Ae Kim[4], PhD; Seung Hyun Kang[5], BEng; Yujin Park[1], PhD; Yoon Jung Chang[1], MD, PhD

[1]Division of Cancer Control and Policy, National Cancer Center, Goyang, Republic of Korea

[2]Faculty of Business and Law, Manchester Metropolitan University, Manchester, United Kingdom

[3]Center for Colorectal Cancer, National Cancer Center, Goyang, Republic of Korea

[4]National Cancer Survivorship Center, National Cancer Center, Goyang, Republic of Korea

[5]Planning Division, Korea Smart Healthcare Association, Seoul, Republic of Korea

Corresponding Author:
Yoon Jung Chang, MD, PhD
Division of Cancer Control and Policy
National Cancer Center
323 Ilsan-ro, Ilsandong-gu
Goyang, 10408
Republic of Korea
Phone: 82 10 8729 5835
Email: eunice.ncc@gmail.com

Abstract

Background: As cancer treatment methods have diversified and the importance of self-management, which lowers the dependence rate on direct hospital visits, has increased, effective cancer care education and management for health professionals and patients have become necessary. The metaverse is in the spotlight as a means of digital health that allows users to engage in cancer care education and management beyond physical constraints. However, it is difficult to find a multipurpose medical metaverse that can not only be used in the field but also complements current cancer care.

Objective: This study aimed to develop an integrated metaverse cancer care platform, Dr. Meta, and examine its usability.

Methods: We conducted a multicenter, cross-sectional survey between November and December 2021. A descriptive analysis was performed to examine users' experiences with Dr. Meta. In addition, a supplementary open-ended question was used to ask users for their suggestions and improvements regarding the platform.

Results: Responses from 70 Korean participants (male: n=19, 27% and female: n=51, 73%) were analyzed. More than half (n=37, 54%) of the participants were satisfied with Dr. Meta; they responded that it was an interesting and immersive platform (n=50, 72%). Less than half perceived no discomfort when using Dr. Meta (n=34, 49%) and no difficulty in wearing and operating the device (n=30, 43%). Furthermore, more than half (n=50, 72%) of the participants reported that Dr. Meta would help provide non–face-to-face and noncontact services. More than half also wanted to continue using this platform in the future (n=41, 59%) and recommended it to others (n=42, 60%).

Conclusions: We developed a multidomain metaverse cancer care platform that can support both health professionals and patients in non–face-to-face cancer care. The platform was uniquely disseminated and implemented in multiple regional hospitals and showed the potential to perform successful cancer care.

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KEYWORDS

metaverse; virtual reality; cancer education; cancer care; digital health; cancer treatment; patient care; cross-sectional survey; digital health intervention

Introduction

Cancer is a major global public health concern. There were approximately 19.3 million new cancer cases and 10.0 million cancer deaths globally in 2020 [1,2]. In South Korea, there were nearly 250,000 and 80,000 of such cases, respectively, in 2019 [3]. Although this disease is closely related to significant psychosocial burdens, it can be cured through early diagnosis or effective cancer treatment [4]. Thus, effective cancer education and care, which can lead to appropriate diagnosis and treatment, are important for the successful management of the disease. The dissemination of knowledge to train health professionals has become vital, especially because the types, symptoms, and treatments of cancers have diversified [5]. In addition, as the implementation of traditional cancer care methods has become difficult owing to the spread of infectious diseases such as COVID-19, self-management and home care have become more critical [6,7]. Digital health care is emerging to rapidly diffuse knowledge and is essential for cancer care.

The rapid development of information and communication technologies has accelerated digital transformation in the health care field. The world is seeking to overcome hostile environments such as the crisis of a superaged society, the outbreak of new infectious diseases, and the disparity in medical resources through digital health care [8-10]. Several studies have revealed the effectiveness of broadly applying digital health care services, including mobile health, telehealth using wearable devices, big data analytics, and artificial intelligence, to prevent and treat various diseases and maintain health [11,12].

As the digital health care industry based on innovative and evolving computing technology is expanding, metaverse technologies (eg, virtual reality [VR], augmented reality [AR], mixed reality [MR], and extended reality [XR]) that make the virtual and real worlds converge and interact are drawing attention as playing a key role in the future of digital health care [13-15]. VR is a technology that allows people to experience the real-like world in a computer-generated virtual world. AR creates an interactive environment by overlapping virtual 2D or 3D objects with the real world. In VR, users are blocked from the real world and are fully immersed in a virtual environment. However, in AR, users can simultaneously interact with virtual objects in the real world [13,16]. MR is a technology that merges real- and virtual-world elements and creates a concurrent virtuality continuum by combining the 2 worlds. In AR, virtual objects are superimposed on the real world and provide additional information such that users can see the natural environment, in which the virtual objects necessary to deliver information are placed. In MR, however, the real and virtual worlds are synchronized so that users can interact with targets in both the physical and virtual components of this shared environment [13,16]. This higher level of linkage boosts the advantages of VR and AR, making users feel that virtual components are physically present in the real world. XR is a comprehensive technology that encompasses a wide range of immersive and interactive technologies including VR, AR, and MR [13,16].

In the metaverse, people can interact with each other and digital objects in real time through avatars and engage in diverse activities, such as education, entertainment, counseling, and socializing. Metaverse provides a more immersive and interactive experience than traditional online services. In metaverse situations, users can move around and interact with digital objects, creating a sense of presence that is not possible in text-based chats or video calls [17,18]. In addition, metaverse services offer more creativity than traditional online services. In this metaverse, users have greater freedom to express themselves creatively through their avatars, build their own virtual environments, and design a wide range of virtual objects, which is not possible in a video call or traditional online game [17,18]. In addition, metaverses provide a more life-like social experience based on a more engaging way of interacting with each other than traditional online services. In this metaverse, users can explore virtual spaces, attend events, and interact with others in a way that feels more natural and authentic, which is not possible through video calls or traditional social network services [17,18]. Therefore, metaverse services can be considered to be superior to traditional online services. However, choosing a metaverse does not necessarily mean completely excluding traditional online services. A metaverse can integrate different types of online services such as videoconferencing, social media, and gaming into a single virtual space. Consequently, users can have seamless and cohesive online experiences across multiple metaverse platforms [17,18]. Although traditional online services are valuable tools for many users, through a new and transformative platform, they offer unique benefits that are not available through existing digital technologies. Previous studies have argued that metaverse technology can successfully meet the demand for non–face-to-face medical services and improve health care quality [16,19-24].

As part of efforts to scrutinize the reasons for using metaverse technology and its effectiveness, research has been conducted to identify the factors associated with the use of metaverse. Many previous studies have applied the technology acceptance model (TAM), well-known as a theoretical framework for predicting the use of new information technologies, to understand the use of metaverse better. The TAM posits that an individual’s perceived usefulness and perceived ease of use of technology determine intention to use, which consequently impacts actual use [25]. This model has been expanded by including new external and contextual factors and different factors from other theories to enhance its explanatory power in various contexts [26]. The findings of existing studies have confirmed that TAM-based factors such as perceived usefulness, perceived ease of use, and intention to use are closely associated with the use of metaverse [27-29]. In addition, according to other prior studies examining metaverse use, perceived enjoyment [30] and perceived immersion [31], whether directly or indirectly, may positively influence intention to use, while cybersickness [32] may negatively impact intention to use. Several metaverse studies have also demonstrated a positive relationship between satisfaction and intention to use [33,34]. To sum up, perceived usefulness, perceived ease of use, intention to use, perceived enjoyment, perceived immersion, and satisfaction are likely associated with using metaverse. Our research focuses on these potential variables in developing the metaverse platform and investigating its user experience.

Furthermore, the effectiveness of metaverse technology has been discussed in the context of cancer. VR, AR, and MR benefit health professionals when applied to develop and use educational or surgical tools [35,36]. Other research has shown that using VR and artificial intelligence enhances doctor-patient risk communication and shared decision-making in surgery [37]. Additionally, VR increases the satisfaction of patients with cancer under oncology care [38], improves therapy training knowledge [39], and reduces cancer-related symptoms (eg, anxiety, distress, and fatigue) [40,41]. Previous studies proposed the potential of AR in patient education and health literacy [42-44]. The multifaceted effectiveness of metaverse technology in different cancer-related groups implies that it may be useful for both cancer prevention and treatment.

Considering that every patient is different, and cancer care is complicated [45], developing and using an integrated metaverse service that can accomplish various aims are advantageous for meeting the needs of health professionals, patients, and caregivers as much as possible. Metaverse and cancer care research are in their early stages, and attempts to apply this emerging technology to cancer care are currently underway. An increasing number of studies [40,46] have demonstrated that metaverse technologies are promising in cancer care. However, these studies are not yet abundant and have been conducted on a small scale, often on single-purpose platforms. It is necessary to deal with a multipurpose platform not only to meet various needs associated with cancer care but also to understand the impact of metaverse on cancer care. To the best of our knowledge, no embodied integrated metaverse cancer care platform that embraces multiple purposes has been developed with combined functions and used in diverse real-world contexts. The challenges of the metaverse, such as inadequate funding, the necessity of careful effort to secure privacy, and an insufficient degree of portraying reality [47-49], may hinder large-scale continuous research. However, it is difficult to explain the authentic potential of metaverse technologies in cancer care simply by listing successful cases on a single platform.

Thus, this paper presents the initial phase of designing and creating a multipurpose metaverse cancer care platform that can be used and maintained steadily in the real world and investigates its usability. As this is the first study to use this new metaverse platform, there are several obstacles (eg, trial and error in developing and using the new metaverse platform, the need for training in platform management, and expensive initial setting cost) in securing many participants. Therefore, the usability test of this new platform is conducted in the form of a basic-level pilot test. Although the usability test recruits a smaller number of participants compared to previous studies and is at a basic level, mentioning the outcomes of the usability test along with the platform development information notably demonstrates the potential of the platform. In addition, despite these limitations, this study has its significance for disseminating and implementing the newly developed multidomain metaverse platform to multiple sites through a national-level project, thus laying the groundwork for large-scale research. We propose that metaverse technology may be well suited to building successful cancer care services. We expect the findings of this study to provide future directions for advancing integrated cancer care platforms.

Methods

Study Design

After demonstrating our cancer care platform to the users, we conducted a multicenter cross-sectional survey to examine their experiences with it.

Procedure

Metaverse Platform Development (Dr. Meta)

Dr. Meta, a metaverse technology-based digital platform for cancer care, was developed at the National Cancer Center (NCC), Korea, in October 2021. It is an XR platform that combines VR and AR elements. The main purpose of its development was to overcome physical constraints (eg, time and space) and educate health professionals (eg, doctors, nurses, and pharmacists) with additional engagement and support in providing good-quality health care services to patients. The metaverse platform development project was supported by the Ministry of Science and ICT of Korea in May 2021 to foster domestic digital health care technology and promote local, non–face-to-face digital content.

Dr. Meta was developed by considering 4 types of metaverses (virtual worlds, mirror worlds, AR, and lifelogging) and their characteristics, as suggested by the Accelerated Studies Foundation [50]. First, virtual worlds are defined as alternative worlds that are similar to or completely different from the reality created by digital data. Users can access avatars whose characteristics are projected, interact with other avatars or virtual objects, and become immersed in virtual space [17,50]. This metaverse platform offers a new virtual space that is unavailable in the real world. It allows users to create their own avatars, select virtual stages or backgrounds, perform activities, and interact with virtual objects (such as 3D organs, medical devices, animals, and plants).

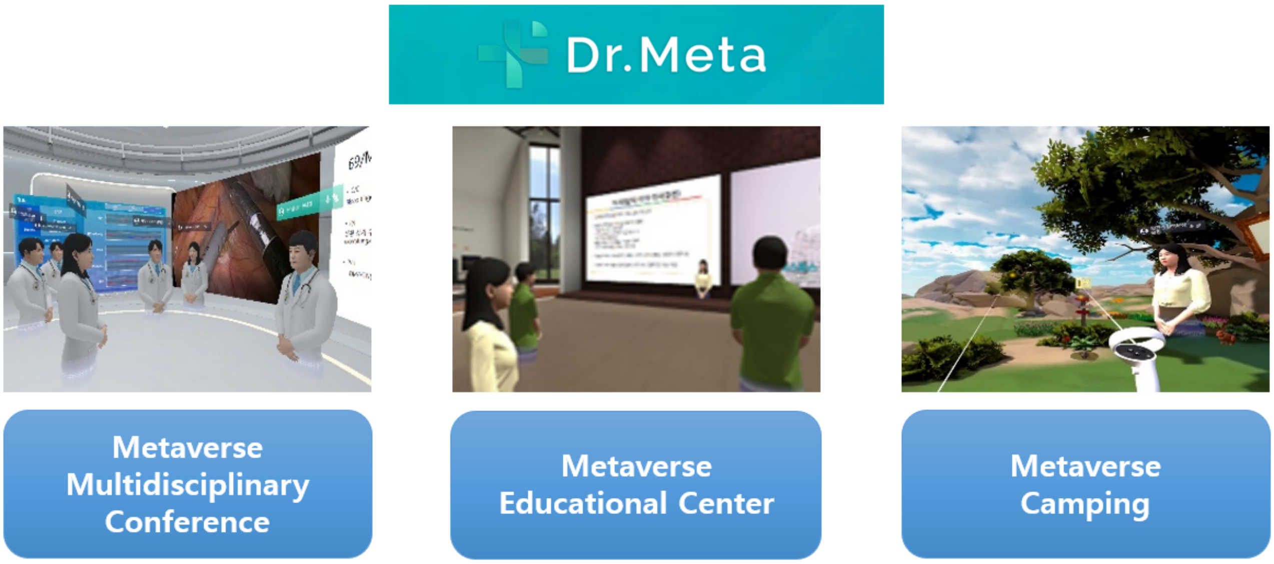
Second, mirror worlds are informationally enhanced worlds created by reproducing the real world. Virtual mapping, modeling, geospatial and other sensors, and lifelogging (history recording) technologies have been used to reflect real-world information as realistically as possible [17,50]. This metaverse platform contains several virtual backgrounds developed by replicating actual conference rooms at NCC Korea. This also includes real-time voice communication. These components may play a role in reflecting real-world environments.

Third, AR offers an interactive world created by overlapping virtual 2D or 3D objects in real space. Location-aware systems and networked information have been used to overlay virtual images with pictures or backgrounds of reality recognized by humans [17,50]. In this metaverse platform, users can upload, arrange, and display virtual objects (both 2D and 3D), actual files (eg, presentations, video clips, and images), and other resources. This exhibiting function may lead to an advanced combination of the real and virtual worlds.

Finally, lifelogging materializes in the digital world by recording, storing, and sharing everyday experiences and information about people and objects. Capturing memory, observation, communication, and behavior modeling with augmentation technologies are used to handle ordinary information [17,50]. This metaverse platform can provide patient charts and computed tomography scan images and has access to web services, including YouTube, Instagram, and other social network services in the virtual space. Users can upload photos and interact with others through voice conversation. They can assess their real-world experiences and information without time and spatial constraints and share them with others. Overall, the characteristics of all 4 types of metaverse were incorporated into the metaverse platform.

Several targeted subplatforms have been developed and operated within large platforms to achieve multidimensional goals. The metaverse platform consists of three subplatforms: (1) Metaverse Multidisciplinary Conference, (2) Metaverse Educational Center, and (3) Metaverse Camping. Metaverse Multidisciplinary Conference allows multiple health professionals from various medical fields and regions to remotely cooperate in real time by accessing the virtual space as avatars and using the 3D medical object data, patient information (eg, electronic medical record), and audio-visual data linked to the program. In Metaverse Educational Center, health professionals from other regions and medical institutions can access the virtual space of this subplatform as avatars to gain theoretical education and experience interactive medical training content. In Metaverse Camping, patients and their family members can use the XR technology in the virtual space with their relatives and acquaintances who live afar to hang out and experience psychological comfort and social support. Figure 1 shows the images of each subplatform of the metaverse platform.

Figure 1. Pictures of each subplatform of Dr. Meta.



As each subplatform has different purposes and targets, its characteristics and functions will inevitably be differentiated to optimize goal achievement. The Metaverse Multidisciplinary Conference and Metaverse Educational Center were developed to assist health professionals in efficient cooperation in real time and aid remote medical training for multiple people. The former tends to be more sensitive to privacy protection and security than the latter. The former focuses on patient treatment and is more likely to handle a patient's personal health records and private information, whereas the latter focuses on knowledge instruction and skill delivery to the audience and is less likely to request sensitive personal data. Nevertheless, health professionals primarily operate these 2 subplatforms. Fundamental activities include sharing information, communicating with other users, and interacting with digital objects. Group-level performance is primarily conducted for collaboration and education, and multiple data formats are used to achieve efficient outcomes. The characteristics of all 4 types of metaverses were found on both subplatforms.

Metaverse Camping was developed to help patients and caregivers feel comfortable and supported and is mostly operated by them, even if doctors join and communicate through it. As feelings of comfort and support occur at the individual level, the functions that focus on individual-level performance or achievement predominantly comprise Metaverse Camping. There is a plan to upgrade this subplatform considering the comfort and support that can be obtained at the social level; nevertheless, at this stage, the emphasis is on individual units. Users can interact with virtual objects and perform actions such as drawing or turning on music in a virtual campsite. Virtual-world characteristics were detected on this subplatform.

After developing the metaverse platform, we disseminated it to 6 (ie, Chonnam National University Hwasun Hospital, Gyeongsang National University Hospital, Jeju National University Hospital, Kangwon National University Hospital, Kyungpook National University Chilgok Hospital, and Pusan National University Hospital) out of 12 regional cancer centers (RCCs). We also support the arrangement of the relevant infrastructure and staff training for its installation and management.

Study Participants

After preparing Dr. Meta's operations, platform demonstrations and usability tests were conducted at 7 cancer centers. Participants aged greater than 19 years were recruited from each cancer center between November and December 2021. Before participating in the survey, participants were requested to read the research information and provide their consent. They could participate in the survey only if they consented voluntarily to do so. Participant inclusion criteria for the study were being aged greater than 19 years and having experience using 1 of 3 subplatforms of this metaverse platform. Participant exclusion criteria for the study were having experience using this metaverse platform but being aged less than or equal to 19 years, being unable to complete self-reported surveys, having a serious physical or mental condition that prevents them from participating in the study, not consenting to the survey, or withdrawing consent during the study. A daily necessity worth about $5 was provided as compensation for participating in the study. We did not ask for information that could identify participants (eg, name and social security number), so the data used in this study was deidentified. Figure 2 shows the participants who used the metaverse platform.

Figure 2. Pictures of participants using Dr. Meta.

Measures

During the survey preparation, we asked for feedback about the initially prepared questionnaire from the platform users. We received their opinions expressing a desire to avoid feeling burdened when participating in the survey after experiencing new metaverse technology. Therefore, we used a simple and concise questionnaire to ensure that participants from various groups, including patients, could easily understand it. Researchers could universally use this questionnaire to evaluate participants' experience using the metaverse platform across different subplatforms. The questionnaire first asked about participants' sociodemographic information (eg, age, sex, and position in the hospital, including patients and caregivers) to assess their characteristics. The next part of the questionnaire consisted of multiple questions evaluating participants' user experience of the metaverse platform. The questions were adapted from previous studies examining potential variables associated with using the metaverse (eg, TAM-based factors) [29,30,34], translated into Korean, abbreviated, and modified to suit the purpose and context of the study. These questions were categorized into individual differences (2 items: "I am usually interested in using new technologies or devices" and "I tend to not experience dizziness or motion sickness easily"), user satisfaction (4 items: "I was generally satisfied with using this XR platform," "This XR platform made me feel interested and immersed," "There was no discomfort (eg, dizziness and nausea) in using this XR platform," and "There was no difficulty in wearing and operating this XR platform device (ie, head-mounted display and controllers)"), and future expectations (3 items: "This XR platform will be helpful for non-face-to-face and noncontact services," "I want to continue using this XR platform in the future," and "I want to recommend this XR platform to others") relevant to the use of Dr. Meta. Each of them was scored on a 5-point Likert scale (1="strongly disagree" to 5="strongly agree"). The final part of the questionnaire consisted of an open-ended question assessing the participants' subjective opinions (ie, suggestions and improvements) about the platform. We used these 9 items and 1 open-ended question to evaluate participants' experiences with the metaverse platform. The questionnaire used in this study is shown in Multimedia Appendix 1.

Statistical Analysis

We conducted a descriptive analysis to examine how participants perceived their experiences using Dr. Meta. This user experience was rated by obtaining the frequency and proportion of participants with positive opinions for each item. The number of participants with positive opinions after using the metaverse platform was calculated by adding those who answered "agree" and "strongly agree." SPSS (version 22.0; IBM Corp) was used for the data analysis.

Ethics Approval

This study was approved by the institutional review board of the NCC Korea and the 6 RCCs (IRB NCC: NCC2021-0331; Chonnam National University Hwasun Hospital: CNUHH-2021-218; Gyeongsang National University Hospital: GNUH2021-11-012-001; Jeju National University Hospital: JEJUNUH2021-10-017; Kangwon National University Hospital: KNUH-A-2021-11-014-001; Kyungpook National University Chilgok Hospital: KNUCH2021-11-032-001; and Pusan National University Hospital: 2111-016-109).

Results

Participant Characteristics

Overall, 74 people participated in the survey after using the metaverse platform, and this study analyzed the data from 70 participants. Of the 70 participants, 3 (4%), 19 (27%), 29 (41%), 15 (21%), and 4 (6%) were aged 20-29, 30-39, 40-49, 50-59, and 60-69 years, respectively. In addition, 19 (27%) participants were male, and 51 (73%) were female. More than half (n=45, 64%) of the participants were health professionals. Table 1 presents the participants' demographic information.

Table 1. Demographic information of the participants.

Characteristics	Total (N=70), n (%)[a]	Metaverse Multidisciplinary Conference (n=15), n (%)	Metaverse Educational Center (n=35), n (%)	Metaverse Camping (n=20), n (%)
Age group (years)				
20-29	3 (4)	0 (0)	2 (6)	1 (5)
30-39	19 (27)	3 (20)	11 (31)	5 (25)
40-49	29 (41)	7 (47)	15 (43)	7 (35)
50-59	15 (21)	4 (27)	7 (20)	4 (20)
60-69	4 (6)	1 (7)	0 (0)	3 (15)
Sex				
Male	19 (27)	9 (60)	6 (17)	4 (20)
Female	51 (73)	6 (40)	29 (83)	16 (80)
Position in the hospital				
Health professionals[b]	45 (64)	14 (93)	29 (83)	2 (10)
Patients	8 (11)	0 (0)	0 (0)	8 (40)
Caregivers	9 (13)	0 (0)	0 (0)	9 (45)
Others[c]	8 (11)	1 (7)	6 (17)	1 (5)

[a]Percentages may not add up to 100% due to rounding.

[b]"Health professionals" includes doctors, nurses, and pharmacists in this study.

[c]"Others" includes hospital administrative staff, educators, social workers, and researchers in this study.

Usability Results

Regarding user satisfaction, this study's results showed that more than half (37/70, 54%) of the participants were satisfied with using Dr. Meta. In total, 50 (72%) participants responded that Dr. Meta is an interesting and immersive platform. Regarding future expectations, over half (n=50, 72%) of the participants reported that the platform would be helpful for non–face-to-face and noncontact services. Furthermore, 41 (59%) participants wanted to continue using the platform in the future, and 42 (60%) wanted to recommend it to others. Table 2 summarizes the overall positive experiences of the metaverse platform's participants.

Moreover, regarding the feedback about the metaverse platform, participants responded to the open-ended question "If you have any suggestions or improvements, please write them in." The most commonly reported one was the difficulty in wearing and operating the XR devices (eg, "The device was heavier than I thought, and wearing it was inconvenient. It was also challenging to operate the platform"; "The device is heavy; thus, it strains my neck and shoulders"; and "People wearing glasses are uncomfortable wearing the device"). Many participants also proposed that it is crucial to improve the quality of content and create realistic materials on various topics to decrease dizziness and increase immersion (eg, "If the virtual space is more realistic, I will be more immersed."). In contrast, the usefulness of metaverse platform in medical education was a representative advantage that the participants mentioned (eg, "It will be very helpful to the community medical field."). Textbox 1 presents more information about the feedback on the participants' experiences with the metaverse platform.

Table 2. The positive experience of the participants after using Dr. Meta.

Items[a]	Total (N=70), n (%)[b]	Metaverse Multidisciplinary Conference (n=15), n (%)	Metaverse Educational Center (n=35), n (%)	Metaverse Camping (n=20), n (%)
Individual differences				
I am usually interested in using new technologies or devices.	43 (62)	13 (87)	20 (57)	10 (50)
I tend to not experience dizziness or motion sickness easily.	24 (34)	3 (20)	11 (31)	10 (50)
User satisfaction				
I was generally satisfied with using this XR[c] platform.	37 (54)	10 (67)	19 (54)	8 (40)
This XR platform made me feel interested and immersed.	50 (72)	13 (87)	26 (74)	11 (55)
There was no discomfort (eg, dizziness and nausea) in using this XR platform.	34 (49)	7 (47)	16 (46)	11 (55)
There was no difficulty in wearing and operating this XR platform device (ie, head-mounted display and controllers).	30 (43)	4 (27)	15 (43)	11 (55)
Future expectations				
This XR platform will be helpful for non-face-to-face and noncontact services.	50 (72)	11 (73)	23 (66)	16 (80)
I want to continue using this XR platform in the future.	41 (59)	11 (73)	17 (49)	13 (65)
I want to recommend this XR platform to others.	42 (60)	11 (73)	18 (51)	13 (65)

[a]Items are based on a 5-point scale (1="strongly disagree" to 5="strongly agree"). The number of participants who had positive opinions after using Dr. Meta was calculated by adding the number of participants who answered "agree" and "strongly agree."

[b]Percentages may not add up to 100% due to rounding.

[c]XR: extended reality.

Textbox 1. The details of feedback on the participants' experience of Dr. Meta.

Advantages

- "It will be very helpful to the community medical field."
- "It was amazing, and I am glad my parent liked it."
- "There was nothing particularly bad about it, and seeing virtual objects in front of me was nice. Also, it was nice to experience healing for a while."
- "It could be useful if the convenience of using the device is improved."
- "Depending on how you use it, it could be helpful."
- "It was great to experience an exciting and immersive new educational system."
- "It is livelier and engaging than face-to-face or previous online training. If the content is well-developed, it can be very effective."
- "If improvements are made to induce interest and overcome physical constraints, this program will be a great way to deliver non-face-to-face education."

Improvements

- "The device was heavier than I thought, and wearing it was inconvenient. It was also challenging to operate the platform."
- "The device is heavy; thus, it strains my neck and shoulders."
- "People wearing glasses feel uncomfortable wearing the device."
- "If the virtual space is more realistic, I will be more immersed."
- "It would be nice to have a variety of content to experience. I was getting bored with the simplicity over time."
- "It was hard to use, and the voice function needed to be fixed."
- "It was inconvenient to wear and use the device. Adding a function that allows users to experience content without the device would be wonderful."
- "I need some guidance on how to operate it."
- "The device is heavy and requires time to get used to the operation."
- "The content should be designed considering different age groups and health conditions."
- "I am worried about contamination problems when multiple people share the device."
- "I wonder if applying this platform in the medical field is realistic because of the expensive cost of the device."

Discussion

Principal Findings

This study aimed to (1) develop an integrated metaverse cancer care platform and (2) examine its user experience. Dr. Meta is a multipurpose metaverse health care platform distributed and used by the local community. To the best of our knowledge, it is not only the first to be developed in South Korea but is also a unique case worldwide. This was possible because this study used a cancer center system established at the national level. Our results showed that more than half of users thought this metaverse platform was satisfying, interesting, and immersive. Although less than half of users indicated positive opinions on no discomfort in using this platform and no difficulty in wearing and operating its device, more than half of users thought it was helpful for non–face-to-face and noncontact services and wanted to use it continuously and recommend it to others. These outcomes were also observed in the pattern of responses to a feedback question. Users primarily mentioned the difficulty in wearing and operating this platform's device. They also raised the necessity of improving the quality of its content. On the other hand, users were favorable about the platform's usefulness as a medical education tool. The metaverse platform will serve as evidence to enable the expansion of the country's medical metaverse project, helping to establish a concrete direction for future research and development. It will also assist in overcoming physical constraints and proceeding with successful non–face-to-face cancer care, positively contributing to solving unequal issues of medical resource accessibility between areas (urban, metro, and rural regions).

Moreover, the findings of this study showed that various groups can use this metaverse platform according to their requirements. When it comes to the subplatforms targeting health professionals, more than half of users thought Metaverse Multidisciplinary Conference and Metaverse Educational Center were satisfying, interesting, and immersive. Even though less than half of users provided positive opinions on no discomfort in using these subplatforms and no difficulty in wearing and operating their device, more than half of users thought these subplatforms were helpful for non–face-to-face and noncontact services and wanted to recommend them to others. Over half of the users wanted to use Metaverse Multidisciplinary Conference continuously but not Metaverse Educational Center. Although the initial cost for the development of metaverse platform was relatively high, health professionals could learn repeatedly at no additional cost once the platform was deployed. Based on the results of other studies using a medical metaverse for health professionals' education

[51-53], it is feasible to predict that this platform will be more effective in providing education that cannot be easily implemented in the real world. It can also serve as a catalyst to activate the training of health professionals by enabling education on invasive treatment [54]. To maximize these advantages, a capability that the virtual world can accurately reflect the real world is needed [55,56]. This metaverse platform can be developed in the future to embody digital twins for this purpose. This should be accomplished through discussions on data sharing and privacy issues.

With respect to the subplatform targeting patients and caregivers, while less than half of users thought Metaverse Camping was satisfying, more than half of users thought it was interesting and immersive. Unlike the other 2 subplatforms, this subplatform received positive opinions on no discomfort in using it and no difficulty in wearing and operating its device from over half of users. In addition, more than half of users thought it was helpful for non–face-to-face and noncontact services and wanted to use it continuously and recommend it to others. Through this subplatform, patients can overcome physical constraints and receive support such as high-quality cancer education, monitoring, and counseling. Consequently, they can enhance self-efficacy regarding health behaviors and gain comfort, similar to other studies [57-59] examining the role of the medical metaverse in patient support. A more immersive environment may provide a greater patient experience without being disturbed by external stimuli [55,60-62]. This metaverse platform can be developed in the future to establish an immersive environment for this purpose. Additional solutions that maximize immersion should be developed, such as preparing more accessories to overcome the inconvenience of wearing such devices.

Furthermore, Dr. Meta provided evidence of a metaverse platform for conducting more sophisticated research. It can act as a stimulus in new studies that test the associations among relevant variables. Verifying the determinants or constructing predictive models using this metaverse platform could be directions for future research. For example, examining the role of immersion in the satisfaction and continuous use of metaverse platform could be an important research topic. These outcomes can guide the theory-driven development of other metaverse health care platforms for different disease contexts.

Future Perspective

The study results prove that metaverse platform has the potential to provide effective cancer care and simultaneously show that it needs to be upgraded to enhance the user experience. Some interesting differences among the subplatforms suggest that certain components of metaverse platform require further improvement. This study's outcomes showed that less than half of the Metaverse Educational Center users wanted to continuously use the Metaverse Educational Center. In addition, less than half of Metaverse Camping users responded that they were satisfied with using Metaverse Camping. We plan to set different future directions to improve subplatforms by accommodating their own purposes.

Regarding Metaverse Educational Center, an interactive environment where users can directly control and interact with virtual objects and spatial elements may allow them to become more engaged with the platform [60-62]. Such improved engagement may help users achieve their goal of sharing information successfully. For example, diverse interactive functions such as performing physical activities through motion recognition, assembling and disassembling 3D anatomical structures, and manipulating 3D medical devices may be useful for delivering messages and acquiring knowledge. These improvements are expected to be widely applicable in other health care fields. In addition to high interactivity, vivid 2D or 3D digital objects that match topics or innovative simulation functions that realistically describe topics may also strengthen users' intentions toward continuous use [63].

Concerning Metaverse Camping, gamification elements (eg, quizzes and rewards) and personalized feedback may help users successfully attain the goal of self-motivation and feeling comfortable [64,65]. This may enhance user satisfaction with the platform. For instance, if users can customize their characters, navigate campsites, complete quests, receive fruit stickers, or watch flower images appearing on trees as rewards, they may experience comfort, fun, or other positive emotions. Thus, users can dynamically interact with new virtual objects and easily immerse themselves in the platform. Among the 4 types of metaverse, these plans are closely related to virtual worlds.

Moreover, improving the voice, movement, and time spent recording functions on both subplatforms may elicit a more positive user experience. Communication within a shorter time interval in the Metaverse Educational Center or recoding the voice diary on Metaverse Camping may make users think that they are putting their daily life information on the platform and that it is tailored. As people tend to favor personalized information [66], these upgrades may encourage them to use the platform. Among the 4 metaverse types, these plans are closely related to lifelogging. In summary, we plan Dr. Meta's future development by focusing more on the virtual world and lifelogging aspects. It is expected that the influence of these improvements will not only be within the subplatform but will also positively affect the evaluation and actual use of the entire platform by stimulating user satisfaction and curiosity.

Furthermore, it is possible to present meaningful directions for future development and maintenance beyond the scope of subplatform improvement. Currently, Dr. Meta is mainly used through the head-mounted display (HMD); however, many participants complained of motion sickness due to the HMD or said that it was difficult to wear and handle. Therefore, we plan to develop different versions of the metaverse platform that can be operated on various media types, such as desktops and tablets, to reduce the dependence on HMD. We will also develop a user-friendly manual to guide the use of Dr. Meta and provide it to the users to minimize inconvenience. In addition, according to their feedback, several participants felt content needed improvement. For example, they stated that the content was monotonous and lacked realism. Thus, we will emphasize vivid and realistic depictions of content that need to be authentic and fantasy elements of content that need to be fictional. We also plan to increase the number of content scenarios and videos that users can choose. Additionally, some participants suggested that providing content that reflects user characteristics might enhance the quality of services. Therefore, in the future, we will prepare various content and matching algorithm systems to satisfy user requirements. Finally, current subplatforms and content are still insufficient to cover the complexity of cancer care. Therefore, we will gradually expand the metaverse platform by developing new subplatforms tailored to target participant groups to diversify its purposes and functions. While securing various subplatforms, we will spur Dr. Meta's operation by applying models and content well-fitted with topics.

While advancing Dr. Meta, we sought to diversify its uses. Our research is currently supported by the Ministry of Health and Welfare of Korea starting in 2022, linked to a government project that focuses on establishing infrastructure and maintaining its setting to disseminate and implement new digital health care technologies in local communities. We aimed to establish an environment in which we could cooperate with health professionals from other hospitals in multiple regions of South Korea. In addition, a platform will be developed to collaborate on education or research with Koreans as well as foreign hospitals and research institutes.

Limitations

Although there were favorable evaluations and expectations of this platform, this study had some limitations. First, the sample size seems to be small. As this was the first study conducted following the development of metaverse platform, the main focus was to explore the field applicability of the newly developed metaverse platform called Dr. Meta. Therefore, although there was a limit to securing a sufficient number of users, this study first examined the feasibility of metaverse platform by conducting a usability test in the form of a pilot test on a small number of people to provide evidence of the potential for practical use of the platform. To address this issue, we will invite new RCCs to our project and recruit participants for an extended period in future research. Dr. Meta is expected to operate more stably in the future; therefore, more participants are expected to be recruited.

Second, it looks like the proportion of participants is unbalanced by position in the hospital. The number of participants who were patients or caregivers was small, and health professionals mainly participated in the study. It is a natural occurrence because 2 of the 3 subplatforms introduced in this study were developed for health professionals, and we even wanted to test the subplatform developed for patients on health professionals first before providing it to patients to ensure safety and appropriateness. Still, it is important to have an even distribution of sufficient participants for good-quality data analysis. We will consider performing large-scale participant recruitment along with applying a statistical methodology that deals with the percentage of participants of each subgroup in the population or its representation, such as stratified sampling, to collect adequate data inclusively in future research.

Third, although presenting the metaverse platform's development information and its outcomes of usability test together shows that the platform is promising for successful cancer care, the basic level of this usability test seems difficult to deal with more elaborate research questions. For example, there was an absence of use of existing validated questionnaires in this study. This study was conducted as an early-stage pilot study, and a questionnaire developed for an exploratory purpose was used rather than a structured one. Furthermore, this study aimed to include patients among the overall participants, so we needed to consider their understanding of the questionnaire. It was decided to use a theory-based but straightforward, easy, and short questionnaire because patients typically need care and can easily get tired after experiencing new metaverse technologies and platforms. It provided flexibility and ease of conducting usability assessments in the real-world field. On the other hand, it was limited in its ability to scrutinize the relationships between variables related to user satisfaction. As this was the first study to use the metaverse platform, it was inevitable that this study focused on introducing its development in detail. Nonetheless, to verify this multidomain platform's potential, we undertook its usability test together regardless of the test level. Considering that medical metaverse research is currently in its infancy, this study may encourage scholars to go beyond the medical metaverse research centered on reviews or single-domain platform studies and practitioners to adopt a large-scale medical metaverse platform. We will design future studies that intensively investigate a target subplatform's features and content based on sufficient participants and an advanced understanding of the topic. For a sophisticated examination of the metaverse platform's user experience and influence, we will upgrade our current questionnaire by adding more theory-based simple items asking about potential other new variables related to the usability of the medical metaverse. We will also consider using a systematically validated usability questionnaire when planning a future study examining a target subplatform with a fixed participant group and topic.

Conclusions

To the best of our knowledge, this study is the first to verify the possibility of developing multidomain metaverse cancer care platforms in South Korea that have the potential for successful non–face-to-face cancer care. This study was the starting point for examining the effectiveness of this metaverse cancer care platform. We will develop the metaverse platform to strengthen user immersion and tailor experiences by highlighting virtual worlds and lifelogging. If the development of hardware devices and software content suitable for this purpose is combined, this medical metaverse platform will successfully ease the burden on patients with cancer. Moreover, the platform has been disseminated and implemented for multiple RCCs. Future developments may solve physical distance and disparities in access to medical resources more effectively. The metaverse platform will be an alternative cancer education method for health professionals against COVID-19 and will be especially helpful for patients not living in urban areas to obtain cancer care benefits. This research provides not only the development of simple medical metaverse platform functions but also an environmental model that can facilitate the sustainable use of the platform. We will progress in more extended future research with more participants to enrich evidence about the effectiveness of Dr. Meta and discover more in-depth scientific insight about this multidomain metaverse cancer care platform.

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

SK contributed to the conceptualization, formal analysis, investigation, methodology, project administration, writing of the original draft, and reviewing and editing of the paper. TJ contributed to the supervision and reviewing and editing of the paper. DKS contributed to the funding acquisition, investigation, and supervision. YC contributed to the data curation and project administration. YAK contributed to the conceptualization and investigation. SHK contributed to the resources and project administration. YP contributed to the project administration and reviewing and editing of the paper. YJC contributed to the conceptualization, funding acquisition, investigation, methodology, resources, supervision, project administration, writing of the original draft, and reviewing and editing of the paper. All authors approved the final version of the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The questionnaire used to evaluate participants' experience using the metaverse platform.

[PDF File (Adobe PDF File), 134 KB - games_v11i1e46242_app1.pdf]

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Abbreviations

AR: augmented reality
HMD: head-mounted display
MR: mixed reality
NCC: National Cancer Center
RCC: regional cancer center
TAM: technology acceptance model
VR: virtual reality
XR: extended reality

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Original Paper

Design Considerations for an Exergame-Based Training Intervention for Older Adults With Mild Neurocognitive Disorder: Qualitative Study Including Focus Groups With Experts and Health Care Professionals and Individual Semistructured In-depth Patient Interviews

Patrick Manser[1], MSc; Manuela Adcock-Omlin[1], DSc; Eling D de Bruin[1,2,3], PhD

[1]Motor Control and Learning Group – Institute of Human Movement Sciences and Sport, Department of Health Sciences and Technology, ETH Zurich, Zurich, Switzerland

[2]Division of Physiotherapy, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Stockholm, Sweden

[3]Department of Health, OST – Eastern Swiss University of Applied Sciences, St.Gallen, Switzerland

Corresponding Author:
Patrick Manser, MSc
Motor Control and Learning Group – Institute of Human Movement Sciences and Sport, Department of Health Sciences and Technology, ETH Zurich
Leopold-Ruzicka-Weg 4, CH-8093 Zurich, Switzerland
Zurich, CH-8093
Switzerland
Phone: 41 79 519 96 46
Email: patrick.manser@hest.ethz.ch

Abstract

Background: Exergames have attracted growing interest in the prevention and treatment of neurocognitive disorders. The most effective exergame and training components (ie, exercise and training variables such as frequency, intensity, duration, or volume of training and type and content of specific exergame scenarios) however remain to be established for older adults with mild neurocognitive disorders (mNCDs). Regarding the design and development of novel exergame-based training concepts, it seems of crucial importance to explicitly include the intended users' perspective by adopting an interactive and participatory design that includes end users throughout different iterative cycles of development.

Objective: This study aimed to determine the capabilities, treatment preferences, and motivators for the training of older adults with mNCD and the perspectives of individuals on training goals and settings and requirements for exergame and training components.

Methods: A qualitative study including expert focus groups and individual semistructured in-depth patient interviews was conducted. Data were transcribed to a written format to perform qualitative content analysis using QCAmap software.

Results: In total, 10 experts and health care professionals (80% females) and 8 older adults with mNCD (38% females; mean age 82.4, SD 6.2 years) were recruited until data saturation was observed.

Conclusions: The psychosocial consequences of patients' self-perceived cognitive deterioration might be more burdensome than the cognitive changes themselves. Older adults with mNCD prefer integrative forms of training (such as exergaming) and are primarily motivated by enjoyment or fun in exercising and the effectiveness of the training. Putting the synthesized perspectives of training goals, settings, and requirements for exergames and training components into context, our considerations point to opportunities for improvement in research and rehabilitation, either by adapting existing exergames to patients with mNCDs or by developing novel exergames and exergame-based training concepts specifically tailored to meet patient requirements and needs.

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KEYWORDS

cognition; exercise; exergame; design; development; neurosciences; technology; training

Introduction

Background

The normal aging process is associated with a decline in physical and cognitive abilities [1,2]. When the cognitive decline exceeds the normal age-related cognitive decline but is not severe enough to interfere with independence in activities of daily living, it can be classified as "mild cognitive impairment" (MCI), representing an intermediate stage of cognitive impairment between the normal aging process and dementia [3-9]. The condition MCI has evolved over the last decades [5] and has recently been incorporated in the latest Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-5) and the International Classification of Diseases 11th Revision, referred to as mild neurocognitive disorder (mNCD) [7,9-11]. The prevalence of mNCD increases with age, while the incidence of mNCD and the progression to dementia is expected to rise, largely because of the globally growing life expectancies and sedentary lifestyles [3,5,12-15]. As currently no effective pharmacological interventions for patients with mNCD exist [16], alternative options to prevent and treat neurocognitive disorders are needed. Targeting modifiable risk factors in midlife may hold promise for mitigating or even preventing neurocognitive disorders in later life [17-21]. The modifiable risk factors for mNCD include the presence of vascular risk factors (ie, metabolic syndrome, hypertension, hyperlipidemia, coronary heart disease, diabetes mellitus, or stroke) [22-24] or a physically or cognitively sedentary lifestyle [25,26]. Consequently, changes in lifestyle that increase physical and cognitive activity and reduce vascular risk factors are protective against cognitive decline [27-35].

Exergames have gained growing interest to prevent and treat neurocognitive disorders [36-38]. "Exergaming is defined as technology-driven physical activities, such as video game play, that requires participants to be physically active or exercise in order to play the game" [39]. One of the major advantages of exergame-based training is that it is widely accepted by individuals with neurocognitive disorders. In addition, it increases training adherence and engagement by facilitating training motivation and satisfaction [40], which in turn may have a positive effect on the effectiveness of improving cognitive functioning [41]. Furthermore, exergames can be used as a form of simultaneous cognitive-motor training with incorporated cognitive task demands [42]. Meta-analytic evidence suggests that simultaneous motor-cognitive training is the most effective type of training for improving cognition in healthy older adults (HOA) [43,44] and older adults with mNCD [44-46]. For exergames specifically, a recent systematic review synthesized evidence from low risk of bias studies showing that there were consistent positive effects favoring exergaming in people with mNCD and dementia [40]. Nonetheless, it is currently difficult to draw reliable conclusions about the effectiveness of exergaming in preventing and treating neurocognitive disorders because of the substantial variations in the exergame-based training used. Therefore, further investigations are needed for the establishment of effective exergame and training components (ie, exercise and training variables such as the frequency, intensity, duration, or volume of training and the type and content of specific exergame scenarios) for cognitive functioning that can be applied with confidence in evidence-based exergame interventions [36].

Regarding the design and development of novel exergames, it seems crucial to explicitly include the intended users' perspectives [47]. Taking the characteristics, needs, and experiences into account should ensure adequate use and therefore the effectiveness of the solution. Baquero et al [48] pointed out that an end user–centered methodological design is most often adopted in the development of computer-based training programs for cognitive rehabilitation of older adults with neurocognitive disorders (NCDs). In an ideal case, this process fulfills the international standards for the development of programs including (1) understanding and specifying the context of use (type, characteristics and tasks of users, and physical or social environment), (2) specifying the user requirements, (3) producing design solutions, and (4) evaluating the design [48,49]. So far, only half of the studies reporting computer-based interventions took the standard "specification of user requirements" into account [48]. This has led to the recommendation that future studies in this field should use an interactive and participatory design that explicitly includes end users throughout different iterative cycles of development [48]. In short, it is important to systematically and thoroughly investigate the specific user requirements and preferences for an exergame-based training concept before it is designed and developed.

Objectives

This study aimed to determine the capabilities, treatment preferences, and motivators for the training of older adults with mNCD and the perspectives of individuals on training goals and settings and requirements for exergame and training components.

Methods

Overview

This study is part of the national project "Brain-IT," which began in August 2020 in Switzerland. The aims of the overall project are (1) to determine the most suitable components for exergame-based training in older adults with mNCD; (2) to explore novel strategies for a real-time adaptive exergame system to individually tailor exergame demands according to users' physical or cognitive capabilities; (3) to incorporate the acquired knowledge into an exergame-based training concept with the aim of halting or reducing cognitive decline and improving quality of life; and (4) to evaluate the effectiveness of the resulting training intervention in older adults with mNCD. The project is guided by a theoretical framework that provides specific guidance in the design, development, and evaluation of exergames for older adults, the "Multidisciplinary Iterative Design of Exergames (MIDE): A Framework for Supporting the Design, Development, and Evaluation of Exergames for Health" [50], which provides specific guidance in the design, development, and evaluation of exergames for older adults. This study is part of the first phase of the project, with the aim to specify a "set of design requirements that includes design considerations, accessibility recommendations, user modeling elements, and technological reflections to be followed in the design and development phase" [47,50], and it was combined with an extensive literature review and reflections on technology scoping and sustainability strategy (see steps 4 and 5 of phase 1 of our recently published methodological paper [47]). For the project, the exergame device "Senso (Flex)" (Dividat AG) was preselected on the basis of (1) our previous research, (2) because this device has already been shown to be feasible and well-accepted in geriatric patients [51] and patients with major neurocognitive disorder [52], and (3) because it is already widely used (and therefore available more widely and for longer term by end users and health care institutions) for motor-cognitive training within geriatric populations, physiotherapies, or rehabilitation clinics in Switzerland. On this basis, this qualitative study was designed to achieve the defined objectives in general; in addition, it also aimed to collect evidence about the previous experiences of experts or health care professionals with different exergame systems [including the "Senso (Flex)"]. In this way, the project team wanted to collect evidence to make an informed decision whether the specific exergame device was suitable for the project, what possible modifications might be needed to optimize the exergame experience for patients with mNCD, and whether and what alternative exergame devices are suggested by the experts (see subsections of "(T2) Treatment Experience and Preferences—Previous Experiences with Exergames ('Senso' specifically)" and "(T5) Exergame and Training Components—Exergame System and Content" in the focus group discussions). Other than parts of these 2 sections that include device-specific findings, none of the remaining sections in this manuscript are device specific.

Study Design

A qualitative study was conducted between November 2020 and January 2021, including expert focus groups and patient interviews; both were organized as semistructured, in-depth interviews. Semistructured, in-depth interviews are the most widely used interviewing format for qualitative research and are generally organized around a set of predetermined open-ended questions, with additional questions and discussion points emerging from the dialogue [53]. The study was planned and reported in accordance with the "consolidated criteria for reporting qualitative research (COREQ)" [54].

The MIDE Framework [50] guided our approach. On the basis of this framework, we integrated multiple stakeholders into the design and development process including exergaming researchers, clinical experts with different backgrounds, a company representing the exergaming industry, and the end users.

Ethics Approval

All the study procedures were performed in accordance with the Declaration of Helsinki. The study protocol (not registered) was approved by the ETH Zürich Ethics Commission (EK 2020-N-154). All interested individuals were fully informed of the study procedures. The expected benefits and risks of the study were explained by the study investigator, who was also able to answer open questions and clarify individuals' uncertainties. It was further verified that withdrawal was permitted at any time during the study without providing any reason. After sufficient time, suitable individuals willing to participate in the study provided written informed consent and were included in the study. No compensation was provided to the participants.

Participants

Experts

Recruitment aimed at including experts and health care professionals experienced with exergame training of older adults with mNCD, preferably (but not necessarily) with the exergame training system "Senso (Flex)" or similar. For this purpose, Dividat AG was asked to provide a contact list of 10 to 15 external experts and health care professionals with a variety in age, sex, educational level, and experience in therapy of older adults with mNCD, who are not employed by Dividat AG or had received any funds from Dividat AG for their work. All recommended experts and health care professionals were contacted via email between November and December 2020. By applying broad inclusion criteria, a rich spectrum of experts and health care professionals were considered in the study, which in turn will foster the usability of the resulting program in clinical practice. The specific eligibility criteria comprised the following aspects: (1) experts or health care professionals (eg, physical therapists, movement therapists, neuropsychologists, or researchers experienced with exergames) experienced with exergame training or with older adults with mNCD; (2) German or English speaking; and (3) age ≥18 years. There were no specific exclusion criteria.

Older Adults With mNCD

Older adults with mNCD were consecutively recruited between November 2020 and January 2021 in collaboration with health care institutions and (memory) clinics in the larger area of Zürich. Leaflets and study information sheets containing researchers' contact details were handed out to suitable patients by their therapists. Suitable patients were identified from medical records and patient registries of memory clinics or from diagnostics that had just been performed. Interested patients were contacted by the research team by telephone or email to clarify or obtain further information about the study procedures and to register interest in participating in the study. Subsequently, all patients were fully informed about the study procedures in a face-to-face meeting at the patient's homes. In addition, patients of interest were screened for eligibility. The eligibility criteria are presented in Textbox 1.

Textbox 1. Description of all eligibility criteria.

- Inclusion criteria
  - Participants fulfilling all the following inclusion criteria were eligible:
    - (1= mild neurocognitive disorder [mNCD]) clinical diagnosis of "mNCD" according to International Classification of Diseases 11th Revision [7] or Diagnostic and Statistical Manual of Mental Disorders 5th Edition [9]) OR (2=sMCI). Patients "screened for MCI" according to the following criteria: (1) informant (ie, health care professional)–based suspicion of mild cognitive impairment confirmed by (2) an objective screening of mild cognitive impairment based on the German version of the using the Quick Mild Cognitive Impairment Screen [55] with (b1) a recommended cutoff score for cognitive impairment (mild cognitive impairment or dementia) of <62/100 [56], while (b2) not falling below the cutoff score for dementia (ie, <45/100 [56])
    - German speaking
- Exclusion criteria
  - The presence of any of the following criteria led to exclusion:
    - Presence of additional, clinically relevant (ie, acute or symptomatic) neurological disorders (ie, epilepsy, stroke, multiple sclerosis, Parkinson disease, brain tumors, or traumatic disorders of the nervous system)
    - Presence of any other unstable or uncontrolled diseases (eg, uncontrolled high blood pressure, progressing or terminal cancer, etc)

Procedures and Data Collection

Expert Focus Groups

The expert focus groups were moderated by the first author (PM) into groups of up to 5 experts. The moderator was a male doctoral student with a master's degree in Health Sciences and Technology (ETH Zürich, Switzerland), who was trained for qualitative research. Owing to the COVID-19 pandemic, all focus group sessions were held as web-based meetings in the form of Zoom sessions (Zoom Video Communications), took approximately 60 to 90 minutes to complete, and were audio recorded. Each session started with a short presentation of the background and overall aim of the project. Subsequently, the aim of this study was presented before starting the focus group discussions. The focus group discussions were organized as semistructured, in-depth interviews with open-ended questions to enable open conversations [53]. The exchange was conducted following a focus group guide (Multimedia Appendix 1) structured along 5 topics, each consisting of multiple key questions. First, the capabilities of older adults with mNCD were discussed, in continuation with insights into training goals and outcomes in the perspective of patients as well as therapists. Thereafter, the exchange focused on treatment experiences and preferences as well as motivators for training of older adults with mNCD. Finally, the requirements and optimal components of the exergame-based training were critically discussed. To focus the moderator's attention on participants' verbal and nonverbal communication and because handwritten notes during interviews are considered relatively unreliable, no notes were taken during the focus group sessions [57].

Patient Interviews With Older Adults With mNCD

The patient interviews were conducted individually with each patient by the first author (PM) and either took place at ETH Zürich (Institute of Human Movement Sciences and Sport, Leopold-Ruzicka-Weg 4, 8093 Zürich) or at the patients' homes, depending on the patients' preferences. The interview sessions were held face-to-face in a quiet room with no one present besides the interviewer, the patient, and, if requested, a care professional or partner as personal support for the patient. We did not set a time limit for the interviews but gave all participants enough time to share their views on the topics discussed. On average, each session took approximately 20 to 30 minutes to complete and was audio recorded. Before starting the interview, the background and overall aim of the project as well as the aim of this study were explained to each patient. The interviews were organized as semistructured, in-depth interviews along an interview guide (Multimedia Appendix 1) [53]. The interview guide was not pilot-tested, as it was developed by the first author (PM) in collaboration with the second author (MA), an experienced clinical neuropsychologist. After questioning the patients' capabilities as well as their previous treatment or training experience and preferences, the interview continued with questions about motivators for training and the preferred components of exergame-based training. Open-ended questions were asked to enable an open conversation [53]. To focus the moderator's attention on patients' verbal and nonverbal communication, no notes were taken during the interviews [57]. Finally, the interviewer was prepared to tailor the interview questions and communication style to the patients' capabilities, and in case of higher levels of impairment, to adopt strategies suggested to optimize communication with patients with NCDs [58,59].

Sample Size

The intended sample size was set at approximately 5 to 10 experts for the focus group sessions and 5 to 10 older adults with mNCD for the patient interviews; however, study participants were consecutively included until data saturation was reached [60].

Data Analysis

First, all audio files were transcribed in written format in Microsoft Word in pseudonymized form. The transcripts were not returned to the participants for corrections or comments. To explore the perspectives of patients and experts or health care professionals, a qualitative content analysis was performed according to Mayring et al [61,62] using QCAmap software [62-64]. The first step in the analysis involved repeated readings of the transcripts and listening to the original audio files to gain a better understanding of the conversation content. Second, the type of analysis (ie, category assignment procedure) was predefined for each of the research questions (ie, key questions of the interview guide). In case of an inductive category assignment procedure, a selection criterion and level of abstraction were defined for each of the research questions. For deductive category assignments, each research question was operationalized into categories, and a corresponding coding guideline (ie, category label, category definition, anchor example, and coding rules) was formulated. On the basis of this, all transcripts were coded line-by-line (ie, including a revision of the category system after a pilot loop). Subsequently, each resulting list of categories was grouped into main categories, and inter- and intra-agreement checks were performed. Finally, the results of each key question were analyzed along the structure (including predetermined themes and topics) of the interview guide that was created according to the guidelines of the MIDE Framework [50]. Thus, the results were structured and analyzed in 2 main themes and 5 topics. First, the section "user modeling" that included 3 topics: (T1) capabilities of older adults with mNCD, (T2) treatment experiences and preferences, and (T3) motivators for training. Second, "therapeutic needs," including (T4) training goals and outcomes and (T5) exergame and training components. Within the topic "(T1) capabilities of older adults with mNCD," the described cognitive capabilities and difficulties were classified into the key neurocognitive domains (as defined by Sachdev et al [10]) in line with DSM-V [9] on agreement between the first (PM) and second author (MA; an experienced neuropsychologist). Within the topic "(T3) motivators for training," the motivators for training were coded and analyzed against the background of the "Self-determination Theory" [65]. The Self-determination Theory [65] accounts for the quality of different levels of motivational regulation in physical activity settings. It is considered useful to gain a better understanding and promote training motivation, enjoyment, and adherence and has demonstrated considerable efficacy in explaining exercise motivation and behavior [66-70]. Data from the qualitative content analysis were combined with quantitative data (ie, frequency of various statements [f] and in the case of patient interviews, the proportion of patients making a statement [in %]) [60]. The coding and data analysis process was cross-checked to enhance the credibility of the analytic procedure [60].

Results

Participants

In total, 11 external experts and health care professionals were contacted by the first author (PM). All experts responded and were interested in participating. Two experts could not participate in the focus group sessions because of time constraints. According to the "integrative" contribution of the MIDE Framework, "perspectives of various stakeholders (*e.g.*, industry partners, data analysts, health care professionals) are considered in the process of designing and developing exergames*"* [50]. In accordance with this, the founder of Dividat AG was involved in one of the focus group discussions as an industry representative. In total, 10 experts and health care professionals (80% females) participated in 1 of the 5 focus group sessions until data saturation was observed and further recruitment was terminated. The focus group sessions were conducted in groups of between 1 (*k*=3) and 3 (*k*=1) experts (median 1.5) and the moderator (PM). The professional backgrounds of the experts and health care professionals included exergaming researchers (n=4), physical and occupational therapists (n=2), neuropsychologists (n=2), project manager therapy (n=1), and founder of an exergaming company (n=1).

For the patient interviews, 8 patients (38% females; mean age 82.4, SD 6.2 years; mean level of cognitive functioning, measured by the German Version of the Quick Mild Cognitive Impairment Screen [55], 56.0, SD 8.2) were invited and interviewed until data saturation was observed and further recruitment was terminated. None of the patients refused to participate or dropped out of the study after providing their written informed consent. The demographic characteristics of the patients are summarized in Table 1.

Table 1. Demographic characteristics of the study population.

	Total sample (n=8)
Age (years), mean (SD)	82.4 (6.2)
BMI (kg/m^2), mean (SD)	23.1 (2.4)
Physical activity (min/week), mean (SD)	298.8 (227.0)
Qmci[a] [55] total score (points), mean (SD)	56.0 (8.2)
Clinical subtype, n (%)	
mNCD[b] due to Alzheimer disease	6 (75)
Mild frontotemporal NCD[c]	0 (0)
mNCD with Lewy bodies	0 (0)
Mild vascular NCD	2 (25)

[a]Qmci: Quick Mild Cognitive Impairment Screen.
[b]mNCD: mild neurocognitive disorder.
[c]NCD: neurocognitive disorder.

Qualitative Content Analysis Results

T1: Capabilities

The experts described a large variety of impairments observed in older adults with mNCD. The most frequently described impairments referred to cognitive functioning (f=43), including impairments in the following neurocognitive domains: executive function (f=23), complex attention (f=11), learning and memory (f=7), visuospatial skills (f=2), language (f=1), and social cognition (f=1). These cognitive changes were also described as affecting psychosocial factors (f=22), mainly by causing psychological distress (f=9) and feelings of insecurity (f=2), leading patients to try to hide their impairments from others (f=2). In addition, an increased fall risk (f=9) and reduced physical resilience (f=7) were observed. Although experiencing difficulties in activities of daily living (ADLs; f=1), patients were described as maintaining their functional independence in ADL (f=2).

In line with the experts' viewpoint, cognitive deterioration (f=22, n=7, 88%) was frequently described by the patients, mainly affecting learning and memory (f=11, n=4, 50% of patients), executive function (f=6, n=4, 50% of patients), and complex attention (f=5, n=2, 25% of patients), whereas only minor restrictions in physical capabilities and mobility were mentioned (ie, impaired balance, [f=2, n=2, 25% of patients], reduced gait speed [f=1, n=1, 13% of patients], increased fall risk [f=9, n=5, 63% of patients], fatigue [f=6, n=3, 38% of patients], and joint pain [f=2, n=2, 25% of patients]). ADLs remained preserved in all patients, but the need for coping strategies was mentioned by 4 patients (50%) to be able to preserve ADLs. From the patients' perspective, the consequences of their self-perceived subjective cognitive decline (f=8, n=6, 75% of patients) with regard to psychosocial factors were most frequently reported (f=36, n=8, 100% of patients), mainly involving psychological distress (f=13, n=2, 25%), feelings of insecurity (f=6, n=3, 38% of patients), depressive symptoms (f=2, n=2, 25% of patients), or fear of repeated falls (f=3, n=1, 13% of patients):

> *A really tedious thing is that you often can't keep up. For example, in discussions or conversations. [...] You often think about what the other(s) have just said and in the meantime he or she has already continued. That's why you often just don't say anything. Of course, most people like it when you don't say anything (*laughs*). So, these people don't get upset about it. But I am.* [P-01]

> *I used to go running a lot. I don't do that anymore. But swimming is still fine. In the worst case, I become a drowned corpse, but at least I can't fall while swimming.* [P-02]

> *I can actually do everything; I just have to be careful because of my dizziness and weakness so that I don't fall. I also have problems with short-term memory. I have to try to remember everything somehow, but I still forget a lot of things.* [P-04]

T2: Treatment Experience and Preferences

Previous Treatment and Training Experiences

To counteract cognitive decline and preserve physical capabilities, mobility, and ADLs, patients have already been on medical training therapy (MTT; f=3, n=3, 38% of patients), have already been on physical therapy (PT; f=2, n=2, 25% of patients), have performed a specific group-based (ie, f=1, n=1, 13% of patients) or individual (f=1, n=1, 13% of patients) cognitive training or meditation (f=1, n=1, 13% of patients), or have reported to have no experience in any specific therapy or training (f=1, n=1, 13% of patients).

From the patient's viewpoint, MTT and PT were perceived as useful (f=3, n=3, 38% of patients), but patients reported that they would have to do it more consistently to profit from it (f=2, n=2, 25% of patients). Computerized cognitive training (CCT) was also perceived as useful (f=1, n=1, 13% of patients) and reported to be challenging, fun, and enjoyable (f=2, n=2, 25% of patients). Nonetheless, patients reported being insecure about the effectiveness of CCT (f=2, n=2, 25% of patients):

> *[In response to PT] [...]my gait has improved. I now take slow and long steps and no longer fall over. However, I would definitely have to do it more consistently.* [P-02]

> *The problem is primarily that my physical therapist only has time for me every 14 days because she is so booked up. Of course, it would be nice if I could go more often. But it is what it is, and I have to live with it.* [P-08]

> *[Patient explains game tasks of CCT] It's not even that simple. This is all fun and useful. But I don't know if it will do any good. [and] I have no intention of stopping. However, at some point I have to ask myself: "Does is go any further? Or is it just going to stay at what I'm currently able to manage?"* [P-01]

According to the experience of experts and health care professionals, only cognitive forms of training or physical exercises were often experienced as boring over time by older adults with mNCD (f=2) and required guidance by a therapist (f=2). More integrative forms of training, including gamified tasks close to everyday life, multimodal animation, and acoustic feedback, were reported to be preferred by patients (f=4):

> *It is often the case that patients are completely dependent during strength training, [and] [...]they just kept on exercising and exercising. [...] They often continue the exercises until you stop them.* [E-10: founder of an exergaming company]

> *Cognitive exercises including "a certain closeness to everyday life and also a multimodal animation[...] and acoustic feedback have been very well received."* [E-03: neuropsychologist]

Previous Experiences With Novel Technologies

Although being described as skeptical about the use of technological devices, experts perceived older adults with mNCD as ready to use technological devices such as heart rate monitors during training (f=9), if its usability is ensured:

> *Well I think using a sensor it's not a problem if the wearable is well designed.* [E-01: exergaming researcher]

> *Many people would certainly be okay with a Polar chest strap, but a monitor to be worn at the wrist would certainly be preferable. If people are told why these sensors are used and what they are measuring, it should be feasible with the chest sensors as well. It may be difficult with certain older ladies or overweight individuals, but for the average individual this should not be a problem.* [E-03: neuropsychologist]

The experts' perceptions coincided with those of patients. All patients were willing to use a heart rate monitor worn with a chest strap during training, provided it was beneficial for their training. In addition, 75% (6/8) of patients stated that their PC or television was usable, whereas 25% (2/8) of patients reported limited usability:

> *[Regarding the use of heart rate monitors during training] [...]provided it's useful I would be ready to wear such a heart rate monitor without having any reservations at all.* [P-01]

> *[About the usability of the television] Sure! All you have to do is press the switch. That's still possible.* [P-07]

> *[About the usability of the personal computer] Yes, using my personal computer works more or less. [...] It is just not something of my generation. I have a computer and I use it, but there are always things I can't do and have to ask my granddaughter.* [P-01]

Previous Experiences With Exergames ["Senso (Flex)" Specifically]

None of the interviewed patients reported any previous experience with exergames in general or with the exergaming system "Senso (Flex)" specifically. Nonetheless, after a short introduction to the system, all patients stated that they would be willing to try it.

On the basis of the previous experiences of the experts and health care professionals, the interaction with the "Senso," its overall usability, and the design of the exergames have been described as good (f=5). Regarding hardware components, minor usability problems have been reported. Patients were observed to unintentionally walk off the middle plate without noticing the feedback on the screen (f=4), constantly change their focus between the game tasks on the screen and the stepping plate to anticipate and plan their movements (f=4), or make too small steps to tap on one of the outer stepping plates (f=1). In addition, the patients needed time to familiarize themselves with the sensitivity of the stepping plate (f=2):

> *[...]the "Senso" is in general well usable and is also very often used.* [E-04: exergaming researcher]

> *The tasks on the "Senso" are very well designed.* [E-08: project manager therapy]

> *[...]the "Senso" is already very user friendly, [but] I had a little problem at the beginning of the experiment where people would accidentally go out of the square in the middle of the "Senso".* [E-09: exergaming researcher]

> *Most of the time, the patients look down at that very moment and thus do not see the message [on the screen] at all.* [E-07: physical and occupational therapist]

Additional usability issues were reported to be linked to the capabilities of older adults with mNCD. First, it has been described that patients are often cognitively overloaded when trying out new games (f=1), by the occurrence of an unexpected situation or technical errors (f=2), or by the cognitive task demands required to interact with the exergame system in general (f=1), which may limit training duration owing to attentional exhaustion (f=2):

> *With new games, patients are often overwhelmed in general, because they don't know what to expect.*

> *They often need time to find their way around.* [E-07: physical and occupational therapist]
>
> *[...] Patients are completely overwhelmed as soon as something unexpected or a technical problem occurs.* [E-03: neuropsychologist]

In contrast, the physical capabilities were reported to not directly affect the usability of the system (f=4), although some patients experienced difficulties with backward steps (f=2), and many patients made use of the handrail to reduce the physical strain (f=6). In some cases, physical limitations (eg, fatigue and joint pain) resulting from static loading have been reported to limit the training duration (f=4):

> *Patients often have problems with backward steps. [and] Patients hold on to the handrail far too often. [...] it is often the case that people hold on because it is simply 'a bit more comfortable.* [E-10: founder of an exergaming company]
>
> *Often it is already difficult and tiring for patients to stand for a longer period of time. It is often easier for them to walk. [and] However, it should be noted that this form of fatigue is not necessarily comparable to fatigue caused by physical training. Fatigue does not necessarily come from physical exertion. It is possible that this type of fatigue is caused by the static load and the resulting joint pain.* [E-06: physical and occupational therapist]

When considering the specific games of the exergaming device "Senso" (video illustrations and explanations of all currently available games can be found at [71]), the simple and clear design structures of the games (f=4) and the intuitive tasks were reported to be highly appreciated by patients and promote good comprehensibility, which was reported for the games "Simple" (f=3), "Birds" (f=3). Nonetheless, there are also games that were reported to cause problems of understanding, in particular the games "Simon" (f=3), "Tetris" (f=3), "Habitats" (f=4), "Targets" (f=1), and "Snake" (f=2). These problems may be related to the game instructions (f=9):

> *[...]Many people are very happy with simple design structures. This should be maintained at all costs when designing new games for MCI patients. However, [...]some kind of adjustment of the game instructions is definitely needed.* [E-10: founder of an exergaming company]
>
> *For patients, a game does not stand out by its great graphics, but by the game tasks as such.* [E-08: project manager therapy]
>
> *[About problems of understanding the games] I think the reasons were that they didn't really understand the instructions well.* [E-09: exergaming researcher]

However, it could also be related to the task demands of the games. It was reported that the patients need some time to familiarize themselves with the game to fully understand it (f=1). According to the experts' experiences, this works well with the games "Simple" (f=4), "Birds" (f=1), "Flexi" (f=1), and in some cases "Habitats" (f=1). At the same time, games such as "Flexi" (f=1), "Habitats" (f=6), "Hexagon" (f=3), "Simon" (f=6), "Ski" (f=4), "Targets" (f=12), and "Tetris" (f=4) were frequently reported to start at an already (too) challenging level for older adults with mNCD and progress too fast while there is a limited range of games or adaptability of task demands at the lower end of difficulty levels (f=9). This was mentioned to be mainly apparent for the cognitive task demands (eg, game speed and task complexity), whereas physical exercise intensity is often (too) low and could be increased (f=4):

> *For MCI-patients, some games are predestined to be used with them, such as "Simple," "Flexi," "Birds" and perhaps also "Habitats." These games don't put so much time pressure and the feeling of having missed something on patients.* [E-08: project manager therapy]
>
> *[...]the increase in the challenge profile from the easiest games ("Simple" and "Birds") to the next more difficult game is too steep for MCI-patients. For example, the game "Targets" is too fast for many patients. The game "Habitats" contains too many stimuli at once, so that the patients no longer know what they have to pay attention to.* [E-07: physical and occupational therapist]
>
> *[...]I have the impression that the internal progression, which is responsible for adapting the game demand, sets the lower limit too high and adapts too quickly, so that the cognitive overload becomes visible very quickly, especially in MCI-patients.* [E-08: project manager therapy]
>
> *One problem with the "Senso," in general, is that the physical intensity might well be higher.* [E-05: neuropsychologist]

Overwhelming task demands may cause frustration or refusal of games (f=6), although the feedback mechanisms to indicate errors work subtle (f=4). In contrast, games that are perceived as being too easy lead to boredom (f=2):

> *For example, the games "Targets," "Ski" or "Hexagon" are very confronting, and patients recognized quite quick: "Okay, I can't do it," and that frustrates patients. [...] Usually, these patients stop in the middle and say something like: "Ah, I don't need that kind of shit." Most of the time, they stop the training session immediately and don't want to continue anymore.* [E-08: project manager therapy]
>
> *My observation was that the negative feedback currently used does not demotivate the patients at all. It is also clear to the patients that they need to know when they are making mistakes and whether they are completing the tasks correctly.* [E-04: exergaming researcher]
>
> *Some of the negative feedback is so subtle that it is not even noticed.* [E-05: neuropsychologist]

T3: Motivators for Training

The experts described numerous motivators for training older adults with mNCD. The most frequently described motivators can be classified as intrinsically regulated motivators (f=44), which are directly related to exergames. Excitement, enjoyment, or fun is perceived as a central motivator for performing exergames (f=4). This was reported to be maintained by the captivating character of exergames (f=1) and multimodal animation (f=1), which is supported by specific game components (eg, game tasks or designs close to everyday life [f=6] or with personal relations or memories [f=1] including music or sound effects [f=8], animals or plants [f=4], landscapes [n=1], or colors [f=1]). In addition, patients were described as intrinsically motivated by gamification (f=6), the feeling of being optimally challenged (n=3), or simply by the variation of training (f=6):

> *For patients, the focus is primarily on having fun with the games. For example, they [...]liked watching birds and listening to birdsong and felt very motivated by the personal connection. Through these personal memories [...] a whole other level of motivation emerged.* [E-08: project manager therapy]

> *I think that those people who enjoy playing games are generally captured by the playful and competitive nature of the games. Furthermore, training with exergames is something completely different compared to classical therapy. Patients appreciate this change from the "dry" standard therapy.* [E-06: physical and occupational therapist]

However, when task demands become too high (f=6) or too low (f=2), patients have been observed to promptly lose their willingness to perform the exergames, as already reported. External motivators such as social support (eg, by therapists or caregivers) or group dynamics have also been reported to improve motivation to train (f=12). Feeling concerned about cognitive deterioration or being confronted by performance classifications can either motivate or induce negative feelings (f=7). Finally, some patients were also reported to be motivated by the effectiveness of exergames (f=2) or performance improvements (f=2):

> *I consider this social support to be very central. [...] If a relative joins in for motivation or support it can be very valuable.* [E-04: exergaming researcher]

> *I think there are always patients who don't want to know how well they are performing. Forcing performance feedback on such people can of course be motivating, but it could also be negative and confirm their limitations.* [E-07: physical and occupational therapist]

From the patients' viewpoint, all patients reported that they could primarily be motivated to train regularly by the effectiveness of the training, helping them achieve their individual success (f=13, n=8, 100%). Alternately, patients reported being motivated by their relatives or partners (f=2, n=1, 13%) and enjoyment of exercising (f=1, n=1, 13%). Having to travel to a training facility was reported to have a negative effect on training motivation and adherence (f=4, n=1, 13%):

> *It would be nice if I could go for a walk in the forest again without falling down. I used to do this four times a week for 75 minutes. It motivates me to train so that I can do this again in the future.* [P-02]

> *It would motivate me if I could improve my abilities (balance) again. [...] I would like to stay independent and modern, not to be called an old lady.* [P-03]

> *The success. I no longer need to be motivated. If I set my mind to it, I do it!* [P-08]

T4: Training Goals and Outcomes

Regarding the training goals, cognitive functioning (f=19) should be targeted in the training intervention in the experts' viewpoint while also addressing ADLs and mobility (f=3), addressing physical capabilities (f=3), and accounting for psychosocial factors (f=2), such as feelings of insecurity. However, the weighting of the training focus differs significantly between experts in different fields:

> *[...] higher order processes (i.e. divided attention or the ability to plan) are affected in most patients. Therefore, it is important to focus on these higher order cognitive functions.* [E-05: neuropsychologist]

> *I think that the coupling of brain functions with physical functions is central. At the same time [...]it is important to focus on what is impaired. If the frontal lobe is impaired, it is certainly important to train executive functions, attention and inhibition.* [E-10: founder of an exergaming company]

> *Primarily physical activation, especially that people get moving and walk. But also, to train the intuitive way of taking steps. [...] The cognitive aspects of the training have always played a subordinate role for me, but they were usually not decisive for the success of the therapy, as this was often trained differently, and I am not an expert in this.* [E-06: physical and occupational therapist]

When asking experts about the training goals of patients, ADLs and mobility (f=5) were the most frequently stated in addition to cognition (f=3) and physical functioning (f=2). In addition, psychosocial factors (f=2) have been reported to include socializing or having fun:

> *I had patients who wanted to continue training because the training made them more confident in their gait. They felt better balance after the training.* [E-06: physical and occupational therapist]

> *The patients also see the cognitive aspects of the training, of course. [...] We often explain to the patients that falls prevention has a cognitive and physical aspect and that these aspects interact. Therefore, the patients mainly go to the training with the aim of improving their gait.* [E-07: physical and occupational therapist]

> *Some people really know what's going on and they know that they have a disease and that they can prevent or slow down the progression by doing physical activity and exergames. But then others don't really know that they have cognitive deterioration and they're just playing a game and having fun without specific training goals.* [E-09: exergaming researcher]

This is consistent with patients' viewpoint who most frequently reported improving gait (f=6, n=5, 50%), memory (f=3, n=3, 38%), and balance (f=2, n=2, 25%) as their primary goal to increase their quality of life. In addition, patients reported being more active (f=1, n=1, 13%), increased functional abilities (ie, cooking; f=1, n=1, 13%), increased strength (f=1, n=1, 13%), or remaining independent in ADLs (f=1, n=1, 13%) as training goals:

> *It is mainly the memory. It is memory because it affects a lot of other things.* [P-01]

> *It would be wonderful, if I could go for a walk in the forest again without falling down.* [P-02]

> *I really want to remain independent. I definitely don't want to become dependent on others.* [P-05]

> *That I can keep things better in my head. That has diminished. That would be nice!* [P-06]

> *I want to have more strength again to increase stability and be able to walk longer.* [P-08]

T5: Exergame and Training Components

Location

Regarding training location, the experts reported that the patients would either prefer individual training at home (f=3) or in a mixed setting, including training at home combined with training at a clinic (f=4). None of the experts stated that patients would prefer exercising at a clinic or training facility in general, as this is often associated with excessive time expenditure. Training at home was reported to be beneficial, because it represents a known environment that makes patients feel more secure. However, the experts also stated that patients may not be capable of performing exercises or exergames independently and therefore need guidance throughout each training session (f=4) or at least partially (f=9); for example, when starting up the system or in case of technical problems:

> *The advantage of training at home is that "it's a known environment and they feel safer at home and also don't have to travel." However, "I would suggest that the help of a guiding therapist with experience will be necessary."* [E-09: exergaming researcher]

> *In a previous investigation [...], patients' feedback was that 70% could imagine doing the training from home. [...] For MCI-Patients specifically, relatives may be involved. But in general, the need for home-based exergame training is there, I would say.* [E-08: project manager therapy]

This is also reflected in the outcomes of the question of whether patients would be capable of performing home-based exergame training; the experts mainly reported that patients are certainly capable (f=4) or should be capable of considering some concerns (f=9) to perform such a training program independently at home. The concerns that need to be considered include the improvement of game instructions (f=2), accessibility of a handrail or similar for safety support (f=2), and avoidance of technical problems (f=2) or the integration of a guided familiarization period (f=1) or support of a care professional or partner (f=2):

> *I think if the system would really work properly then you could use it at home. However, if you just have some minor technical problems is already like a no-go to use it at home at all.* [E-01: exergaming researcher]

> *It would certainly be good if the patients could complete an accompanied training for a certain period of time in order to facilitate the transfer to training at home.* [E-04: exergaming researcher]

> *[...] some kind of adjustment of the instructions is needed [...], especially for this patient group and for independent training in the home-based setting. [...] The instructions have to be adapted in such a way that understanding can be achieved without someone having to stand next to the patients all the time.* [E-10: founder of an exergaming company]

Of those patients who responded to the question and had a clear preference regarding the training location, most (6/7, 86%) patients would clearly prefer to train individually at home, because it is less time consuming and more flexible. One patient did not have a clear preference; she simply wanted to perform the exercises where it was easiest for her and preferred group exercises:

> *For me, it is important that the training can be done independently at home. If I have to go to the doctor somewhere every time, it's simply too much work.* [P-01]

> *Preferably at home, if I can. Then I can also choose the time when I want to exercise. I have lived my whole life with a packed schedule. Now I want to be a little freer and more flexible.* [P-03]

Safety

The experts reported an increased risk for falls, as patients with mNCD (1) are easily distractable and (2) have difficulties in self-assessment and impaired planning abilities. Therefore, it was recommended to use the handrail in the beginning to minimize the risk of falls (f=3), which was also requested by 1 patient. In the case of a home-based exergaming system—which may not have a handrail—thorough and clear safety instructions are recommended (f=1):

> *Especially in the beginning, until the patients have understood what it is all about, it is very important to instruct using the handrail.* [E-04: exergaming researcher]

> *I definitely need a railing to prevent falls during training. I often fall down if I don't have anything to hold on to.* [P-02]

Instruction, Familiarization, and Guidance

As illustrated earlier, certain adaptations are required to enable a more independent use of the exergaming device. First, patients should be familiarized with the exergaming device and the corresponding games considering the following key elements: (1) start at an easy level (f=7), for example, by using the game "Simple" (f=4), (2) ensure that patients voluntarily try out the device (f=3), (3) ensure that you are not too confronting (f=2), (4) give patients enough time to familiarize with the new task (f=1), and (5) start with a reaction game, then progress to games for specific domains of neurocognitive function (f=1):

> *It is very important to start very slowly and at a low difficulty level until the patients can better assess their abilities on the "Senso". […] Since the game "Simple" waits for a reaction from the individual, it is very suitable to start with.* [E-04: exergaming researcher]

> *We always start with a reaction game so that the patients can learn the coupling of the cognitive-motor functions and learn to interact with the environment. Later on, we focus on specific cognitive functions.* [E-10: founder of an exergaming company]

Regarding the instructions, some adjustments are needed to improve comprehensibility. Currently, there is instructional text before starting each game. However, patients with mNCD have been reported to have limited comprehension of instructions. Therefore, adaptations are needed in the instructions of exergames in general and for a home-based exergaming system in particular. The experts mainly suggested to use step-by-step (f=3) instructions based on a combination of visual (ie, written instruction or video demonstration) and verbal instructions (f=4) guided by an experienced therapist (f=1). In case of more severely impaired patients or for home-based exergaming systems, it was suggested that practical demonstrations (f=2), video instructions (f=6) or even interactive "trial run" instructions (f=5) could improve comprehensibility of the games:

> *The transfer from the written instructions to the understanding of what is to be done in the game is sometimes difficult.* [E-06: physical and occupational therapist]

> *Personally, I would replace the written instructions with a short (few seconds) video sequence showing the most important functions of the games.* [E-08: project manager therapy]

> *I would recommend combining visual and verbal instructions. For example, through a visual presentation with additional step-by-step verbal instructions. Verbally we can "pick up" the patients very well and get a feeling whether the patients have understood the instructions.* [E-03: neuropsychologist]

> *[...], some kind of adjustment of the instructions is needed. [...] It is definitely important to pursue and use these adaptations, especially for this patient group and for independent training in the home-based setting", because "in the case of more severe impairments, it is often necessary to demonstrate the games step by step by yourself. [...] In other gaming systems there is a short test phase with explanations and trial runs [...]. However, this would have to be offered as an option, since most patients will no longer need it after a few sessions.* [E-10: founder of an exergaming company]

Finally, when guiding patients through their training sessions, social support and guidance by a care professional or partner might be beneficial (f=3). However, it was also mentioned that this might be critical because of personal conflicts or patients' psychological constraints (f=2):

> *Family members could play an important role in reminding and motivating patients to complete their training.* [E-06: physical and occupational therapist]

> *I don't think it's always a good idea to include family members as guidance, because the pressure to perform gets higher for the patients, since they try to hide their impairments from others. A health care professional like a nurse for example or physical therapists would be better than a husband or wife, I think. They already have a lot of fights in the households, because things are not working out as they should.* [E-09: exergaming researcher]

From a patient's perspective, all patients reported that they can imagine training alone, provided they had received thorough instructions and understood their tasks. One patient additionally requested regular support from a care professional or partner:

> *Yes, I think so. Once I learn that, I'm sure I can do it independently.* [P-03]

> *If I am supported by you or by my partner, then I can certainly train partly independently.* [P-07]

Exergame System and Content

Previous experiences of older adults with mNCD using the exergaming system "Senso" are illustrated earlier. Building on this, several game-specific adaptations were suggested by the experts (f=9):

> *More time should be provided between the balls so that the flood of information is reduced (it is often overwhelming when several balls are visible on the screen very quickly).* [E-07 (physical and occupational therapist): for the game "Targets"]

> *In the initial phase, until patients' have understood all the game tasks [...], the speed must definitely be reduced.* [E-06 (physical and occupational therapist): for the game "Habitats"]

> *There are already enough opportunities to increase the task difficulty. [...] However, it is very important to note that the game difficulty is adjusted downwards so that it is easier to start the training.* [E-08: project manager therapy]

In addition to these game-specific adaptations, multiple novel game designs and elements have been suggested and discussed by focus groups to address patients' needs optimally. In general, it has been recognized that there is a need for new games specifically targeting the neurocognitive functions of learning and memory (f=4) and executive functions (ie, working memory and cognitive inhibition; f=2). Specific game design suggestions were discussed for such a memory or working memory game. Additional suggestions for new game designs and elements include the use of music, addition of visual reminders to guide patients within the games, or adaptations in performance feedback:

> *With the "Senso", a certain spectrum of neurocognitive function domains is covered. However,*

> *games for working memory, inhibition or memory are completely missing. In the case of memory, there is currently only one game available specifically targeting the training of short-term memory span.* [E-05: neuropsychologist]

> *I think music would be very motivating for people with MCI or dementia also if is music from their youth or music they like. It's also been described in the literature that music has so many good effects on people when they have heard a song that they liked before and they are singing that song.* [E-09: exergaming researcher]

> *In addition, it would be good to include reminders, for example at the edge of the screen, which patients can use for orientation. [...] Additionally, [...] it would certainly be helpful here if the program not only displayed the performance curve, but also provided a reason or explanation.* [E-03: neuropsychologist]

As general requirements when designing new games, the experts recommended using simple graphics and ensuring good contrast (f=14), a comfortable relation, and good usability of the exergames (f=4) using easily comprehensible and clearly designed tasks (f=2) with a certain closeness to everyday life (f=7). Multimodal animations, including multisensory feedback (f=7), should additionally be integrated by focusing on positive reinforcement mechanisms (f=2) to motivate the patients during exergaming. In addition, it is important that the main task is in the center of the screen (f=1) and that only elements that are related to the game task are included (f=5). Moreover, too confronting performance feedback (f=1) and unexpected appearance or technical problems (f=2) should be avoided:

> *It is very important to create a good contrast. [...] It's generally important for the older population to keep the graphic representation as simple as possible, because for older people, the game is not characterized by great graphics, but by the game task as such. The main importance is that the right level of challenge is offered.* [E-08: project manager therapy]

> *It is much better to present a simple graphic and focus on the aspects that need to be trained. [...] unnecessary graphic gimmicks should be avoided!* [E-04: exergaming researcher]

> *It is important to have a main action that is in the center of the screen and to ensure that the player will have primary task in the center. If you put any secondary tasks into the games, it can be confusing for the patients.* [E-02: exergaming researcher]

> *Spontaneously, I would say that games close to everyday life are more popular. [...] These games were much better received than abstractly structured games ("visual exploration tasks").* [E-03: neuropsychologist]

> *My experience so far is that games that are designed to be more relevant to everyday life (and simpler) work better. Therefore, new game designs should be based on what patients know from their everyday lives.* [E-06: physical and occupational therapist]

Training Components

The recommended exercise frequency ranged from 2 (f=3) to 5 or more (f=4) training sessions per week, largely dependent on training location and motivation. The recommended session durations ranged from a maximum of 15 to 20 minutes (f=3) up to 30 minutes (f=2), with the aim of reaching a moderate exercise volume of approximately 150 minutes per week (f=1). Shorter sessions and a higher training frequency have been reported to be preferable to reach this training volume, mainly owing to attentional exhaustion:

> *The more the better! I would prefer shorter training sessions, especially because of attentional exhaustion. Here I would recommend a maximum of 30 minutes and at least 5 sessions a week. This is much better than training for 2 hours at a stretch!* [E-03: neuropsychologist]

> *I would recommend a training frequency of 2 – 3x/week. [...] The training duration is difficult to estimate. Some patients are already exhausted after 2 minutes, others can easily train for 20 minutes.* [E-10: founder of an exergaming company]

> *I think that a training frequency of 3x/week is already (too) much. 2x/week should be possible to arrange. 1x/week definitely works. This may be because three appointments, in combination with other activities, may already be too much for patients. If the training could be done at home, the training frequency could certainly be increased up to 4 - 5x/week. In this case, motivation could still be difficult.* [E-07: physical and occupational therapist]

> *I would aim for a training volume of 150 min/week. As far as I know, this is considered moderate for older patients. I would consider 100 min/week as the lower limit. A minimum of 3 x per week for 30 min would also be okay at best.* [E-08: project manager therapy]

Exercises requiring a coupling of physical and cognitive functions were described as preferable and should be prescribed domain-specific depending on the patient's abilities:

> *I think that the coupling of brain functions with physical functions is central. Whether this is ultimately an attention game, or a training of the executive functions is something I don't consider central at the beginning. Of course, it also plays a role here which cognitive functions are impaired. [...] If the frontal lobe is impaired, it is certainly important to train executive functions, attention and inhibition.* [E-10: founder of an exergaming company]

To maintain the training program in the long term (preferably >12 weeks), motivation is a key factor that can be facilitated by the playful character of the exergames and a variation in the choice of games. Nonetheless, patients seem to prefer a certain routine:

> *Of course, the training should be maintained over a certain amount of time at a stretch. So not just two*

> *weeks, but ideally longer (more than 12 weeks). Of course, motivation is also a very central point. If the training is varied and has a playful character, this should be feasible.* [E-03: neuropsychologist]

> *Patients are generally routine-oriented, which can also be observed in general. Therefore, it is also important to introduce a new game every now and then. The patients primarily prefer the familiar games and should therefore be challenged to a certain variety.* [E-10: founder of an exergaming company]

The physical exercise intensity should be maintained at a light to moderate level, while the focus should be on game complexity that should be challenging but feasible. Game complexity can be varied on multiple levels, for example, (1) stability support (use of handrail with both hands, 1 hand, or no support), (2) stepping direction, (3) game choice and tasks included, (4) game duration, or (5) game speed:

> *Adding new games. I always start with the game "Simple" and sometimes in the first session I also introduced "Birds" when I think it would be possible. If not, then I will do it the next session. If somebody is really performing well and understanding all the instructions, then I also progress to the game "Targets" and even "Birds".* [E-09: exergaming researcher]

> *I also often started with just stepping movements forward [...] and included the step direction to the right at a later timepoint.* [E-10: founder of an exergaming company]

> *We have a routine that we usually do the training sessions over 3 weeks and do the first 3 sessions with holding, just to get a feel for the games. After that, we gradually go back to holding on with one arm and without holding on.* [E-08: project manager therapy]

From the patients' viewpoint, a high training frequency (mean preferred training frequency 5.21 times per week; n=7), ranging from 2 times per week (n=1, 13%) to daily sessions (n=4, 50%)) with short session durations (mean preferred session duration 23.4, SD 10.3 minutes; n=8), ranging from 10 minutes (n=1, 13%) up to 30 minutes (n=3, 38%) was preferred. Five of 6 (83%) patients who responded to the questions about how long they would prefer to do the training stated that they would prefer to continue the training as long as they profit from it and are able to do it. All patients preferred a training that is individually adapted to apply moderate (4/5, 80% of patients) to high physical (1/5, 20% of patients) intensity and moderate (3/5, 60% of patients) to high (2/5, 40% of patients) cognitive challenges:

> *If the device was at home, I would do the training every day.* [P-01]

> *I don't want to make a guarantee now, but I could do a short training session every day for like 20 minutes or so. But I can't promise that I'll do 40 minutes every day, because I also want to do other things. Especially when the weather is nice, I like to go outside. And then I also must do the housework, which also takes time.* [P-03]

> *I think about 30 minutes is good. If it goes on too long or is too strict, then I get tired of it. I don't like that. That would be counterproductive.* [P-05]

> *If I have the device, I could do this training forever. As long as I still have the strength to do it.* [P-02]

> *I would need a bit of a start-up period first. If it's not effective, I'll stop again. Additionally, I don't know how my health will be in the future. But as long as I'm reasonably fit, I'll definitely want to do it.* [P-07]

Individualization

Individualization of the exergame intervention concept should mainly account for two aspects: (1) task type (ie, choice of exergames to individually focus on neurocognitive functioning; f=4) and (2) task demands (ie, adapting the game demands according to the individual capabilities to maintain a challenging but feasible cognitive load; f=5). In addition, it was recommended to change between games with different task demands to enable the maintenance of attention over the entire training duration (f=2) and to supervise training exertion (f=3):

> *It is important to have a system that will adapt the games according to the participant's performance.* [E-02: exergaming researcher]

> *The physical intensity is often not a problem, and it should primarily be the complexity of the training that is individually adapted so that it is doable and still has a certain physical demand.* [E-10: founder of an exergaming company]

> *[...] We also have to check whether somebody is very fatigued [...]. Sometimes you have to let someone take a rest because they will not always feel when they have to take a rest.* [E-09: exergaming researcher]

> *One should "[...]alternate between games that focus primarily on performance and less on cognitive aspects with more cognitively demanding games."* [E-08: project manager therapy]

Discussion

Principal Findings

The objective of this study was to determine the capabilities, treatment preferences, and motivators for training older adults with mNCD, as well as their perspectives on training goals, settings, and requirements for exergames and training components. This will—together and in line with a synthesis of the optimal evidence-based informed decisions—serve as basis for user modeling, determination of therapeutic needs, and definition of a set of requirements for the game design and development process of a novel exergame-based training concept. To the best of our knowledge, this is the first study to systematically and thoroughly investigate user requirements and preferences for an exergame-based training concept before it is designed and developed specifically for older adults with mNCD based on these findings.

The results of our qualitative study, which included focus groups with 10 experts or health care professionals and individual semistructured, in-depth interviews with 8 older adults with mNCD, yielded the following key findings: (1—capabilities) from a patients' viewpoint, the psychosocial consequences of their self-perceived cognitive deteriorations might be more burdensome than the cognitive changes themselves; (2—treatment preferences) more integrative forms of training (such as exergaming) including gamified tasks close to everyday life, multimodal animation, and acoustic feedback are preferred by patients. None of the interviewed patients reported any previous experience with exergaming, but all patients described the handling of different technologies as feasible despite some challenges and were willing to try out exergaming; (3—motivators for training) from the expert's viewpoint, the most frequently described motivators to train can be classified as intrinsically regulated motivators such as excitement, enjoyment, or fun in exercising that is maintained by the captivating character of exergames supported by specific game components (eg, game tasks or designs close to everyday life or with personal relations or memories including music or sound effects, animals or plants, landscapes, or colors); the feeling of being optimally challenged; and the variation of training. All patients reported that they could primarily be motivated by the effectiveness of the training, helping them to achieve success on an individual basis; (4—training goals and outcomes) the most important training goals of older adults with mNCD include improvements in ADLs and mobility (gait and balance) and memory, because these outcomes were described as central to improving their quality of life; (5—exergame and training components) the use of home-based exergames as a form of simultaneous-incorporated motor-cognitive training should be prescribed with a domain-specific training focus depending on a patient's cognitive abilities, a high training frequency (4-5 training sessions per week), short session durations (20-25 minutes), and individual adaption and progression of task type and demands to reach a light to moderate level of physical intensity and a challenging but feasible game complexity. To maintain the training program in the long term (preferably >12 weeks), motivation is a key factor and should be facilitated by the playful character of the exergames, variation in the choice of games, and ensuring that the patients are optimally challenged. To make home-based training interventions feasible, multiple factors that need to be considered were identified. Patient-friendly game instructions are needed, while the accessibility of a handrail or similar for safety support, avoidance of technical problems, and the integration of a guided familiarization period or support from a care person need to be ensured to make home-based exergame training feasible. As general requirements for exergame design, simple graphics with good contrast and easily comprehensible and clearly designed tasks with a certain closeness to everyday life should be used. Multimodal animations, including multisensory feedback that focuses on positive reinforcement mechanisms, should be integrated to motivate patients during exergaming. In addition, it is important that the main task be in the center of the screen and that only elements that are related to the game task are included. Moreover, confronting performance feedback and unexpected appearances or technical problems should be avoided.

Capabilities of Older Adults With mNCD

A variety of cognitive changes mainly affecting the neurocognitive domains of learning and memory, complex attention, and executive function were discussed by the focus groups and mentioned by the patients, whereas no serious restrictions on physical capabilities, mobility, and ADLs were reported. This is in line with DSM-5 [9]. According to the definition of mNCD, modest (ie, for mNCD, performance typically lies in the 1-2 SD range) deterioration in cognitive functioning can be observed, whereas the capacity for independence in everyday activities is preserved [9]. However, from the patient's perspective, the most prominent consequences of their disorder were described as affecting psychological factors, mainly by causing psychological distress, feelings of insecurity, and depression. It is well known that depression and anxiety are common in older adults with mNCD [72,73]. In addition, patients with depression have higher rates of conversion to dementia, indicating that depression is an important risk factor for cognitive decline and progression to dementia. This emphasizes the importance of assessing depressive symptoms in older adults with mNCD [72].

Treatment Experience and Preferences

Most of the interviewed patients had already gained experience with different treatment or training approaches to counteract cognitive decline and preserve physical capabilities, mobility, and ADLs. Although MTT, physiotherapy, and CCT were perceived as useful, the patients reported being insecure about the effectiveness of these approaches or that they would have to (be able to) do it more consistently to profit from it, which was described to be limited by the availability of therapists. More integrative forms of training, including gamified tasks close to everyday life, multimodal animation, and acoustic feedback, were reported to be preferred by patients.

This is in line with the literature, showing that "research involving older adults has found that CCT programs are associated with high satisfaction levels, and that they are also a feasible option for individuals with MCI, with equal or better adherence rates when compared with traditional cognitive training" [74-76]. This is also evident in the use of exergames. Exergame-based training interventions are widely accepted in individuals with mNCD, and exergames increase or enhance participants' motivation to engage in rehabilitation activities [40]. This is also reflected by the adherence rates to different types of exercises in patients with mild to major NCD. Recent systematic reviews and meta-analyses synthesized mean adherence rates of 70% [77] for physical exercise interventions, whereas the mean adherence rate was higher for exergame-based interventions at 84% [78]. To the best of our knowledge, there is no systematic review that has synthesized adherence rates to CCT. However, Turunen et al [79] investigated adherence to a long-lasting multidomain CCT among a sample of 631 older adults at risk of dementia. It was shown that only 20% of participants completed at least half of their CCT sessions, and only 12% of participants completed all (maximal number of training sessions=144) of their training sessions. In addition, 37% of the participants did not train at all, whereas "previous use of computers, better memory, being married/cohabiting, and positive study expectations were independently associated with the greater probability of starting the CCT. Previous computer use was the main determinant of the number of CCTs completed after the training was initiated" [79]. Therefore, when comparing these findings, it appears that exergame-based interventions have the highest adherence rates among different training programs. This is consistent with findings in HOAs, where adherence to technology-based training programs was higher than that to traditional training programs, independent of study site or level of supervision [80]. This finding may be largely explained by the high level of enjoyment in using technology-based physical exercise programs [80]. Technology-based training systems offer several advantages over traditional training programs that may contribute to a more enjoyable exercise experience. For example, exergames can provide real-time feedback and positive reinforcement while exercising and can monitor performance over time [80]. In addition, exergames enable individual real-time adaptivity of physical and cognitive task demands according to the participants' performance or physiological response (eg, heart rate and brain activity), which is considered a key advantage of serious video games (such as exergames) [81-83]. In fact, the findings of our study suggest that applying an optimal challenge is central to promote the use of exergames in patients with mNCD in the long term.

When considering the experts' previous experience in the use of exergames (ie, "Senso") with patients with mNCD, the interaction with the device, its overall usability, and the design of the exergames were described as good. Especially the simple and clear game design structures were reported to be highly appreciated by patients and to promote good task comprehensibility. Various minor usability issues were reported, including difficulties in the interaction with the exergame training system "Senso" (eg, unintendingly walk off the middle plate without noticing the feedback on the screen), but mainly, usability issues that related to capabilities of older adults with mNCD (eg, limited comprehensibility of the game instructions) were reported. These usability issues need to be considered and addressed when developing a training concept specifically for older adults with mNCD. Nevertheless, it is important to emphasize that these are only minor usability issues, and only minor refinements are required to optimize the exergame experience. This is also illustrated by recent studies showing that exergame-based training programs using the "Senso" are feasible; usable; and widely accepted in different populations including community-dwelling older adults [84], geriatric inpatients [51], and patients with major NCD [52], chronic stroke [85], or multiple sclerosis [86]. Therefore, when designing and developing an exergame-based training concept specifically for older adults with mNCD, these refinements should primarily target the adaptability and individualization of task demands and the optimization of the instruction of the exergames.

Motivators for Training

The motivating factors most frequently described by experts were classified as intrinsic motivators. These were described as being maintained by the captivating character of exergames and promoted by specific game components such as game tasks or designs close to everyday life or with a personal relation or memory, including music or sound effects, animals or plants, landscapes, or colors. In addition, patients were described to be intrinsically motivated by gamification and the feeling of being optimally challenged. From a patient's perspective, the effectiveness of the training, which helped them achieve their individual success, was clearly the most prominent motivator.

This is consistent with reports in the literature. More autonomous forms of motivation can be promoted by various factors, although these factors may vary depending on the population. For example, a small case-control study compared the motivational factors for using a balance exergame platform between healthy younger and older adults. It was shown that "older adults were more intrinsically motivated by the joy of playing and extrinsically motivated by the perceived health effects (physical and cognitive), with less regard for the in-game rewards" [87]. To provide effective interventions to promote physical activity [88] in patient with NCDs, a new theoretical model has recently been introduced. This theoretical model is based on the review of existing theories that explain behavior change in relation to physical activity in HOA, which were then adapted and integrated to a new theoretical model called the "PHYT in dementia" [88]. In this framework, several additional key elements for promoting behavioral changes in physical activity have been proposed. These consist of self-efficacy, including embarrassment (eg, supervision of activity had a negative impact on engagement in the intervention), personal concerns (eg, fear of falling), and routine (eg, flexible integration of physical activity intervention into daily life regarding place and time of performance), as well as appropriate challenges [88]. A detailed awareness of participant motivators is required, especially for the preference that the routine can be performed at home and at different times during the day [88], because self-determined motivation may be a central aspect of adherence to home-based training programs [89].

Training Goals and Outcomes

The interviewed experts recommended to mainly target cognitive functioning when developing a training concept for older adults with mNCD, while ADLs and mobility, physical capabilities, and psychosocial factors should also be accounted for. This is consistent with the patients' viewpoint that most frequently reported improving gait and memory as their primary training goals to increase their quality of life.

Similar results have been documented in the literature. According to a survey of patients who completed a multicomponent behavioral intervention for patients with MCI and their caregivers, quality of life was the most important outcome priority for patients with MCI, followed by self-efficacy, depression, basic ADLs, memory-based ADL, anxiety, and memory performance [90].

Exergame and Training Components

The use of exergames as a form of simultaneous-incorporated motor-cognitive training is recommended, which should be prescribed domain-specifically, depending on a patient's cognitive abilities. Previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI have used commercially available exergame systems [76,91-96] or exergames that were specifically developed for patients with mNCD or MCI [97-100], which comprised sensor-based stepping platforms [94], video camera–based or wireless remote device systems [76,91,95,97,99], or exergames that were controlled using a cycle ergometer or similar [92,93,96,98,100]. The training programs can be classified as simultaneous-additional [92,93,96,98] or simultaneous-incorporated [76,91,94,95,97,99,100] motor-cognitive training that was applied targeting 1 [93,100] or multiple [76,91,92,94-99] neurocognitive domains, including complex attention [76,91,92,94-99], executive functions [76,91,92,94-100], learning and memory [91,93-95,97-99], or visuospatial skills [76,97,99]. Only one of these studies applied training that individually prescribed content on the basis of a patient's cognitive abilities [96]. However, it has not been performed or reported in a reproducible manner.

Therefore, so far and to the best of our knowledge, 11 studies have been published that investigated exergame-based motor-cognitive training in older adults with mNCD or MCI. Most of these studies designed or used exergames that could be classified as simultaneous-incorporated motor-cognitive training. Incorporating cognitive tasks into motor tasks may be more beneficial for consolidating neuroplasticity [42], because (1) it leads to greater (motor) cognitive improvements, (2) it is closer to daily life situations, (3) no prioritization effects occur, which can be observed in motor-cognitive training with additional cognitive tasks, and (4) multiple sensory systems are stimulated at the same time, which may provide an optimal basis for cognitive processes such as learning [42]. Meta-analytic evidence suggests that simultaneous motor-cognitive training is the most effective type of training for improving cognition in HOA [43,44] and in older adults with mNCD [44-46]. Nevertheless, it remains to be evaluated whether the incorporation of cognitive tasks into exercise or training interventions indeed results in more distinct effects on cognitive performance compared with simultaneous motor-cognitive training with a non–task-relevant secondary cognitive task [42]. Finally, there seems to be room for improvement regarding the domain-specific prescription of the training content, considering a patient's cognitive abilities and the adaptation and development of exergames specifically for patients with mNCD. This may be especially relevant when considering the large heterogeneity in the clinical symptoms of older adults with mNCD. Remarkably, most previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI have used commercially available exergame systems [76,91-96], in which the training content does not specifically target patients with mNCD. This is consistent with the findings of HOA. In a systematic review, Valenzuela et al [80] emphasized that in HOA, most studies used commercially available exergame systems. It was argued that these systems may be difficult to use for those with little or no experience with technology, because these systems often lack clear instructions, present too much graphical information, and have not been designed and developed to provide optimal training components for the target population and aims of the studies in which they were used [80]. In fact, all previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI have used exergames with complex 2D or 3D virtual environments [76,91-100]. This may not be optimal because the limitation that such systems may be difficult to use for those with little or no experience with technology could be even more pronounced in patients with mNCD, as these patients are easily distracted and quickly overwhelmed by the task demands. Indeed, according to the recommendations of the interviewed experts, it is beneficial to focus on the aspects that need to be worked on by implementing easily comprehensible and clearly designed exergame tasks and to only present elements that are directly related to the game tasks while avoiding unnecessary graphical information or distractors.

According to the recommendations of the interviewed experts, the training program should be maintained over the long term (preferably ≥12 weeks). A training frequency of 2 to 5 or more training sessions per week was recommended, largely depending on the training location and motivation. In addition, it is recommended to reach a moderate training volume of approximately 150 minutes per week. To reach this training volume, shorter training sessions and a higher training frequency should be applied, because longer training sessions might lead to attentional exhaustion in this group of patients. Therefore, the experts recommended session durations between 15 and 20 minutes up to a maximum of 30 minutes. Previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI have prescribed training programs over durations of 5 weeks [97], 6 weeks [91,94,98,100], 12 weeks [96,99], 3 months [93,95], 24 weeks [76], or 6 months [92]. The prescribed training frequency was 1 time per week [76], 2 times per week [94,96,99], 2 to 3 times per week [95], 3 times per week [97,98], 3 to 5 times per week [92,93,100], or 5 times per week [91] with session durations of 15 minutes [99], 18 to 30 minutes [94], 20 to 80 minutes [97], 25 to 30 minutes [91], 20 to 40 minutes [93], 30 to 45 minutes [100], 40 to 45 minutes [98], 45 minutes [92], 60 minutes [96], 90 minutes [76], or not reported [95], resulting in a weekly training volume of 30 minutes [99], 36 to 60 minutes [94], 60 to 200 minutes [93], 90 minutes [76], 90 to 225 minutes [100], 100 to 145 minutes [97], 120 minutes [96], 120 to 135 minutes [98], 125 to 150 minutes [91], 135 to 225 minutes [92], or not reported [95]. Therefore, most of these studies prescribed a training volume that was in line with the recommendations of the experts in this study. However, the session durations often exceeded the experts' recommendations, whereas the training frequency was lower than recommended. To avoid attentional exhaustion of the patients during training, future training concepts might consider prescribing shorter session durations while increasing the training frequency to achieve a similar training volume per week. This might actually improve the effectiveness of the intervention because higher training frequencies have already been shown to promote the effectiveness of physical (ie, ≥4 times per week) [101] and cognitive training (ie, >3 times per week) [102], while shorter session durations (ie, ≤30 minutes) [101] of physical exercise have been shown to exert more pronounced training effects. These findings might also apply to simultaneous motor-cognitive training. A meta-analysis revealed that training frequency is a significant moderator of the effects of physical and motor-cognitive training interventions on cognitive functioning, favoring higher training frequencies (≥5 times per week) in a mixed population of HOA and patients with mNCD [103]. Finally, a high training frequency (approximately 5 times per week) with short session durations (approximately 20 minutes) would also match the preferences of the interviewed patients in this study.

The experts reported that the training should preferably be individually carried out at the patients' homes, not only because it represents a known environment that makes patients feel more secure and represents a less-confronting environment for them (because they do not have to hide their impairments from others when training alone), but also to allow higher training frequencies. Nonetheless, to ensure that training in patients' homes is feasible, multiple factors need to be considered. For example, improvements in game instructions are required, a handrail or similar needs to be made available to allow safety support during training, and technical problems must be avoided. In addition, a guided familiarization period and part-time supervision or support from a care professional or partner should be integrated to make the transfer to home-based exergaming easier. Previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI have administered individual [91] or group-based [76,96,99] training sessions, and the training setting (ie, individual vs group sessions) has not been clearly reported [92-95,97,98,100]. The training sessions were conducted at the hospital [91], in a nursing home [94], at day-care centers or memory clinics [99], at a centrally located church [76], at patients' homes [93,100], or the training location was not clearly reported [92,95-98]. The training sessions were supervised by a therapist [91,94,96], or supervision was not reported [76,92,93,95,97-100]. Consistent with summarized previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI, most cognitive training programs to date have also been conducted in group sessions [104]. However, most of our interviewed patients clearly stated that they would prefer to train individually at home or with the support of a care professional or partner. Therefore, it might be worthwhile to put more effort into designing and developing exergames that can be used individually at home. This would possibly also reduce the barriers of patients with mNCD to engage in exergame-based training programs in the long term.

Regarding training demands, the experts recommended focusing on game complexity to ensure a challenging but feasible cognitive demand. Physical exercise intensity should be maintained at a light to moderate level. To allow individualization of the cognitive demand in training, two main aspects should be considered: (1) task type (ie, choice of exergames to individually focus on neurocognitive functioning) and (2) task demands. To allow individualization of task demands, the following factors should be varied based on the experts' recommendations: (1) stability support (use of handrail with both hands, one hand, or no support), (2) stepping direction, (3) game choice and tasks included, (4) game duration, or (5) game speed. Previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI have applied relatively effortful, high cognitive demands [92], low [97] to moderate [96-98] physical exercise intensities, or have not reported the physical [76,91-95,99,100] or cognitive [76,91,93-100] exercise load or training progression in a clearly reproducible way. This exemplifies the fact that the optimal cognitive load for motor-cognitive training remains unknown. To the best of our knowledge, there has only been 1 meta-analysis to date that compared the effects of training interventions on cognitive functioning in relation to different task complexities and found no difference between simple and complex cognitive games [105]. Therefore, further investigations are needed to identify the optimal cognitive training demands and optimize the monitoring and progression of training programs. For physical exercise intensity, the recommendations of the interviewed experts are in line with those of previous studies applying exergame-based motor-cognitive training in older adults with mNCD or MCI. This also matches the analysis of the moderating variables of the training parameters that influence the effectiveness of the interventions. Based on meta-analytic results from motor-cognitive training in older adults with mNCD, moderate physical training intensity [45] has been shown to be most effective in improving cognitive function. Finally, moderate physical exercise intensity would also match the preferences of the patients interviewed in this study.

Implications for Research

Our findings serve as a basis for user modeling, determination of therapeutic needs, and definition of a set of requirements for the game design and development of novel exergame-based training concepts. To increase the probability that the resulting training will be deemed feasible in future clinical practice, these considerations should be integrated to guide the decision process for the most suitable exergame design and intervention components when developing novel exergames and exergame-based training concepts.

Limitations

The outcomes of this qualitative study must be interpreted with some caution, considering the following limitations. First, none of the interviewed patients with mNCD belonged to the clinical subtypes of mild frontotemporal NCD or mNCD with Lewy bodies. Depending on the clinical subtypes and the associated clinical pictures of the patients, different findings may have emerged from patient interviews. However, a substantial fraction (ie, ≥60%) of mild or major NCD is attributable to Alzheimer disease, whereas mild vascular NCD is the second most common cause of NCD after Alzheimer disease; frontotemporal NCD only accounts for approximately 5% of cases [9]. Therefore, the included study population appeared to be representative of these clinical subtypes. Second, owing to difficulties in recruiting patients, those screened for MCI according to predefined criteria were recruited in addition to patients with a clinical diagnosis of mNCD, which increased the heterogeneity of the study population. By contrast, in our project, we aimed to develop an individualized exergame-based training concept not only to treat clinically diagnosed patients with mNCD but also to prevent progression to dementia in individuals at risk who might not have been diagnosed (yet). Third, owing to the COVID-19 pandemic, all focus group sessions were held as web-based meetings. Face-to-face focus group sessions might have promoted livelier exchanges and may have led to additional insights.

Conclusions

The psychosocial consequences of patients' self-perceived cognitive deterioration may be more burdensome than the cognitive changes themselves. Older adults with mNCD prefer integrative forms of training (such as exergaming) and are primarily motivated by enjoyment or fun in exercising and the effectiveness of the training. Putting the synthesized perspectives of training goals, settings, and requirements for exergames and training components into context, our considerations point to opportunities for improvement in research and rehabilitation, either by adapting existing exergames to patients with mNCD or by developing novel exergames and exergame-based training concepts specifically tailored to meet patient requirements and needs.

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Data Availability

The data supporting the findings of this study are available from the corresponding author (PM) on reasonable request.

Authors' Contributions

PM was responsible for the conception and protocol development of this study under the supervision of EDdB. MAO contributed to the study conception. PM was responsible for the recruitment of participants, data collection, data analysis, and writing of the manuscript. Data coding and analysis was cross-checked by MAO. All authors have contributed to the revision of the manuscript. All authors have read and approved the submitted version.

Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as potential conflicts of interest. Dividat AG was asked to suggest suitable participants for the expert focus group discussions by providing a contact list of experts and health care professionals, as the company is well connected with institutions for geriatric populations, physiotherapies, and rehabilitation clinics in Switzerland. Therefore, we were able to identify experts and health care professionals who experienced exergame training with older adults with mild neurocognitive disorder. Experience was preferred with the exergame training system "Senso (Flex)" or similar. In addition, the founder of Dividat AG was partaking in one of the focus group discussions as an industry representative in line with the Multidisciplinary Iterative Design of Exergames framework. Dividat AG had no other role in the study and did not play any role in the design and conduct of the study; they also did not play any role in the data analyses, interpretation, or decision to submit results.

Multimedia Appendix 1
Interview guides.
[DOCX File , 32 KB - games_v11i1e37616_app1.docx]

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Abbreviations

ADL: activities of daily living
CCT: computerized cognitive training
DSM-5: Diagnostic and Statistical Manual of Mental Disorders 5th Edition
HOA: healthy older adults
MCI: mild cognitive impairment
MIDE: Multidisciplinary Iterative Design of Exergames
mNCD: mild neurocognitive disorder
MTT: medical training therapy
NCD: neurocognitive disorders
PT: physical therapy

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Original Paper

Differences in Brain Activity and Body Movements Between Virtual Reality and Offline Exercise: Randomized Crossover Trial

Hee Jin Kim[1*], MD, PhD; Jea Woog Lee[2*], PhD; Gangta Choi[1], MSc; Junghoon Huh[3], PhD; Doug Hyun Han[1], MD, PhD

[1]Department of Psychiatry, College of Medicine, Chung-Ang University, Seoul, Republic of Korea

[2]Department of Information & Technology in Sport, College of Sports Science, Chung-Ang University, Anseong-si, Gyeonggi-do, Republic of Korea

[3]Department of Human Motor Behavior, College of Sports Science, Chung-Ang University, Anseong-si, Gyeonggi-do, Republic of Korea

[*]these authors contributed equally

Corresponding Author:
Doug Hyun Han, MD, PhD
Department of Psychiatry
College of Medicine
Chung-Ang University
Heuk Seok Ro 84
Seoul, 06974
Republic of Korea
Phone: 82 2 6299 3132
Fax: 82 2 6298 1508
Email: hduk70@gmail.com

Abstract

Background: Virtual reality (VR) has been suggested to be effective at enhancing physical exercises because of its immersive characteristics. However, few studies have quantitatively assessed the range of motion and brain activity during VR exercises.

Objective: We hypothesized that 3D immersive VR could stimulate body movement and brain activity more effectively than standard exercises and that the increased range of motions during 3D immersive VR exercises would be associated with orbitofrontal activation.

Methods: A randomized crossover trial was conducted to compare exercises with and without VR. A total of 24 healthy males performed the same motions when exercising with and without 3D immersive VR, and the recorded videos were used for motion analysis. Hemodynamic changes in the prefrontal cortex were assessed using functional near-infrared spectroscopy.

Results: There were significant differences in the total angle (z=−2.31; P=.02), length (z=−2.78; P=.005), calorie consumption (z=−3.04; P=.002), and change in accumulated oxygenated hemoglobin within the right orbitofrontal cortex ($F^{1,94}$=9.36; P=.003) between the VR and offline trials. Hemodynamic changes in the right orbitofrontal cortex were positively correlated with the total angle (r=0.45; P=.001) and length (r=0.38; P=.007) in the VR exercise; however, there was no significant correlation in the offline trial.

Conclusions: The results of this study suggest that 3D immersive VR exercise effectively increases the range of motion in healthy individuals in relation to orbitofrontal activation.

Trial Registration: Clinical Research Information Service KCT0008021; https://cris.nih.go.kr/cris/search/detailSearch.do/23671

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KEYWORDS

virtual reality exercise; near-infrared spectroscopy; spectroscopy; hemodynamic; blood flow; hemoglobin; brain; prefrontal cortex; orbitofrontal cortex; immersion; virtual reality; VR; exercise; range of motion; physical activity; fitness; motion; movement; randomized; calorie

Introduction

Virtual reality (VR) is an artificially created sensory experience using digital technology, which provides users with a subjective sense of "being there" [1]. The format of VR, referring to the structure of the information displayed, can be either 2D or 3D multimedia. The main difference between the 2 formats is the level of interactivity, with 3D environments allowing changes in the user's point of view, navigation, and interaction with objects and people. The display devices, which are the technological equipment used to visualize the formats, are classified based on the level of immersion they provide: nonimmersive, semi-immersive, and immersive. Nonimmersive systems are simple devices that use a single screen, such as a desktop PC. Semi-immersive systems, such as the Cave automatic virtual environment and the Powerwall display, provide a stereo image of an environment using a projection linked to the observer's position. Immersive systems, such as a head-mounted display (HMD), isolate the user from external world stimuli [2]. An HMD gradually follows the users' movements, quantifies the position and direction of articles in reality, and creates a corresponding stereoscopic view. Users perceive themselves to be situated in a virtual environment and are temporarily unable to recognize behaviors and objects in the real environment [1].

VR is expected to have enormous potential in fields such as education, training, and entertainment [3]. In particular, the application of VR technology is promising in the field of sports, as it can overcome human limitations due to technical innovations, thus allowing for the development of effective training methods [4].

VR application in sports can increase motivation, enjoyment, and physical performance [5]. This may be due to the unique characteristics of VR, such as immersion, interaction, and infinite degrees of freedom in spatial and temporal situations [6,7]. Fox and Bailenson [8] showed that physical activity could be increased through a reinforcement mechanism using immersive VR technology. Jones et al [9] demonstrated that immersion in VR exercises was positively correlated with motivation, pleasure, and enjoyment after exercises. In addition, participants can interact with objects in a stereoscopic visual space without spatial limitations, which can be manipulated in various ways, depending on individual needs [10]. Athletes can use VR exercises to learn new sports strategies and compete with their virtual partners [10]. By using the unlimited spatial and temporal boundaries of VR, injury-prone skills can be safely trained [11]. For example, VR allows ski jumps and downhill skiing in a safe environment [11].

The shortcomings of physical exercise using an immersive VR have been attributed to the use of HMDs. Exercising while wearing an HMD can be uncomfortable due to sweating and head bumps [12]. In addition, HMDs can be impractical for movement accuracy and speed. They can also be potentially dangerous (eg, when the device blocks the vision of the moving treadmill while running [12]). Furthermore, interactive VR display systems linked to various eye-movement systems can cause motion sickness [13].

VR exercises are effectively used in the rehabilitation of patients who have lost motor skills [5,14]. They are also used to increase the physical fitness of patients with chronic medical conditions, such as hemodialysis or dementia, and developmental disorders, such as intellectual disability or autism [15,16]. Most previous studies on VR exercises have been conducted on patient groups [5,14-16]. However, VR exercises are increasingly used by athletes and other sports-related professionals, as they enable individualized training with real-time feedback without coaches [11,12]. Moreover, VR exercises have recently been widely used in the public sphere to promote physical fitness [5]. When applied to healthy individuals, VR exercise can increase exercise speed, heart rate, balance, motivation, enjoyment, adherence, executive function, and neuroplasticity [17-20]. Although many studies have suggested the qualitative effectiveness of VR exercise, few have quantitatively assessed its effectiveness [12].

Previous studies have suggested that the brain regions of interest in response to VR and physical exercises are the dorsolateral prefrontal cortex (DLPFC), ventrolateral prefrontal cortex (VLPFC), and orbitofrontal cortex (OFC) [9,21,22]. Of these 3 major prefrontal cortical regions, a functional near-infrared spectroscopy (fNIRS) study showed that VR stimuli activated the OFC [21]. The OFC has been associated with emotional and behavioral regulation, decision-making, maintenance of behavioral flexibility, and processing of anticipated rewards and punishments [23]. Inappropriate functioning of the OFC can lead to disinhibition, preservation, and impulse control problems [24]. Owing to the functions of rewards and decisions, the OFC can be associated with VR-induced immersion and flow [8,25].

This study aimed to investigate whether immersive VR technology can enhance physical exercise, in terms of the range of motion and brain activity, in healthy individuals. Kinematics and resting state fNIRS methodologies were adopted to demonstrate the quantitative effectiveness of 3D immersive VR exercise. Kinematics is useful for objectifying human movements and comparing different subjects or situations, such as before and after treatment or training in various fields (eg, sports science) [26]. For example, knee and hip angles at foot strikes during running have been quantified using 2D video recording and motion analysis software [27]. Vertical jump height, frequently used as an indirect measure of muscle power in the lower extremities, was also estimated using the video method [28]. In VR rehabilitation studies, the difference in ranges of motion before and after treatment was measured to assess improvement [29]. fNIRS is a noninvasive functional brain imaging tool that measures cortical hemodynamic activity [30]. Near-infrared light penetrates the brain, and oxygenation changes in regional cerebral blood flow are recorded [31]. fNIRS has the advantages of safety, low cost, portability, tolerance to motion artifacts, and good temporal and spatial resolution, overcoming the shortcomings of conventional brain imaging modalities, such as electroencephalography and functional magnetic resonance imaging (fMRI) [32,33]. fNIRS has been used in various fields, including sports medicine, neuroscience, behavioral science, clinical studies, and brain-computer interfaces [30].

We hypothesized that 3D immersive VR exercises would be more effective than offline physical exercises in increasing the range of motion and calorie consumption during exercise. In addition, we hypothesized that the effectiveness of 3D immersive VR exercises is associated with brain activation within the OFC before and after exercise.

Methods

Sample Size

The sample size was calculated using G*power software (Heinrich-Heine-Universität Düsseldorf) [34] based on a statistical test using repeated measures ANOVA. A type 1 error of .05 and a statistical power of 0.9 were used. The correlation among repeated measures was set conservatively at 0. Based on previous similar studies, an effect size of 0.25 was estimated. Based on these calculations, 22 participants were required. After estimating a 10% dropout rate, the required total sample size was set at 24 participants.

Participants

Through flyer advertisements, 24 healthy males were recruited for this study from Chung-Ang University. The inclusion criteria were as follows: (1) male sex, (2) age 20 to 29 years, and (3) no psychiatric or medical illness. The exclusion criteria were as follows: (1) history of head trauma; (2) history of substance abuse, including alcohol, tobacco, and drugs; and (3) IQ<80. The participants were instructed not to consume any food, caffeine, or alcohol 3 hours prior to participation in the study.

Ethics Approval

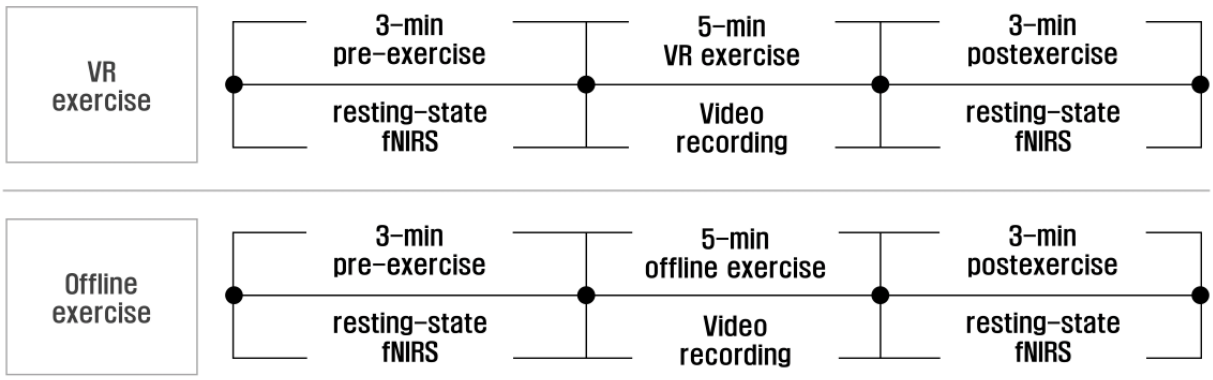
The institutional review board of Chung-Ang University approved this research protocol (1041078-201908-HRSB-231-01). Written informed consent was obtained from all participants.

Study Procedure

Overview

This study was a randomized crossover trial that compared responses to 3D immersive VR and offline exercises. The participants were blinded to the study hypotheses. Each participant underwent 1 3D immersive VR trial and 1 offline trial in a randomly assigned order at 10-minute intervals. Each session consisted of (1) a 2-minute practice to become familiarized with each exercise; (2) a 2-minute pre-exercise resting-state fNIRS measurement; (3) a 5-minute exercise, either 3D immersive VR or offline; and (4) a 3-minute postexercise resting-state fNIRS measurement (Figure 1). This trial was conducted in a curtained, dimly lit gym at a temperature of 23 °C with minimal ambient noise to control external noises as much as possible. The participants were instructed not to speak or move their heads during the fNIRS measurement to maintain good tissue-electrode contact. A 10-minute interval was given between sessions to return noncortical hemodynamic variables, such as skin blood flow and middle cerebral artery blood flow, to baseline levels.

Figure 1. Study design. fNIRS: functional near-infrared spectroscopy; VR: virtual reality.



Both VR and offline exercises consisted of 40 identical movements derived from Pilates. Pilates was chosen because it is a beneficial exercise method for healthy adults that enhances flexibility, muscular activity, and coordination [35]. In both exercises, the sequence was in the order of 8 types of simple behaviors involving just the body, arms, or legs; 16 types of 2 complex behaviors involving the body plus arms or legs; and 16 types of 3 complex behaviors involving 3 parts of the body, arms, and legs. The reason for exercising in this order was to gradually increase the number of muscle groups involved, starting from warming up. A resistance band (TheraBand) was applied to each participant in both sessions to maintain adequate exercise intensity and prevent less controlled behaviors. Pilates exercise with a resistance band was reported to increase muscle activity by more than 50%, whereas Pilates exercise without a resistance band increased muscle activity by only 20% [36].

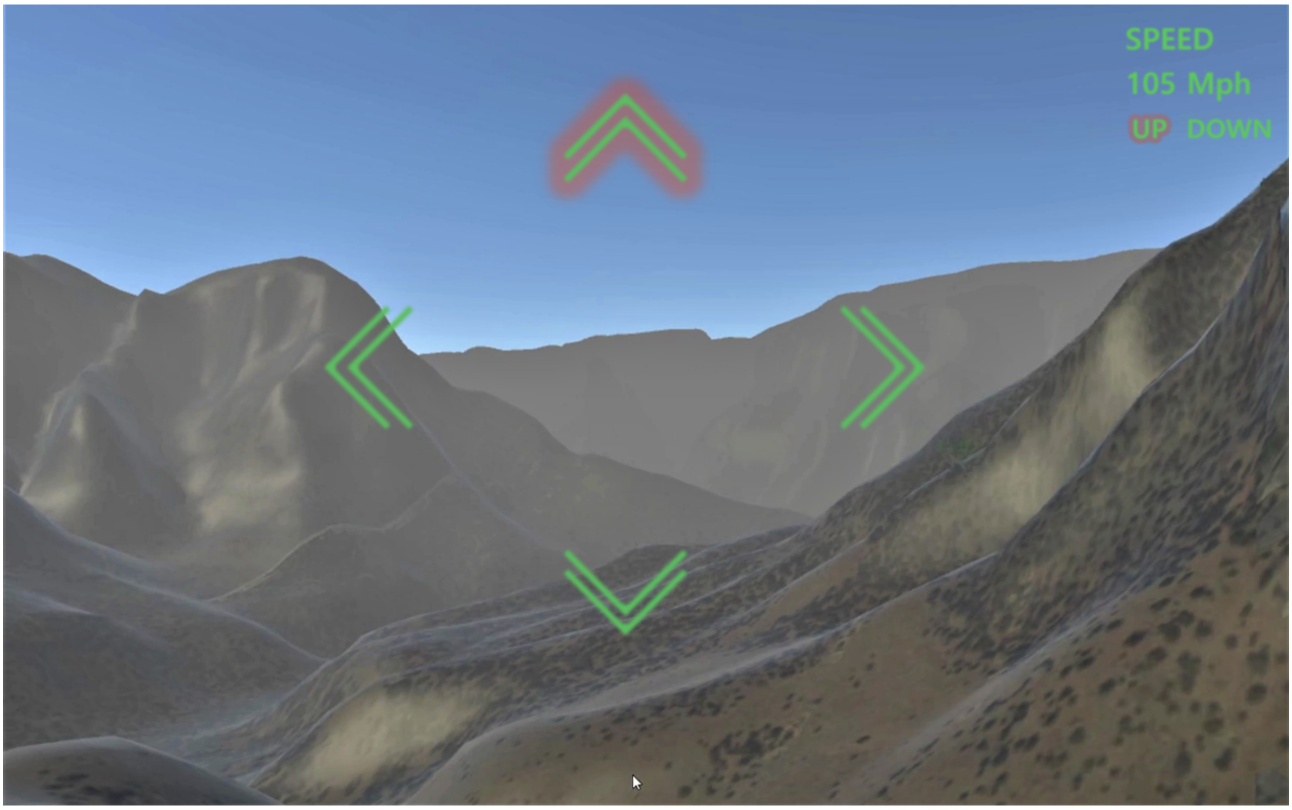
Before the VR exercise, the research staff provided brief instructions on the 3D immersive VR system and environment and asked the participants to report whether they experienced any discomfort while wearing the HMD, such as head bumps, sweating, or motion sickness. The research staff checked for any obstacles the participants might encounter during the VR exercise and monitored and provided immediate assistance to the participants during the exercise in case of danger. With the help of the research staff, the participants were positioned 2 m horizontally away from the VR device, wearing the HMD and holding resistance bands in both hands at shoulder level.

In this study, the Vive Cosmos Elite (High Tech Computer Corp) and Kinect V1 (Microsoft) were used as the HMD and motion sensors, respectively. A 3D map–based immersive VR software system that allows participants to interact with the VR environment was developed using Unity3D Engine (Unity Technologies). The Grand Canyon landscape was designed to enable participants to fly between canyons without crashing by performing the aforementioned movements in sequence. During the VR exercise, participants were asked to fly over the canyon without bumping into it, following visual and audio guidance. The direction in which to move, whether to accelerate or decelerate, and flight speed were displayed on the VR screen in real time, serving as visual instructions (Figure 2). When the participants tilted their upper body right, left, forward, or backward in the virtual space, they rotated right, left, upward, or downward, respectively. They could accelerate or decelerate by lifting or lowering their right arm.

In contrast, during the offline exercise, the participants performed movements in a standard manner following a demonstration by a professional instructor. In both sessions, audio guidance, such as “lean right and raise your left arm” were provided.

The research staff helped the participants accurately perform each movement in both sessions. They provided immediate feedback for incorrect movements and high-risk situations. The movements performed by the participants in the VR and offline conditions were considered identical since the audio guidance, use of the resistance band, and real-time feedback on behavior by the research staff were the same for all participants.

Figure 2. A representation of the virtual environment.

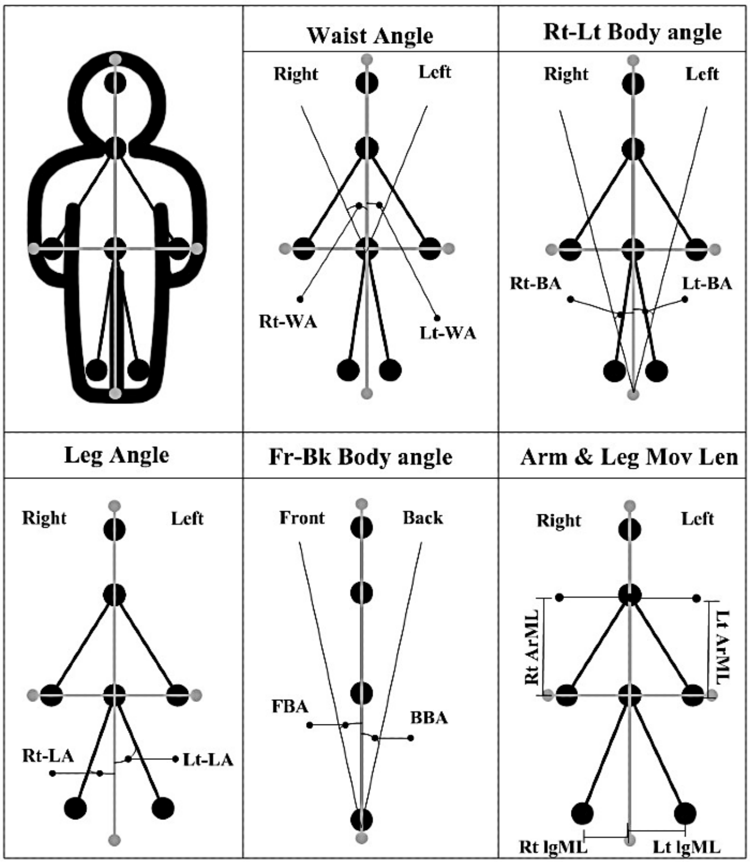


Motion Analysis to Measure Motion Angle, Length, and Retention Time

Participants’ movements during the VR and offline exercises were recorded using an iPhone 11 camera (Apple). The participants were asked to stand at the designated site 1.5 m away from the camera to maintain a constant camera angle. The recorded video was analyzed using the open-source video analysis software Kinovea (version 0.8.15; Kinovea Open-Source Project) [21]. Kinovea determines the distance between the camera and the recorded object by measuring the subject passing in front of the camera [21]. It has various analysis and measurement tools for adding annotations, drawing lines, and calculating distances and angles [37] and has been used in numerous sports and clinical studies [22-24]. Previous studies have shown the reliability and validity of the software at distances of up to 5 m with an angle of 90° to 45° [21].

In the motion analysis, eight types of motion angles were measured: (1) right waist angle, (2) left waist angle, (3) right body angle, (4) left body angle, (5) right leg angle, (6) left leg angle, (7) forward body angle, and (8) backward body angle. Additionally, four types of movement lengths were measured: (1) right arm movement length, (2) left arm movement length, (3) right leg movement length, and (4) left leg movement length (Figure 3). The total angle and movement length for simple behaviors, 2 complex behaviors, and 3 complex behaviors were calculated using each angle and movement length involved in each behavior. For example, for simple behaviors, 8 angles and 4 lengths were used to calculate the total angle and movement lengths. Two complex behaviors consisting of 16 movements, 24 angles, and 16 lengths were measured to calculate the total angle and movement length. Finally, 3 complex behaviors consisting of 16 movements, 24 angles, and 32 lengths were measured to calculate the total angle and movement length (Multimedia Appendix 1).

Figure 3. Movement angle and length. From top: Rt (Lt)-WA: right (left) waist angle; Rt (Lt)-BA: right (left) body angle; Rt (Lt)-LA: right (left) leg angle; FBA (BBA): forward (backward) body angle; Rt ArML: right arm movement length; Lt ArML: left arm movement length; Rt lgML: right leg movement length; Lt lgML: left leg movement length.



Comparison of Calories Using the Metabolic Equivalent of Task Formula and Motion Retention Time

Calorie consumption during each session was calculated using each participant's weights, motion retention time (from the start to the end of the movement), and the metabolic equivalent of task (MET) of the Pilates motion, according to the MET formula [38]. The MET formula has been adopted in various clinical studies, and its reliability has been demonstrated through meta-analyses [39,40]. MET is defined as the level of intensity of various physical activities, including daily activities and low-intensity to high-intensity exercises. The Pilates movements performed by the participants in this study were rated as 3.5 MET.

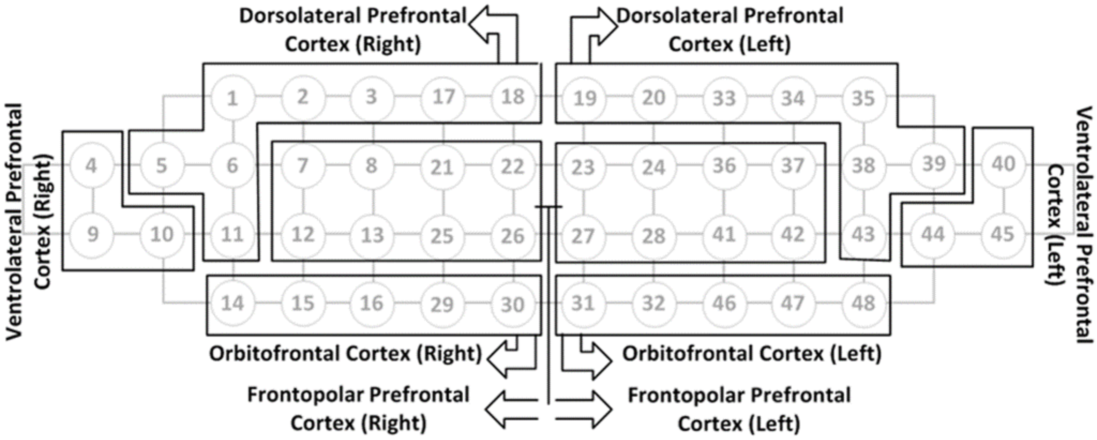
Hemodynamic Changes in the Frontal Cortex

Hemodynamic changes within the prefrontal cortex were assessed using a high-density fNIRS device (NIRSIT, OBELAB Inc). The curved panel of the NIRSIT has 24 laser diodes (sources) emitting 2 wavelengths (780 nm and 850 nm) of light and 32 photodetectors with a sampling rate of 8.138 Hz. The unit distance between the source and photodetectors was 15 mm. In this study, only the 30-mm channels were analyzed, since 30 mm is the most suitable sensor-detector separation distance for measuring cortical hemodynamic changes.

The fNIRS data were processed using the analysis toolbox provided by the fNIRS device manufacturer. The light signals in each wavelength within the 48 channels were filtered using a band-pass filter (between 0.0 Hz and 0.1 Hz) to reduce noise due to external light and body movements. Data derived from channels representing low-quality information (signal-to-noise ratio<30 dB) were not included in the hemodynamic analysis set to prevent misinterpretation. Relative hemodynamic changes during exercise were calculated using the modified Beer-Lambert law [41]. The accumulated oxygenated hemoglobin (accHbO2) values represent the activation of the prefrontal cortex during a resting state. Although both oxygenated and deoxygenated hemoglobin data could be obtained, previous studies have revealed that oxygenated hemoglobin has superior sensitivity and signal-to-noise ratio; therefore, only oxygenated hemoglobin data were used for this analysis [26,28].

The values (mean and SD) of accHbO2 were gathered from 8 regions of interest: the right and left DLPFC, right and left frontopolar cortex (FPC), right and left VLPFC, and right and left OFC. The right and left DLPFCs were composed of channels 1, 2, 3, 5, 6, 11, 17, and 18 and channels 19, 20, 33, 34, 35, 38, 39, and 43, respectively. The right and left FPC were composed of channels 7, 8, 12, 13, 21, 22, 25, and 26 and channels 23, 24, 27, 28, 36, 37, 41, and 42, respectively. The right and left VLPFCs were composed of channels 4, 9, and 10 and channels 40, 44, and 45, respectively. The right and left OFCs were composed of channels 14, 15, 16, 29, and 30, and channels 31, 32, 46, 47, and 48, respectively (Figure 4).

Figure 4. The channel configuration.



Statistical Analyses

For total behaviors, simple behavior, 2 complex behaviors, and 3 complex behaviors, the differences in total angles, total movement length, and consumed calories were compared using the Mann-Whitney *U* test. The statistical significance of the total angle and total movement length in the total behaviors was set at 0.02 (0.05/3, angle, length, and calories). In the post hoc test, the statistical significance of the total angle and total movement length in the simple behaviors, 2 complex behaviors, and 3 complex behaviors was set at *P*=.02 (.05/3, angle, length, and calories). Between the VR and offline situations, the difference in the change in accumulated oxygenated hemoglobin (ΔaccHbO2) from baseline and exercise was compared using repeated measures ANOVA. The statistical significance was set at *P*=.006 (.05/8, 8 brain regions). Correlations between the differences in accHbO2 within the right OFC, total angles, and total movement lengths were assessed using Pearson correlation coefficient. Statistical significance was set at *P*=.03 (.05/2, angle and length). Statistical analyses were performed using SPSS software (version 24.0; IBM Corp).

Results

Differences in Movement Including Angle and Length Between Offline and VR Trials During Exercise

During exercise, there were significant differences in the total angle (*z*=−2.31; *P*=.02) and length between the VR and offline trials (z=−2.78; *P*=.005). The VR group showed a 13.3% wider total angle range and an increase of 14.1% in the total movement length compared with the offline group. In the post hoc analysis, the VR group moved significantly more in simple and complex behaviors, except for the total angle in 2 complex behaviors, compared to the offline group (Table 1).

Table 1. Differences in angle and distance between the VR[a] and offline trials[b].

Types of behavior and parameters	VR trial, mean (SD)	Offline trial, mean (SD)	Statistics
Total behavior			
Angle total (°)	1359.39 (125.55)	1200.26 (195.68)	*z*=−2.31; *P*=.02
Length total (cm)	2568.20 (342.38)	2250.82 (382.20)	*z*=−2.78; *P*=.005
Calorie total (kcal)	9.36 (2.60)	5.79 (3.01)	*z*=−3.04; *P*=.002
Simple behavior (trunk leaning over)			
Angle total (°)	172.30 (19.2)	147.8 (27.64)	*z*=−2.74; *P*=.005
Length total (cm)	224.93 (34.3)	197.70 (31.9)	*z*=−2.53; *P*=.01
Calorie total (kcal)	2.46 (0.55)	1.18 (0.69)	*z*=−4.30; *P*<.001
2 complex behaviors (trunk leaning over + lifting arm or leg)			
Angle total (°)	449.26 (118.57)	415.87 (69.17)	*z*=−1.14; *P*=.27
Length total (cm)	966.09 (118.57)	860.06 (107.01)	*z*=−3.10; *P*=.001
Calorie total (kcal)	4.42 (1.35)	2.95 (1.58)	*z*=−2.55; *P*=.01
3 complex behaviors (trunk leaning over + lifting arm + lifting leg)			
Angle total (°)	737 .83 (63.61)	636.55 (112.77)	*z*=−2.72; *P*=.006
Length total (cm)	1377.18 (202.88)	1193.05 (125.55)	*z*=−2.69; *P*=.006
Calorie total (kcal)	2.47 (0.86)	1.65 (0.97)	*z*=−2.63; *P*=.009

[a]VR: virtual reality.

[b]*P*<.02 was considered to be significant.

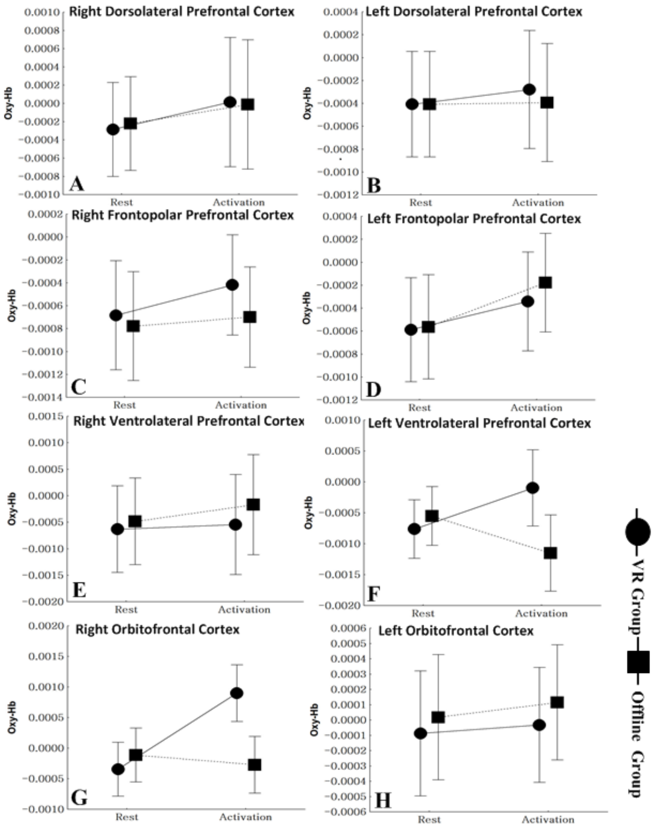
Differences in Consumption Between Offline and VR Trials During Exercise

During exercise, there were significant differences in the total calories between the VR and offline trials (*z*=−3.04; *P*=.002). During exercise, the VR group consumed 61.7% more calories than the offline group. In the post hoc analysis, the VR group showed significant calorie consumption with 2 complex and 3 complex behaviors compared to the offline group (Table 1).

Differences in ΔaccHbO2 Between Offline and VR Trials During Exercise

During exercise, significant differences were observed in ΔaccHbO2 between the offline and VR trials within the right OFC ($F^{1,94}$=9.36; *P*=.003) but not within the left VLPFC ($F^{1,94}$=5.69; *P*=.02), left DLPFC ($F^{1,94}$=0.06; *P*=.81), right DLPFC ($F^{1,94}$=0.02; *P*=.89), right VLPFC ($F^{1,94}$=0.06; *P*=.81), left OFC ($F^{1,94}$=0.01; *P*=.91), left frontopolar prefrontal cortex ($F^{1,94}$=0.05; *P*=.89), or right frontopolar prefrontal cortex ($F^{1,94}$=0.21; *P*=.65) (Figure 5).

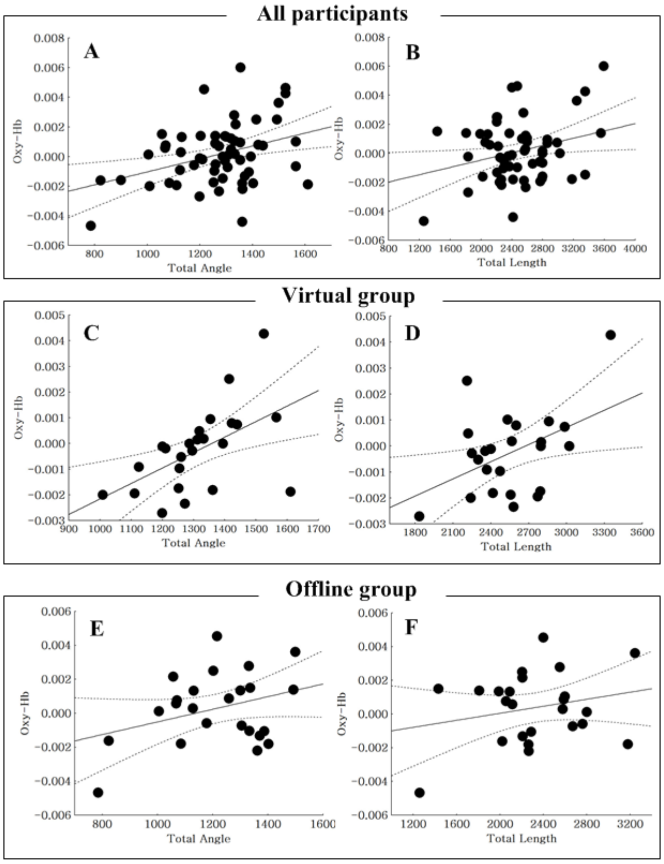
Figure 5. Difference in the accumulated oxygenated hemoglobin (ΔaccHbO2) between the offline and virtual reality trials during exercise. *P*<.006 was considered to be significant. Oxy-Hb: oxygenated hemoglobin; VR: virtual reality.



Correlation of ΔaccHbO2 With Total Angle and Movement Length

In all participants, the ΔaccHbO2 within the right OFC was positively correlated with the total angle (*r*=0.36; *P*=.005). However, it was not significantly associated with the total movement length (*r*=0.28; *P*=.03). In the VR group, the ΔaccHbO2 within the right OFC was positively correlated with total angle (*r*=0.45; *P*=.001) and total movement length (*r*=0.38; *P*=.007). In the offline group, the ΔaccHbO2 was not significantly correlated with total angle (*r*=0.28; *P*=.40) or total movement length (*r*=0.29; *P*=.37) (Figure 6).

Figure 6. Correlation between accumulated oxygenated hemoglobin in the orbitofrontal cortex (OFC) and movement change. *P*<.025 was considered to be significant. Oxy-Hb: oxygenated hemoglobin.



User Experience During VR Exercise

Of the 24 participants, 3 (12.5%) reported motion sickness, and 8 (33.3%) reported sweating after wearing the HMD device; however, none reported HMD slipping or severe discomfort.

Discussion

Principal Results

In this study, VR exercise increased the range of motion, calorie consumption, and brain activity within the OFC compared with offline exercise. In addition, increased brain activity within the right OFC was correlated with an increased range of motion.

Improvement of Movement Range and Calorie Consumption in Response to Immersive VR Stimuli

Our findings are consistent with previous studies on various patient groups. However, no studies have reported changes in the range of motion due to VR exercise in healthy individuals, as in this study [5]. VR exercises have been suggested to improve the range of motion in patients undergoing rehabilitation, both in the short term [42,43] and in the long term [14,44]. Immersive VR physical therapy significantly reduces pain and enhances the range of motion in patients with burn injuries (immediate effect) or chronic frozen shoulders (chronic effect) compared with standard therapies [14,42]. In addition, a 4-week VR exercise program in patients who underwent a stroke was more effective than a conventional program in improving the active range of motion and other scores, such as the Fugl-Meyer assessment score, Wolf motor function test score, and modified Barthel Index [44]. Children with cerebral palsy also reported a greater range of motion, better motion control, and greater interest as an acute effect after performing VR exercises than after conventional exercises [43]. In addition, the results of this study are in line with those of previous studies showing that participants who engaged in VR exercises had higher heart rates and burned more calories than those who performed standard exercises [45]. Therefore, VR has the potential to enhance physical exercises, and it may be a viable complement or alternative to traditional weight loss programs [46].

The larger range of motion and caloric consumption in the VR exercise may be associated with immersion. Immersion can be divided into 3 forms: sensory, imaginative, and challenge-based [47]. Sensory immersion is associated with audiovisual stimulation, and imaginative immersion is related to absorption in the narrative or identification with a character (eg, feelings of empathy and atmosphere). Challenge-based immersion is related to the balance between the activity's demands and an individual's motor and mental skills [48]. Challenge-based immersion is very close to the "flow" experience described by Csikszentmihalyi [49]. Immersion and flow share common features such as concentration, distortion of time perception, loss of self-awareness, and intrinsic motivation toward an activity [49]. The flow of physical exercise is related to peak performance [50]. The flow experienced during exercise is an autotelic experience with total concentration, merging of action and awareness, and the paradox of control [51]. In this respect, we cautiously suggest that VR exercise could be more immersive and helpful in achieving peak performance than exercise alone since sensory and imaginative components are added to the challenge-based immersion of physical exercise.

Increased Brain Activity Within OFC in Response to VR Stimuli

Another important finding of our study was that there were significant differences in brain activation within the right OFC between offline and exercise groups. To date, only a few studies have specifically investigated orbitofrontal activity in response to VR exercises. Most studies have focused on prefrontal activation caused by VR stimuli. Mao et al [52] suggested that VR training activates the prefrontal cortex and improves spatial orientation and motor function. However, recent studies have suggested that the OFC is one of the candidate brain regions that respond to VR [29]. Landowska et al [21] reported hemodynamic changes within the DLPFC and OFC in response to VR therapy for acrophobia. Dong et al [53] suggested that the activation of the OFC in response to VR tasks was greater than that observed in response to slide-based (control) tasks. Moro et al [54] reported that oxygenation in the OFC was increased when an incremental swing balance task in an immersive VR environment was performed. One possible explanation for this is that VR-induced immersion stimulates reward circuits involving the OFC. The OFC is responsible for sensory integration, regulation of visceral responses, learning, prediction, and decision-making for reward and affective values [55,56]. In addition, visual stimulation and immersion in VR are robustly involved in reward circuits [57].

The results of the correlation study between ΔaccHbO2 within the right OFC and the range of motion during VR and offline exercise showed that an increase in the range of motion and right OFC activation was correlated only in the VR group but not in the offline group. Thus, we suggest that immersion and visual stimulation of 3D immersive VR distracts the user from unpleasant interoceptive sensations caused by physical exercise. It is suggested that distraction caused by VR can reduce the perception of physical discomfort through an intercortical modulation of the anterior cingulate and OFC [9,58,59].

Additionally, the functional hemispheric differences shown in the results of this study are in line with a previous study that suggested that the more pronounced the shift in brain activity to the right hemisphere, the more flow experienced by elite tennis players [60]. Less synchronized brain activity in the left hemisphere and more coherent brain activity in the right hemisphere have been suggested to reflect less interference from irrelevant verbal-analytical processes with motor control mechanisms [60].

Strengths

To the best of our knowledge, this is one of the earliest studies to quantitatively evaluate the effects of 3D immersive VR exercise on brain hemodynamics in healthy individuals. Each participant's movement was measured using professional video analysis software, unlike other studies based on subjective performance improvement or satisfaction. Another strength of this study is that we directly compared performance in 3D immersive VR and real-world environments while performing the same activities. This comparison is important to reveal how 3D immersive VR influences exercise performance and brain activity. Finally, this study presents the potential for developing smart headsets by integrating wearable devices and connected technologies, such as VR, brain activity measurement, and motion tracking. Although these were performed with different devices in our study, using an integrated smart headset could enable effective exercise and immediate checking of the exercise amount and the consequent changes in brain activity. These wearable technologies and connected solutions with VR capabilities are already widely adopted in the workplace to promote occupational safety, productivity, and worker health. Examples include the Xsens MVN Animate and Xsens MTw Awinda for body movement tracking and the Muse 2 Melon's headband and IMEC's wireless electroencephalogram headset for brain wave sensing [61].

Limitations

This study had some limitations. First, due to the small number and gender disparity of the participants, the results cannot be generalized. In a follow-up study on VR exercise, scaling up the sample size by including virtual participants could be considered. However, this was not possible in this study due to the crossover design comparing VR and offline exercise. Second, there were limitations in the adequate pixel rate, capture rate, maximum aperture, depth of field capture, and frame capture rate of the iPhone 11, which was used as a video recording device. Third, since the fNIRS device used in this study can only measure brain activity within the prefrontal lobe, activity in other cortical regions and deep brain areas was not measured. Further studies using other functional imaging devices, such as fMRI, are required to determine the activity of the entire brain. Fourth, we did not employ additional physiological measures. The use of systemic physiologically augmented fNIRS in future studies may yield more meaningful results. Finally, a standardized questionnaire to check the inclusion and exclusion criteria and to assess motion sickness after VR exercise was not used in this study.

Conclusions

This study confirmed that 3D immersive VR exercise is more effective at increasing the range of motion and calorie consumption during exercise in healthy individuals via activation within the OFC.

Acknowledgments

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Conflicts of Interest

None declared.

Editorial Notice

This randomized study was only retrospectively registered. The authors regret that the trial could not be registered prospectively due to an oversight in the process. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
Performances for simple and complex behaviors.
[DOCX File , 17 KB - games_v11i1e40421_app1.docx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 97 KB - games_v11i1e40421_app2.pdf]

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Abbreviations

accHbO2: accumulated oxygenated hemoglobin
DLPFC: dorsolateral prefrontal cortex
fMRI: functional magnetic resonance imaging

fNIRS: functional near-infrared spectroscopy
FPC: frontopolar cortex
HMD: head-mounted display
MET: metabolic equivalent of task
OFC: orbitofrontal cortex
VLPFC: ventrolateral prefrontal cortex
VR: virtual reality
ΔaccHbO2: change in accumulated oxygenated hemoglobin

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Original Paper

Measured and Perceived Exercise Intensity During the Performance of Single-Task, Cognitive-Motor Dual-Task, and Exergame Training: Transversal Study

Matthieu Gallou-Guyot[1], PT, PhD; Anaick Perrochon[1], PhD; Romain Marie[2], PhD; Maxence Bourgeois[1], PT; Stephane Mandigout[1], PhD

[1]HAVAE, UR 20217, Université de Limoges, Limoges, France
[2]3iL Ingénieurs, Limoges, France

Corresponding Author:
Matthieu Gallou-Guyot, PT, PhD
HAVAE, UR 20217
Université de Limoges
123, avenue Albert Thomas
Limoges, F–87000
France
Phone: 33 607087516
Email: matthieu.gallou.guyot@gmail.com

Abstract

Background: The physical and cognitive loads borne during exergaming may differ from more conventional cognitive-motor dual-task trainings.

Objective: The aim of this pilot transversal study was to compare objectively measured and perceived exercise intensity during exergame, cognitive-motor dual-task, and single-task training sessions.

Methods: We recruited apparently healthy young adults who carried out one session of each type of training: exergaming, cognitive-motor dual-tasking, and single-tasking. We used a custom-made exergame as support. The sessions lasted 30 minutes, were spaced at least 24 hours apart, and took place in random order for each group of 4 participants. We used heart rates to assess exercise intensity and the modified Borg scale to assess perception of intensity. In all, 16 apparently healthy young participants carried out all sessions.

Results: There was no difference between the different types of training in mean heart rates (P=.27), peak heart rates (P=.50), or Borg scale scores (P=.40). Our custom-made exergame's objectively measured and perceived physical load did not differ between cognitive-motor dual-task and single-task training.

Conclusions: As a result, our exergame can be considered to be as challenging as more traditional physical training. Future studies should be conducted in older adults with or without cognitive impairments and incorporate an assessment of cognitive performance.

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KEYWORDS
exergame; dual-task; exercise intensity; heart rate; cognitive load; active video game; physical activity

Introduction

Exergames (EGs), or "active video games," are video games played on a digital device, including a wide range of interfaces [1] that require physical activity when played [2]. EGs are a singular form of cognitive-motor dual-task (CMDT) training, which is known to be efficient in terms of both cognitive and physical functions [3,4]. In addition, EGs are considered fun and are enjoyed by most users, as they facilitate exercise in an attractive, motivating, and interactive environment [5]. However, EGs must be sufficiently demanding to induce effects, with regard to cognitive as well as physical loads [2,6], and their efficiency depends to some extent on their intensity.

As a singular form of CMDT training, EGs should not differ in terms of the physical level of solicitation. The tasks players are asked to perform are similar, one of them being cognitive and the other physical, with the difference residing in the support used. Previous studies have shown that most EGs induce moderate [7-10] to vigorous [8,9,11] exercise intensity in healthy young adults. However, there seem to be large variations in intensity between different EGs, depending on the hardware (primarily Kinect or Wii) or game used [11,12]. For example, EGs such as Wii Bowling induce low-intensity physical activity [8], whereas Kinect Boxing or "Your Shape Fitness Evolved 2012" indeed induce vigorous physical activity [9,11]. Variability in exercise intensity between tailor-made EGs is likely to be even greater.

Significant heterogeneity in exercise intensity during exergaming raises questions about the impact of the support used. Would exercise intensity be the same during similar physical training sessions presented in either single-task (ST) or CMDT conditions, whether using a tailor-made EG as a support or not? To our knowledge, no study has compared exercise intensity during exergaming and ST training, and only one study has compared exercise intensity during CMDT and ST training in healthy young adults [13], showing higher intensity under CMDT than ST conditions.

To date, we have been unable to conclusively determine the impact of the training support (ie, direct comparison between exergaming and CMDT training) or the impact of a concurrent cognitive task (ie, direct comparison to ST conditions, considered as the reference modality for physical training) on the level of physical solicitation in healthy young adults. The aim of this pilot transversal study was to compare objectively measured and perceived exercise intensity during EG, CMDT, and ST training sessions.

Methods

Participants

Apparently healthy students from the University of Limoges volunteered for this pilot transversal study. The inclusion criteria were young adults aged between 18 and 35 years and fluent in French. The exclusion criteria were having a contraindication to physical activity or having eaten or drunk during the previous 2 hours.

Ethical Considerations

In accordance with the Declaration of Helsinki as revised in 2013, the volunteers had received an information document detailing the protocol and gave their written consent to participate.

The study was carried out as part of student work in initiation to research during the year 2021. According to French regulations (Jardé law) [14], ethics review was not required.

Procedure

Participants were recruited during practical exercise courses. They carried out 3 types of training: EG, CMDT, and motor ST. The training sessions were designed identically: physical exercises (ST), with concurrent cognitive tasks (CMDT), using an EG as support (EG). The exercise sessions were organized in groups of 4 participants, and the order of training was randomized for each group. They lasted 30 minutes and were spaced at least 24 hours apart. They were divided into eight 3-minute-long exercise sequences (see Table 1), with 30 seconds of rest and instructions in between; therefore, effective physical activity lasted approximately 24 minutes. An instructor supervised, giving instructions and assisting the participants. Sessions were suspended in the event of an injury, significant pain, or heart rates above 90% of the theoretical maximums [15]. We have illustrated the differences between EG, CMDT, and ST training during stepping performance in Figure 1.

During EG training, sessions consisted of multiple dual tasks using a custom-designed EG as support (Figure 2). This EG was developed in the *Handicap, Activités Vieillissement, Autonomie, Environnement* laboratory, using the "Virtual Carpet," which is associated a video projector and HTC Vive cameras and trackers, as the play area [16-18]. The projected scene was a schematic city, and players were asked to move to different points of interest during exercises. Detection by the Vive trackers of a player's position at a point of interest triggered a change of scene and launched a mini-game, which was carried out by all the players. The motor tasks were mainly stepper, muscle strength, and balance activities. The cognitive tasks were verbal fluency, arithmetic, mental inhibition and flexibility, visuospatial memory, processing speed, and planning. Some exercises required gymnastic equipment (stepper, Swiss or medicine balls, chairs). The training sessions were designed to match with the American College of Sports Medicine [19] and the World Health Organization [20] guidelines and recommendations on physical activity, as well as the recommendations designed to prevent falls in older adults [21]. Details on the exercises are indicated in Table 1.

During the CMDT training, the participants used the same gymnastic equipment, and the sessions were made up of the same associations of cognitive and motor dual tasks as in the EG group but without using the EG (see exercise details in Table 1).

Finally, ST training required the same gymnastic equipment and the same motor tasks as those carried out during EG and CMDT training but without a concurrent cognitive task (see exercise details in Table 1).

Table 1. Details of the exercises proposed during the different types of training.

Training	Stepper (with and without a step)	Visuospatial memory and balance	Muscular strength and coordination
EG[a]	Arrows are displayed successively on the projected scene, and participants must reproduce them on a pad with 1 foot, 2 feet, doing a squat, a lunge, etc. The additional cognitive tasks are to not reproduce an arrow (go or no go), to invert them (mental flexibility), or to render them with a time lapse (working memory).	Eight elements displayed within the projected area will turn on and off at a fixed frequency, constituting a growing span. Participants must memorize this sequence and then recall it while moving around. At the same time, they perform motor exercises (knee raising, buttocks to heels, squats, lunges, and jumping jacks). The additional cognitive tasks are to not consider one of the icons or to recall the span from the end.	Participants must perform muscle-strengthening exercises (eg, squat and lunges). At the same time, they must (1) solve mental arithmetic exercises appearing on the projected scene; (2) alternate the exercises performed according to the images appearing on the projected scene; and (3) perform a "categories" game or build a word giving a letter, one at a time.
CMDT[b]	The instructor shows a sequence of movements that the participants must reproduce in mirror (step, squat, lunge, etc). The additional cognitive tasks are to not reproduce an arrow (go or no go), to invert them (mental flexibility), or to render them with a time lapse (working memory).	Participants must displace a total of 8 plots, one at a time. The plot-placing order constitutes the span. Participants must memorize this sequence and then recall it while moving around. At the same time, they perform motor exercises (knee raising, buttocks to heels, squats, lunges, and jumping jacks). The additional cognitive tasks are to not consider one of the icons or to recall the span from the end.	Participants must perform muscle-strengthening exercises (ie, squats and lunges). At the same time, they must (1) alternate the exercises performed according to the auditory or visual stimuli given by the instructor and (2) perform a "categories" game or build a word giving a letter, one at a time.
ST[c]	The instructor shows a sequence of movements that the participants must reproduce in mirror (step, squat, lunge, etc). There is no additional cognitive task.	The instructor demonstrates static and dynamic balance exercises to perform. The participants must perform movements of the limbs and trunk and pass a medicine ball while standing on a Swiss ball or standing on one leg. There is no additional cognitive task.	Participants perform a game mixing together muscle strengthening of the lower limbs and motor coordination by dribbling with a ball. There is no additional cognitive task.

[a]EG: exergame.

[b]CMDT: cognitive-motor dual-task.

[c]ST: single-task.

Figure 1. Illustration of the differences between exergame (EG), cognitive-motor dual-task (CMDT), and single-task (ST) training, during the performance of a stepping task. The instructor is represented in blue.

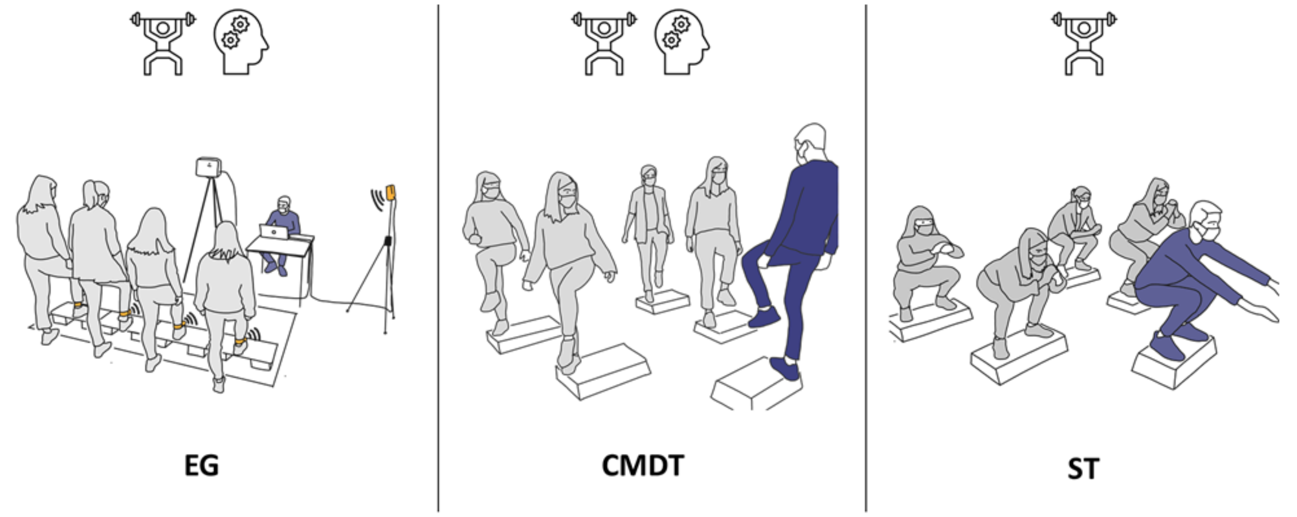

Figure 2. Illustration of the exergame. (1) Video projector, (2) HTC Vive infrared cameras, (3) computer, and (4) HTC Vive trackers. In this example, only 2 participants are performing a stepping exercise.

Outcomes

The primary outcome was the objectively measured exercise-intensity level assessed in terms of mean and peak heart rates (HRs) during training. We used HR because it is considered the most practical parameter to monitor, especially as regards reliability, safety, and cost [22]. We used validated chest HR Polar H10 monitors (Polar Electro Oy) [23], measuring the participants' HR_{mean} and HR_{peak} during the 3 types of training.

The secondary outcome was the rating of perceived exertion, using a validated modified Borg scale [24] completed by participants at the end of each training session.

Statistical Analysis

Quantitative variables were described according to mean and SD or median and IQR. The normality of data distribution was assessed using Shapiro-Wilk tests. Comparison between HR_{mean}, HR_{peak}, and Borg scale scores during the different trainings (EG, CMDT, and ST) was carried out using a 1-factor ANOVA or a Friedman test according to the normality of the variables concerned. Statistical analysis was performed using RStudio (Rstudio, Inc), and result significance was set at P<.05.

Results

In all, 16 apparently healthy young participants volunteered for the study (6 males, 10 females). Sociodemographic characteristics are presented in Table 2.

Although mean and peak HR variable distribution was normal during the 3 types of training, the Borg scale scores were not. There was no difference between the different types of training (EG, CMDT, and ST) for any of the variables studied: HR_{mean} ($F_{2,45}$=1.33; P=.27), HR_{peak} ($F_{2,45}$=0.7; P=.50), and Borg scale scores (χ^2_2=1.85, P=.40; see details in Table 3).

Table 2. Participant characteristics.

Characteristic	Value, mean (SD)
Age (years)	24.6 (3.1)
Height (m)	1.72 (0.11)
Weight (kg)	69.1 (15.1)
BMI	23.1 (3.2)
HR[a]$_{resting}$ (bpm[b])	66.9 (10.4)
HR_{max} (bpm)	187.2 (1.2)

[a]HR: heart rate.

[b]bpm: beats per minute.

Table 3. Results depending on type of training.

Result	EG[a]	CMDT[b]	ST[c]
Borg scale score (out of 10), mean (SD)	3.1 (1.4)	3.6 (1.3)	3.3 (1.0)
HR^{d}_{mean} (bpm[e]), mean (SD)	119.8 (12.2)	123.8 (16.1)	128.1 (14.7)
Percentage of theoretical HR_{max} (%)	64	66	68
HR_{peak} (bpm), mean (SD)	157.9 (10.1)	163.0 (12.8)	161.7 (14.5)

[a]EG: exergame.

[b]CMDT: cognitive-motor dual-task.

[c]ST: single-task.

[d]HR: heart rate.

[e]bpm: beats per minute

Discussion

This pilot transversal study was aimed at comparing objectively measured and perceived exercise intensity during EG, CMDT, and ST training sessions in healthy young adults. We observed no differences in mean or peak HR or perceived exertion between the 3 types of training.

Perceived and Measured Physical Activity Intensity

In our study, physical activity intensities during EG, CMDT, and ST training sessions did not statistically differ. This finding is discrepant with the results of a previous study, which showed higher HR_{mean} under CMDT than ST training [13]. Our results even seemed opposed, with a tendency toward higher HR_{mean} during ST training of nearly 10 beats per minute, close to 70% of theoretical HR_{max}, and moderate intensity [25]. This difference with our study may be due to the nature of the requested tasks. Exercise intensity varies considerably according to type of movement, the body part involved (upper or lower limb), the level of difficulty of a given game (frequency and speed), or the participants' previous experience as players [26-28]. In the study by Herold et al [13], subjects were asked to carry out squats under both conditions while additionally counting backward in CMDT training[13]. In our study, the physical and cognitive tasks were not only more varied but also and above all more complex (see Table 1). In addition, it is important to note the impact that different interfaces can have when comparing interventions. For instance, the quality of immersion and interaction highly impacts the user experience and the usability of immersive EGs [29]. We tried to reduce these effects of complexity and interface by proposing similar and transferable exercises between the different types of training. As a result, the exercises carried out in this study during training sessions were the same in EG, CMDT and ST conditions, with the differences consisting solely of the concurrent cognitive task and the use of a given game as support. In fact, instruction comprehension and error correction were time-consuming, decreasing effective exercise duration and HR over the course of the 30-minute sessions. Understanding more complex combined tasks during CMDT training along with adaptation to new game rules and to a new environment during EG may have been more time-consuming than during ST training.

Previous studies assessing the level of solicitation during exergaming in healthy young adults through HR have shown moderate [7-10] or vigorous [8,9,11] exercise intensity, with highly pronounced variability between studies according to the software or hardware used. Our custom-made EG seemed to induce moderate exercise intensity, equivalent to the physical exercises requested under CMDT or ST conditions. This is a relevant and interesting finding; since exercises under ST conditions are considered as the reference modality for physical training, their equivalence during exergaming and dual-task training enabled us to consider our EG as sufficiently soliciting to induce physical results, while adding a cognitive load in a playful environment.

Moreover, perceived physical intensity assessed through the Borg scale did not differ between the 3 types of training and was globally moderate. The perception of effort by participants in this study was correlated with the results obtained from the percentage of theoretical HR_{max} [25]. This is in line with previous studies showing that adults correctly estimate their less vigorous physical efforts [25,30].

Limitations

The first limitation of this study is the sample, for which no a priori sample size was carried out. However, our population was homogeneous and showed relative stability in physical intensity. This pilot study constitutes a proof of concept specific to our EG in a highly specific context and population. Consequently, the small extension of the knowledge provided by our study is specific, which complicates its extrapolation to other forms of EGs or populations.

A second limitation is due to the assessment exercise intensity modalities. In this study, given its reliability, safety, and cost, we used HR as a reflection of exercise intensity, whereas other studies have used more direct parameters such as oxygen consumption [8,31] or blood lactate responses [32] to assess exercise intensity during exergaming. Moreover, the software we used did not enable us to analyze HR in detail. It would be relevant to estimate the HR profile to determine whether it remains stable and close to the mean or varies with peaks and rest. Lastly, the assessment of effective HR_{max} rather than theoretical HR_{max} would have made it possible to evaluate reserve HR, thereby limiting impact of interpersonal variability.

Future Studies

Most of the EGs in which the intensity was assessed in previous studies were commercial video games [7-11]. This is broadly the case, especially insofar as commercial active video games are frequently used in rehabilitation [33]. The main consequence is a lack of control over qualitative and quantitative physical and cognitive exercises. Tailor-made software using mainstream hardware is designed to suit the specific needs of a given audience [34] while applying an easily available and relatively inexpensive solution. For example, the training of older adults presents specificities, in both form and in substance. Understanding is maximized through slow animations, large fronts, and simple rules [35]. With age, physical and cognitive capacities decline while cognitive-motor interference increases [36,37]. Fall prevention in older adults should focus on strength, postural control, stepping, and gait training [38-40], along with mental inhibition and flexibility, processing speed, and visuospatial memory [41-43]. In fact, a fall prevention training protocol with our EG seems possible and relevant, insofar as it facilitates the simultaneous training of cognitive and physical functions. By applying our pilot study's values and methodology, future studies may assess the extent to which and the efficacy with which our EG solicits in older adults. In addition to its pronounced beneficial effects, our EG may help promote physical activity [44], which is a point of major importance among older adults.

In this study, we investigated physical aspects, not cognition. However, cognitive efficiency and HR may be correlated; a meta-analysis found that participants with better cognitive task results often demonstrated greater cardiac parasympathetic control than those with poorer cognitive performance [45]. This question could be investigated using hybrid systems, coupling functional near infrared spectroscopy, and electroencephalogram headsets [46].

Conclusion

This pilot transversal study showed that a custom-made EG that could induce moderate perceived and objectively measured exercise intensity, equivalent to CMDT and ST training in healthy young adults. As a result, our EG can be considered as being as relevant as more traditional physical training with regard to exercise intensity. Future studies should investigate the cognitive and physical level of solicitation of our EG in older adults, who are likely to draw benefit from CMDT training.

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Authors' Contributions

MG-G contributed to conceptualization, methodology, investigation, writing–original draft, and visualization. AP contributed to conceptualization, methodology, writing–original draft, and project administration. RM contributed to development and writing–review and editing. MB contributed to investigation. SM contributed to conceptualization, methodology, writing–original draft, project administration, and supervision.

Conflicts of Interest

None declared.

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Abbreviations

CMDT: cognitive-motor dual-task
EG: exergame
HR: heart rate
ST: single-task

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Original Paper

Research Status and Emerging Trends in Virtual Reality Rehabilitation: Bibliometric and Knowledge Graph Study

Ting Fan[1], MD; Xiaobei Wang[2], BNAD; Xiaoxi Song[3], MD; Gang Zhao[4], PhD; Zhichang Zhang[1], MEng

[1]Department of Computer, School of Intelligent Medicine, China Medical University, Shenyang, China

[2]Department of General Practice, The First Hospital of China Medical University, China Medical University, Shenyang, China

[3]Liaoning Education Informatization Construction Center, LiaoNing Institute of Education, Shenyang, China

[4]Department of Health Promotion, School of Intelligent Medicine, China Medical University, Shenyang, China

Corresponding Author:
Zhichang Zhang, MEng
Department of Computer
School of Intelligent Medicine
China Medical University
No 77 Puhe Road
Shenyang North New Area
Shenyang, 110122
China
Phone: 86 18900910770
Email: zczhang@cmu.edu.cn

Abstract

Background: Virtual reality (VR) technology has been widely used in rehabilitation training because of its immersive, interactive, and imaginative features. A comprehensive bibliometric review is required to help researchers focus on future directions based on the new definitions of VR technologies in rehabilitation, which reveal new situations and requirements.

Objective: Herein, we aimed to summarize effective research methods for and potential innovative approaches to VR rehabilitation by evaluating publications from various countries to encourage research on efficient strategies to improve VR rehabilitation.

Methods: The SCIE (Science Citation Index Expanded) database was searched on January 20, 2022, for publications related to the application of VR technology in rehabilitation research. We found 1617 papers, and we created a clustered network, using the 46,116 references cited in the papers. CiteSpace V (Drexel University) and VOSviewer (Leiden University) were used to identify countries, institutions, journals, keywords, cocited references, and research hot spots.

Results: A total of 63 countries and 1921 institutes have contributed publications. The United States of America has taken the leading position in this field; it has the highest number of publications; the highest h-index; and the largest collaborative network, which includes other countries. The reference clusters of SCIE papers were divided into the following nine categories: kinematics, neurorehabilitation, brain injury, exergames, aging, motor rehabilitation, mobility, cerebral palsy, and exercise intensity. The research frontiers were represented by the following keywords: *video games* (2017-2021), and *young adults* (2018-2021).

Conclusions: Our study comprehensively assesses the current research state of VR rehabilitation and analyzes the current research hot spots and future trends in the field, with the aims of providing resources for more intensive investigation and encouraging more researchers to further develop VR rehabilitation.

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KEYWORDS

mobility; rehabilitation; virtual reality; bibliometric; technology; training; interactive; research; exercise; resources; cerebral palsy; adult; video games

Introduction

In recent years, the number of people with rehabilitation needs has increased, particularly among groups of older patients, patients with disabilities, patients with chronic diseases, and patients with functional and cognitive impairments. The loss of movement, sensation, balance, and cognition, as well as other aspects, seriously affects patients' quality of life, work, study, and social life [1,2]. Such patients require long-term, consistent rehabilitation training and guidance [3]. However, traditional rehabilitation training has a number of problems, including fixed rehabilitation centers, a lack of rehabilitation resources, uninteresting training processes, high treatment costs, and a lack of automatic guidance and incentive mechanisms. These result in a lack of confidence in the rehabilitation process, which in turn affects the outcomes of rehabilitation treatments [4,5].

With the gradual popularization of virtual reality (VR) technology, rehabilitation training systems based on VR technology have been gradually applied in sports, exercise, and functional rehabilitation for various diseases and have achieved positive effect results [6,7]. The combination of VR technology and rehabilitation medicine can enable more patients to train regularly at home or in the community, as VR rehabilitation systems provide an immersive experience that stimulates patients' interest and improves their participation, thus overcoming the disadvantages of fixed centers and the lack of resources [8]. Furthermore, VR rehabilitation systems can sense and record a patient's movement and biological data via sensors to further improve existing rehabilitation programs [9]. This rehabilitation technology is a useful supplement to traditional rehabilitation and is a promising new research direction in the field of rehabilitation medicine.

A comprehensive bibliometric review is required to help researchers focus on future directions based on the new definitions of VR technologies in rehabilitation, which reveal new situations and requirements. Although bibliometric methods have yielded positive results in a variety of fields, we found that there is still a significant gap in the research on VR rehabilitation and its development trends by using bibliometric methods.

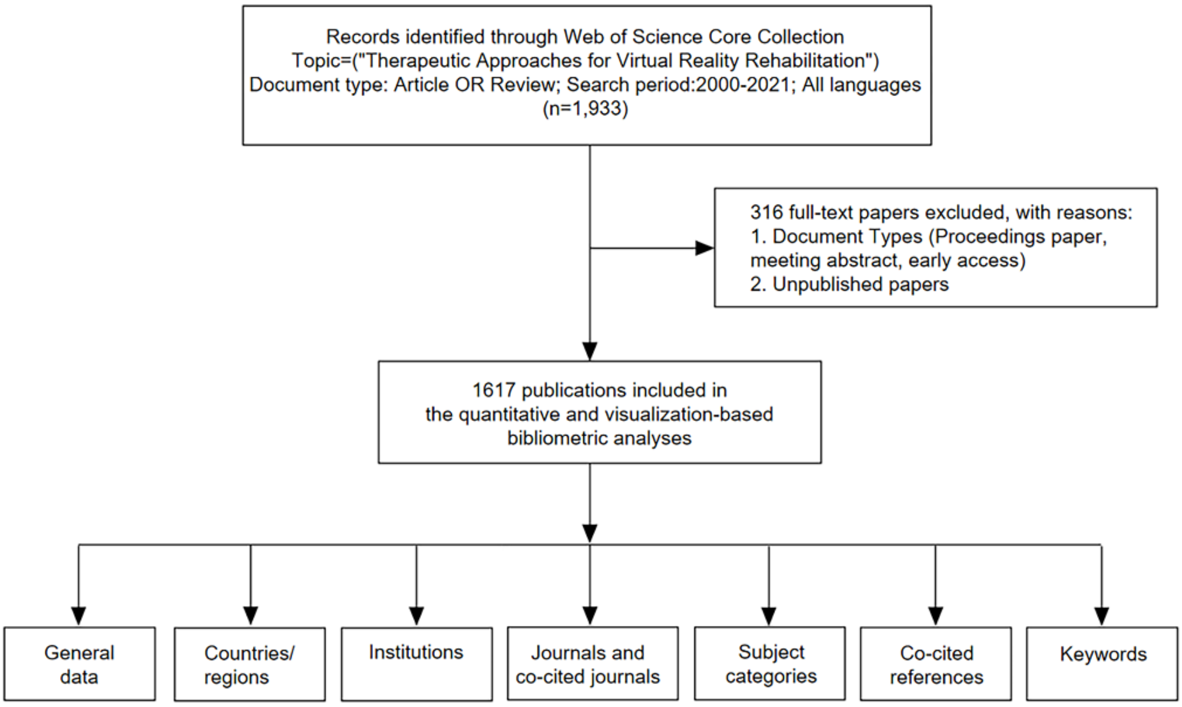
We used bibliometric methods to analyze SCIE (Science Citation Index Expanded) papers on studies related to VR rehabilitation research. Articles from different countries, regions, and research institutions were included. We identified papers in journals, gathered the top 10 citations, and enumerated how many times these citations were used. The VR rehabilitation knowledge base was analyzed by grouping authors' co-occurring keyword networks. Burst citations were used to identify research hot spots on this topic, which could provide a useful reference for future research [10,11]. These analyses will provide rehabilitation specialists with a macroscopic understanding of the knowledge domain as a whole, as well as a microscopic characterization. Compared to other reviews, our study is timely and visual and provides an impartial approach to developing and exploring particular knowledge domains. Our findings may encourage more researchers to conduct additional research in this field to further develop VR rehabilitation methods. The following basic information was gathered from studies: titles, abstracts, author information, institutions, countries, regions, keywords, and citations.

Methods

We created a clustered network, using the 46,116 references cited in 1617 published papers. The data came from the Web of Science Core Collection (WSCC), which was accessed on January 20, 2022. The search covered articles published from 2000 to 2021. The following search string, which included the search terms, was used: *Virtual Reality OR VR OR AR OR Augmented Reality*. Further, we limited our search to original articles and reviews, and the Web of Science category *Rehabilitation* was selected. To determine study inclusion, the aforementioned basic information was collected from articles in the WSCC. However, the following papers were excluded: (1) irrelevant proceedings and meetings papers, (2) chapters in books, (3) duplicated articles, and (4) unpublished papers with limited information. In total, 1617 papers were included, with duplicates excluded. The search and analysis procedures are outlined in Figure 1.

We defined most publication traits, including institute, country, journal, and keywords. We used Journal Citation Reports (2020 version; Clarivate) to identify impact factors, which reflect scientific research value [12]. All data were processed by using CiteSpace V (Drexel University) and VOSviewer (Leiden University). Both programs are used for collaboration network analysis to link publication traits [11,13]. From these analyses and measures, we obtained data on research hot spots, evolution paths, knowledge structures, and new trends in VR rehabilitation.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of study selection. The diagram shows details on the selection criteria for virtual reality rehabilitation publications from the SCIE (Science Citation Index Expanded) database and the steps of bibliometric analysis.

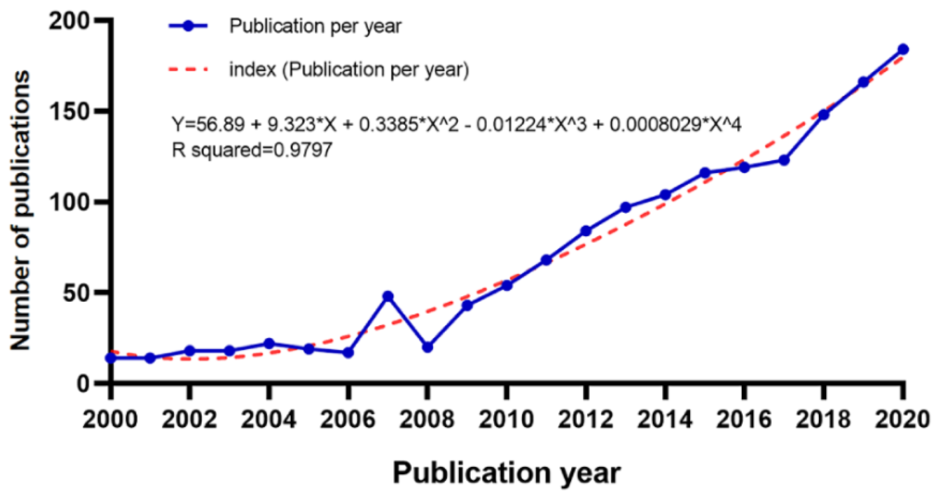


Results

Study Distribution by Publication Year

Between 2000 and 2021, a total of 1617 papers on VR rehabilitation were published. Emerging trends in VR rehabilitation research–related studies are outlined in Figure 2. From 2000 onward, VR rehabilitation research rapidly accelerated. In Figure 2, the blue line denotes the increasing trend in the annual number of studies from 2000 to 2021, whereas the red broken line represents the publication index, which also increased. In the initial 2000 to 2006 research period, publication numbers per year were relatively stable and were <25, suggesting an initial period of exploratory VR rehabilitation research. However, the rise in rehabilitation demands and the increased development of supporting technologies, which are due to the increased interest in applying VR to medicine and rehabilitation and the increasing, widespread use of VR technology, have resulted in a proliferation of publications since then. The number of publications in last decade accounted for more than 80% of the total publications found.

Figure 2. Trends in the number of publications on virtual reality rehabilitation.



Analysis of Countries and Institutes

The analyzed publications included contributions from a total of 63 countries and 1921 institutes. The top 10 countries and institutes are outlined in Tables 1 and 2, respectively, whereas collaborations between countries and between institutes are shown in Figure 3 and Figure 4, respectively. The United States published the most studies (n=663), followed by Canada (n=143). The United States also had the top h-index (59), followed by Canada (29) and Australia (21). Rutgers State

University New Brunswick had the most publications (n=52), followed by McGill University (n=45). Rutgers State University New Brunswick also had the highest h-index (27). On a global level, research institutes and associated research staff are collaborating and sharing experiences. However, although the United States has played a leading role, the international collaboration rates of the United States are low.

Table 1. The top 10 countries in terms of publications.

Rank	Countries	Publication count, n	h-index
1	United States of America	663	59
2	Canada	143	29
3	Australia	96	21
4	England	92	29
5	South Korea	83	26
6	Italy	81	26
7	Israel	71	27
8	Brazil	68	21
9	Netherlands	67	17
10	Spain	61	21

Table 2. Top 10 institutions in terms of publications.

Rank	Institutions	Publication count, n	h-index
1	Rutgers State University New Brunswick	52	27
2	McGill University	45	17
3	Pennsylvania Commonwealth System of Higher Education	38	13
4	Tel Aviv University	38	16
5	University of Wisconsin System	38	12
6	University of Haifa	37	19
7	University of Illinois System	35	15
8	US Department of Veterans Affairs	34	13
9	Veterans Health Administration	34	13
10	University of Wisconsin Madison	33	11

Figure 3. The cooperation of countries and regions that contributed to publications on virtual reality rehabilitation. CC: co-citations; CST: Central Standard Time; LBY: Look back year; L/N: Maximum Links Per Node; LRF: Link Retaining Factor; WoS: Web of Science.

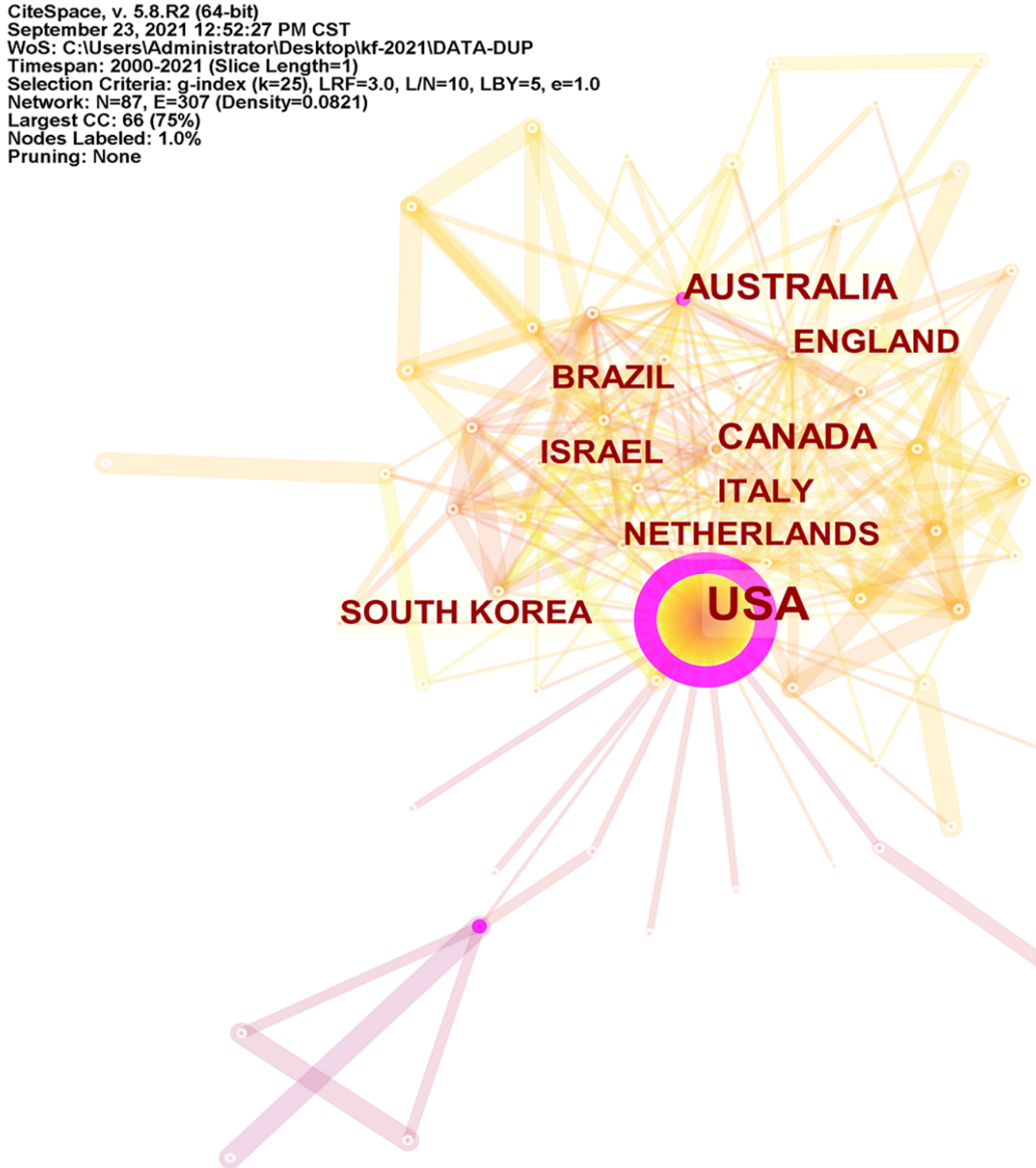


Figure 4. The cooperation of institutions that contributed to publications on virtual reality rehabilitation therapy. CC: co-citations; CST: Central Standard Time; LBY: Look back year; L/N: Maximum Links Per Node; LRF: Link Retaining Factor; WoS: Web of Science.

Analysis of Journals

A total of 241 journals published articles related to VR rehabilitation; the top 10 are outlined in Table 3, and collaborations between cited journals are shown in Figure 5. *Archives of Physical Medicine and Rehabilitation* was the top journal (publications: n=847), followed by *Physical Therapy and Rehabilitation* (publications: n=608). Among these journals, *Cochrane Database of Systematic Reviews* had the highest impact factor (9.266), followed by *Stroke* (7.914).

Academic journals represent and reflect knowledge exchange in the research arena, where citing papers form a knowledge frontier and cited papers form a knowledge basis. A journal overlay dual map was assembled, as presented in Figure 6, wherein citing journals are shown on the left, cited journals are shown on the right, and citation relationships are represented by colored lines. These lines show that studies published in the molecular biology and genetics sector; the health, nursing, and medicine sector; the sports rehabilitation and sports sector; and the psychology, education, and social sector were usually cited in studies published in the medicine, medical, and clinical sector and the psychology, education, and health sector.

Table 3. The top 10 journals in terms of publications.

Rank	Cited journals	Publication count, n	h-index	Impact factor (2020)
1	*Archives of Physical Medicine and Rehabilitation*	847	197	3.966
2	*Physical Therapy and Rehabilitation*	608	150	3.021
3	*Disability and Rehabilitation*	550	111	3.033
4	*Journal of NeuroEngineering and Rehabilitation*	550	94	4.262
5	*Stroke*	484	319	7.914
6	*Neurorehabilitation and Neural Repair*	454	106	3.919
7	*CyberPsychology & Behavior*	420	143	4.157
8	*Clinical Rehabilitation*	411	110	3.477
9	*Journal of Rehabilitation Medicine*	357	96	2.912
10	*Cochrane Database of Systematic Reviews*	324	273	9.266

Figure 5. The network map of cited journals contributed to publications on virtual reality rehabilitation. CC: co-citations; CST: Central Standard Time; LBY: Look back year; L/N: Maximum Links Per Node; LRF: Link Retaining Factor; WoS: Web of Science.

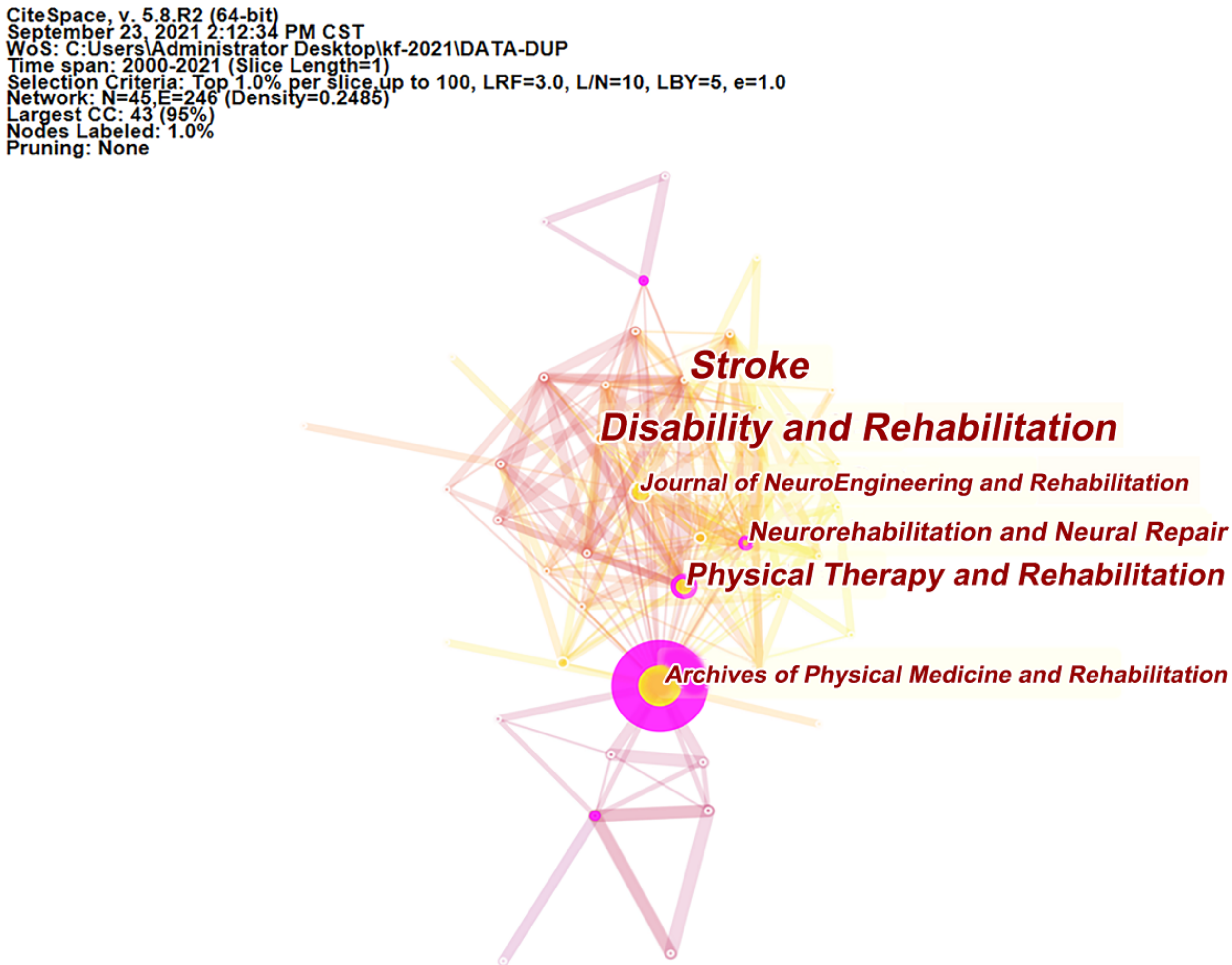
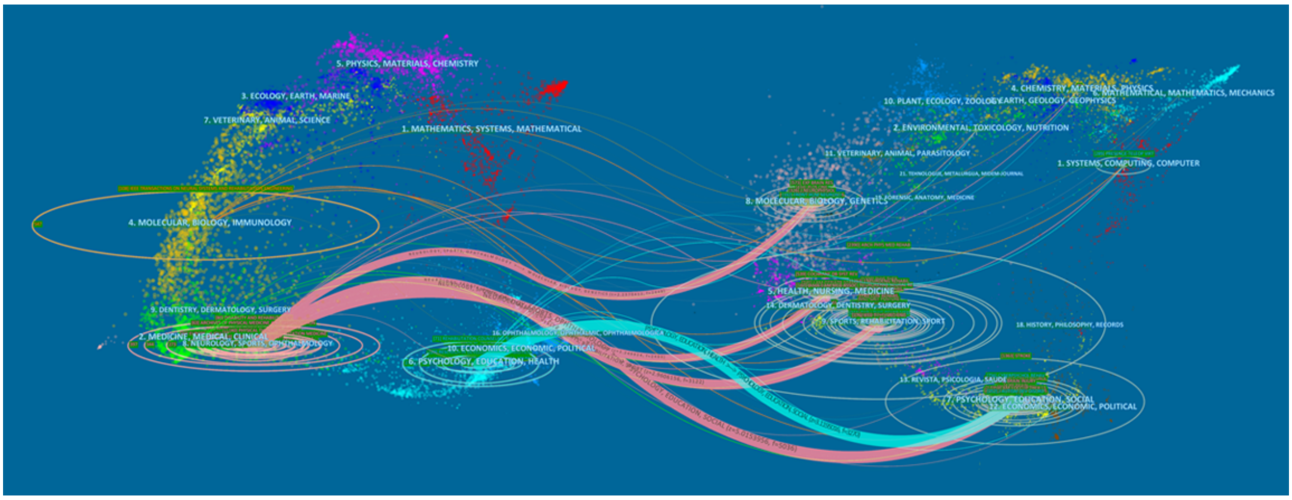


Figure 6. The dual map overlay of journals that contributed to publications on virtual reality rehabilitation.



Analyzing Citations

A citation is a vital bibliometric indicator, with frequently cited studies greatly influencing their research areas. We list the top 10 most highly cited publications in Table 4. *Effectiveness of Virtual Reality Using Wii Gaming Technology in Stroke Rehabilitation* by Saposnik et al [14], which was published on 2010 in *Stroke*, was the most highly cited article (cited 58 times); the article verified the effectiveness of rehabilitation for participants with stroke by using Wii (Nintendo Co, Ltd) gaming technology. Laver et al [15,16] published 2 articles with the same title—*Virtual reality for stroke rehabilitation*—on 2011 [15] and 2015 [16] in *Cochrane Database of Systematic Reviews*. These studies evaluated the rehabilitation impact of

VR technology for patients with stroke in accordance with the status quo in different periods.

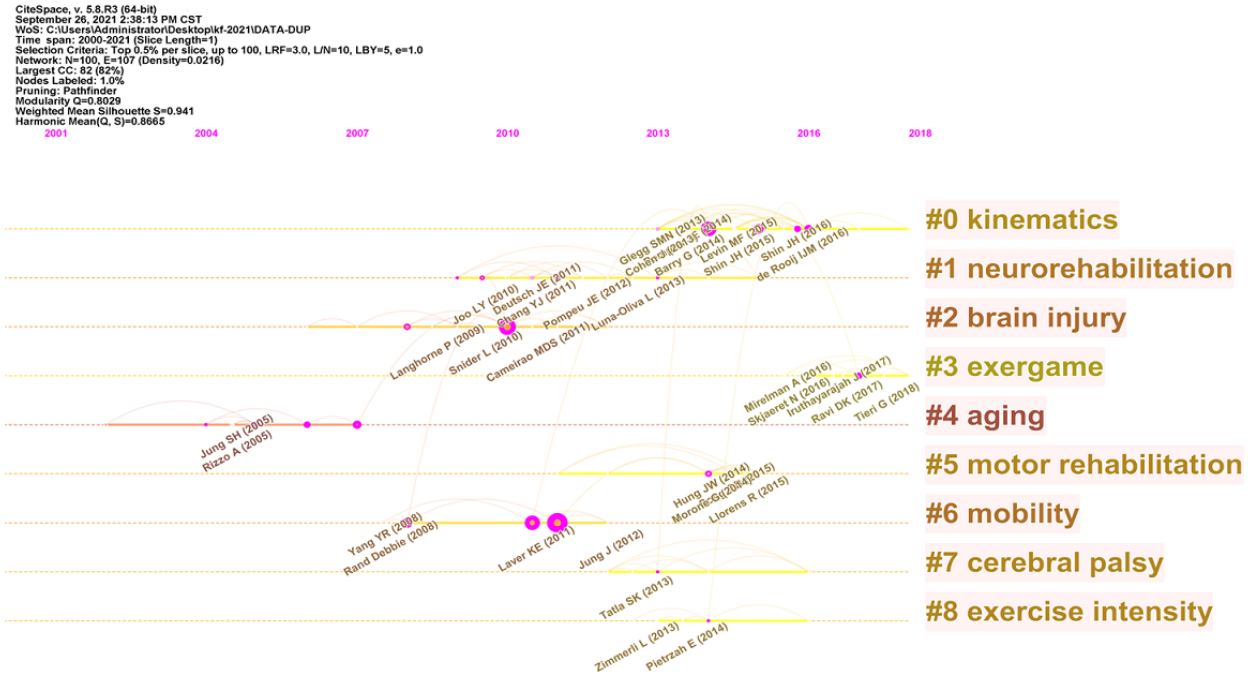
In network research, betweenness centrality reflects node importance in a network; thus, a higher betweenness centrality signifies an important study [23]. The betweenness centralities of the top 10 studies are shown in Table 4.

A cocited document–centered clustering investigation was proposed to identify subnodes and connecting nodes in VR rehabilitation. To assess the scientific relevance of publications, we established a network of cocited references (Figure 7). The cluster settings were as follows: the number of years per slice was set to 1, and the top 0.5% of articles were selected for analysis; a pruning algorithm was used. The modularity Q score was 0.8029 (>0.5), which showed that the network was well separated into loosely coupled clusters. The weighted mean silhouette score was 0.941 (>0.5) and suggested acceptable cluster homogeneity. Study index items were used as cluster markers. The largest cluster—cluster 0—was labeled as *kinematics*, cluster 1 was labeled as *neurorehabilitation*, cluster 2 was labeled as *brain injury*, cluster 3 was labeled as *exergame*, cluster 4 was labeled as *aging*, cluster 5 was labeled as *motor rehabilitation*, cluster 6 was labeled as *mobility*, cluster 7 was labeled as *cerebral palsy*, and cluster 8 was labeled as *exercise intensity*.

Table 4. The top 10 cited articles on virtual reality (VR) in rehabilitation.

Rank	Authors and published year	Title of cited article	Citation count, n	Centrality	Interpretation of the findings
1	Saposnik et al [14], 2010	*Effectiveness of Virtual Reality Using Wii Gaming Technology in Stroke Rehabilitation*	58	0.04	This article verified the effectiveness of rehabilitation for participants with stroke by using Wii (Nintendo Co, Ltd) gaming technology.
2	Saposnik and Levin [17], 2011	*Virtual Reality in Stroke Rehabilitation: A Meta-Analysis and Implications for Clinicians*	51	0.10	This study performed a meta-analysis to determine the added benefit of VR technology in arm motor recovery after stroke.
3	Deutsch et al [18], 2008	*Use of a Low-Cost, Commercially Available Gaming Console (Wii) for Rehabilitation of an Adolescent With Cerebral Palsy*	37	0.04	This document is the first report on using low-cost, commercially available gaming technology for the rehabilitation of an adolescent with cerebral palsy.
4	Laver et al [15], 2011	*Virtual reality for stroke rehabilitation*	37	0.12	This study evaluated the effects of VR and interactive video gaming on upper limb, lower limb, and global motor function.
5	Lohse et al [6], 2014	*Virtual Reality Therapy for Adults Post-Stroke: A Systematic Review and Meta-Analysis Exploring Virtual Environments and Commercial Games in Therapy*	31	0.14	This analysis systematically reviewed the evidence for VR therapy in adults after stroke.
6	Levin et al [19], 2015	*Emergence of Virtual Reality as a Tool for Upper Limb Rehabilitation: Incorporation of Motor Control and Motor Learning Principles*	27	0.01	This article discussed how to exploit VR training environments and provided evidence concerning applications for upper limb motor recovery.
7	Laver et al [16], 2015	*Virtual reality for stroke rehabilitation*	27	0.02	This paper assessed the effectiveness of VR rehabilitation training.
8	Joo et al [20], 2010	*A feasibility study using interactive commercial off-the-shelf computer gaming in upper limb rehabilitation in patients after stroke*	26	0.02	The aim of this study was to assess the feasibility of using the Nintendo Wii as an adjunct to conventional rehabilitation for patients.
9	Adamovich et al [21], 2009	*Sensorimotor training in virtual reality: A review*	25	0.01	This paper discussed possible underlying mechanisms in the area of VR rehabilitation and provided some development direction.
10	Holden [22], 2005	*Virtual Environments for Motor Rehabilitation: Review*	25	0.05	In this paper, the state of VR applications in the field of motor rehabilitation was reviewed.

Figure 7. Reference cocitation map of publications on virtual reality rehabilitation. CC: co-citations; CST: Central Standard Time; LBY: Look back year; L/N: Maximum Links Per Node; LRF: Link Retaining Factor; WoS: Web of Science.



Analysis of Co-occurrence and Burst Keywords

Keywords in similar publications were identified and processed. The top 20 keywords, which had a high link strength, are outlined in Table 5. As well as identifying thematic areas in this research field, our keyword examination of all articles (N=1617) identified 50 keywords with at least 16 occurrences (Figure 8).

We investigated hot spot shifts from a temporal perspective, using the top 2 keywords with the strongest citation burst—*video games* (2017-2021) and *young adults* (2018-2021; Figure 9).

Table 5. Total link strength of the top 20 occurring keywords.

Rank	Keywords	Occurrences, n	Total link strength
1	*virtual reality*	543	1305
2	*rehabilitation*	318	924
3	*stroke*	242	671
4	*vocational rehabilitation*	85	115
5	*balance*	82	232
6	*cerebral palsy*	78	205
7	*gait*	54	160
8	*upper limb*	42	138
9	*upper extremity*	41	143
10	*video games*	41	138
11	*employment*	37	80
12	*technology*	37	75
13	*augmented reality*	37	69
14	*traumatic brain injury*	35	94
15	*exercise*	32	98
16	*postural balance*	31	96
17	*telerehabilitation*	29	84
18	*cognition*	29	82
19	*disability*	28	52
20	*motor learning*	27	96

Figure 8. The network map of keywords. This shows 50 keywords and is divided into 9 clusters.

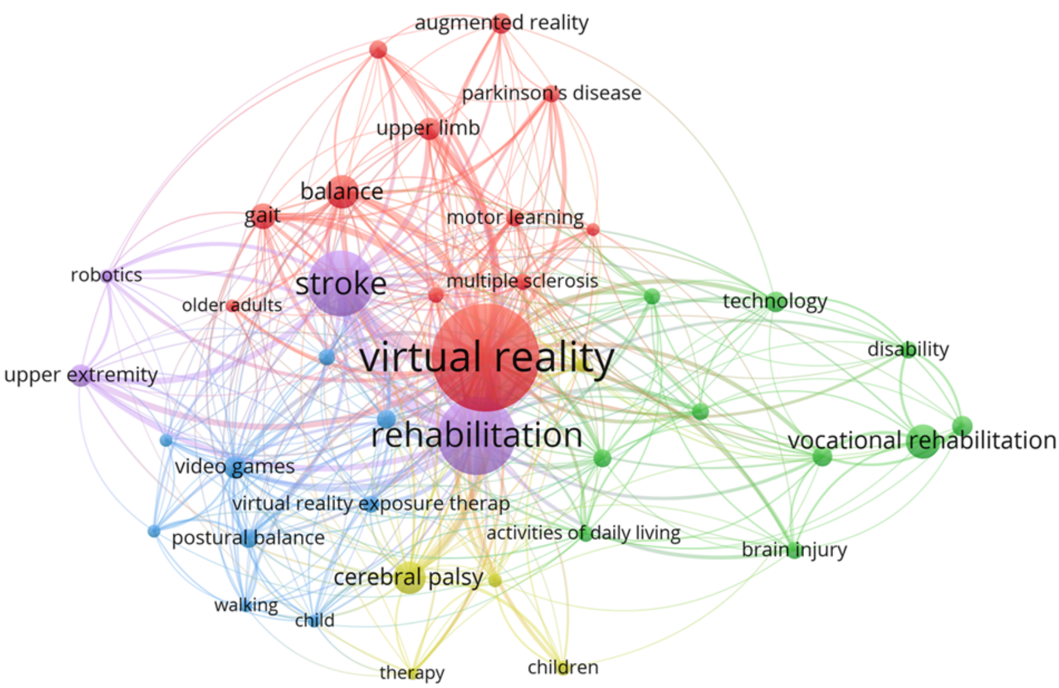


Figure 9. The top 25 keywords with the strongest citation bursts from publications on virtual reality rehabilitation.

Discussion

General Data

This study analyzed 1617 SCIE papers that were published between 2000 and 2021 and were related to the research of VR rehabilitation. The United States published the highest number of studies (663/1617, 41.01%), and Canada published the second highest number of studies (143/1617, 8.84%). Most of the core research institutions in this field are from the United States and Israel. The US Food and Drug Administration's encouragement of digital therapy innovation is the main reason that the largest number of publications is in North American countries, led by the United States. Israel encourages entrepreneurship in the high-tech industry; as such, 4 of the top 10 universities in this field are in Israel. The most widely read journal was *Journal of NeuroEngineering and Rehabilitation*. These findings showed that *Journal of NeuroEngineering and Rehabilitation* significantly contributed to research in this area. *Journal of NeuroEngineering and Rehabilitation* focuses on the publication of research results in the fields of neuroscience, biomedical engineering, and rehabilitation, which is very much in line with the publication of papers in this field and has attracted the attention of relevant researchers. We also examined the top 10 cited publications; the top article by Saposnik et al [14] appeared in *Stroke* and was cited 58 times.

The Knowledge Base and Current Research Characteristics

In previous studies, different VR-assisted rehabilitation systems were investigated in this field, with remarkable results. As indicated in Figure 7, after cocited reference clustering, key clustering nodes identified knowledge bases in this area, as follows: cluster 0 (*kinematics*), cluster 1 (*neurorehabilitation*), cluster 2 (*brain injury*), cluster 3 (*exergame*), cluster 4 (*aging*), cluster 5 (*motor rehabilitation*), cluster 6 (*mobility*), cluster 7 (*cerebral palsy*), and cluster 8 (*exercise intensity*). To this end, we described VR rehabilitation research knowledge bases by using different clusters, with time considerations.

For cluster 0, the *kinematics* cluster, scientists designed a VR rehabilitation system based on kinematics theory to measure, monitor, and predict outcomes; they achieved good results. For example, researchers developed various VR scenes for rehabilitation training for cervical vertebrae injuries; lower limb injuries of athletes; and arm, hand, and trunk movements in patients with stroke. They proposed kinematic evaluation and measurement methods based on the VR environment [24-26].

In cluster 1, the *neurorehabilitation* cluster, the research interest in VR technology for neurorehabilitation is increasing. Scientists have experimentally demonstrated the role of VR systems in neural rehabilitation and motor assistance from the perspectives of patients with impaired visuospatial perception after stroke, the augmented effect of intermittent theta burst stimulation on neurorehabilitation programs, and the use of motor imagination in brain-computer interfaces. Therefore, VR programs are considered safe and can be performed with standard neurorehabilitation protocols in patients with neurological conditions [27-29].

In cluster 2, the *brain injury* cluster, scientists demonstrated the experimental results of VR training systems for patients with brain injury, for those with acute onset central nervous system damage, and for vocational rehabilitation training from both the experimental perspective and the retrospective perspective. Importantly, most patients were responsive to VR training and showed improvements in gait function, balance control, vocational rehabilitation training, and other aspects [30-32].

In cluster 3, the *exergame* cluster, McMahon et al [33] investigated VR exergaming to augment physical activity in students (high school) with intellectual and developmental disabilities. Their findings indicated that when students used the VR exercise exergaming intervention, they increased the duration and intensity of their physical activity. Nambi et al [34], in their psychological and hormone analysis study, discovered that VR exergame training was effective for American soccer players with chronic low back pain when compared with conventional exercise training programs. In a multicenter controlled trial, Meyns et al [35] demonstrated that exergaming in children with spastic cerebral palsy improved balance after previous poor balance performances.

In cluster 4, the *aging* cluster, several investigations concentrated on upper limb rehabilitation intervention and overall skill improvement for older patients. Molina et al [36] analyzed the impacts of 13 VR sports games on physical function in older patients. Another group investigated the elbow and shoulder movements of older patients with chronic stroke, using the Predict Recovery Potential algorithm. The training improved motivation, but the benefits of physical function in aging were unknown [2,37].

In cluster 5, the *motor rehabilitation* cluster, scientists investigated various VR training devices. A team, for example, used VR-enhanced robot-assisted gait training to monitor the gait, motion, balance, fear of falling, and independence of 15 patients with chronic stroke. The researchers observed that cognitive performance and gait speed in tasks improved among study participants (P<.05) [38]. Maier at al [39], in their systematic investigation on randomized controlled trials, identified the benefits of specific VR systems for rehabilitating upper limb function and activity after stroke and reported that specific VR systems were highly beneficial for upper limb recovery when compared with conventional therapies.

In cluster 6, the *mobility* cluster, researchers designed remote VR and augmented reality rehabilitation training treadmills to record training data from patients with Parkinson disease or stroke. The experimental results showed that flexibility and balance improved and that VR rehabilitation methods could provide personalized rehabilitation strategies while also improving patient participation [40,41]. To identify the benefits of a VR-based interventional therapy, a previous scoping review reported that dynamic balance measures improved significantly following a therapeutic intervention; therefore, robust study designs that focus on intensity and dose responses from VR training could improve the efficacy of methods for treating mobility disorders [42].

In cluster 7, the *cerebral palsy* cluster, scientists studied gait, spatial perception exercises, functional mobility, exoskeletons, visuomotor construction, and other aspects of cerebral palsy in children by using data obtained through a VR rehabilitation training system. Bimanual performance and cognitive rehabilitation gains improved significantly during gait rehabilitation [43-45]. Furthermore, an augmented reality real-time feedback approach that incorporated infrared recognition technology was used to assess temporal and gait parameters during gait training in children with cerebral palsy. Importantly, cadence, velocity, functional ambulation, and bilateral step and stride length were augmented after the intervention [46].

For cluster 8, the *exercise intensity* cluster, scientists discovered that training factors (training intensity, prolonged activity, and rest were optimized) could potentially provide training optimization stimuli. de Vries et al [47] identified some elements of VR balance games that could potentially provide strength training stimulation. Baniña et al [48] investigated the relationship between upper limb motor recovery and exercise intensity in participants with subacute stroke. Importantly, they found that VR rehabilitation could be used to generate intensive exercise programs; however, clearer exercise progression guidelines should be published.

Scientific Frontiers and Future Research Trajectories

Keywords represent current research issues or topical concepts, while emerging trends and research frontiers are represented by burst keywords. We used the CiteSpace program to gather burst keywords and identified 2 scientific frontier areas with the strongest citation bursts—video games (2017-2021) and young adults (2018-2021).

Video Games

We found that VR video games are simple and appealing to patients and therefore encourage patient participation. Measurements and assessments that were taken after testing VR video games with 12 older patients and 13 children with intellectual disabilities showed clinical improvements in motor capabilities and a positive effect on quality of life [49,50]. Jung et al [51] investigated the impact of Xbox Kinect (Microsoft Corporation) training on lower extremity motor function in adolescents with spastic diplegia cerebral palsy. The outcome measurements, which were measured by using standard industry tools, showed that adolescents displayed significant improvements. A previous randomized controlled trial assessed the impact of a VR dance training program, which involved using an Xbox 360 Kinect game, on kyphosis angle and respiratory parameters in young women with postural hyperkyphosis and showed that dance games were an effective therapy [52]. Deutsch et al [53] asked 15 individuals with mild to moderate lower extremity deficits in the chronic poststroke phase to use the Kinect Light Race game and showed that video games provided comparable intensity, improved accuracy, greater enjoyment, and less exertion when compared with standard care activities. The application of VR-based video games in the field of rehabilitation is the current potential research direction.

Young Adults

VR rehabilitation training research has primarily focused on sport rehabilitation aspects, such as the spine, gait, or balance, with fewer studies on teenagers when compared to studies on adults. The burst keyword *young adult* appeared between 2018 and 2021, indicating that scholars have begun to pay attention to the positive physiological, social, and psychological impacts on teenagers. Fralish et al [54], in a case study of 6 VR sessions over a 3-week period, reported that specific VR programs were putatively physiologically and psychosocially helpful (mood improvement) for young adults with physical disabilities. Smith et al [55] proposed a VR job interview training system for participants with severe mental illness and transition-aged youth with autism spectrum disorders, which resulted in improved interview skills and employment access.

Conclusions

In this study, we used a bibliometric analysis to objectively, comprehensively, and systematically analyze the VR rehabilitation research literature. We identified the knowledge bases, current topical hot spots, and oncoming trends in this area. In this research field, the areas with acceptable knowledge bases included kinematics, neurorehabilitation, brain injury, exergaming, aging, motor rehabilitation, mobility, cerebral palsy, and exercise intensity. We theorize that future emerging trends and frontiers will focus on video games and young adults. We also identified contemporary research topics and future trends in VR rehabilitation research and provided guidance for future research in this exciting area.

Although papers that were published at different times were gathered for this study, some were not comprehensive in nature and may have introduced publication bias, thereby affecting study outcomes.

Limitations

Our study still has some limitations to be addressed. Although the WSCC database is reliable, other databases, such as non-English databases, should also be considered to ensure that all relevant papers are collected. Additionally, the rapid progress in the field of VR technology application limits the timeliness of this bibliometric study. Further, the VR-based rehabilitation activities we investigated included some gaming exercises, exergames, and video games that were not clearly defined. Finally, the results of the included studies only reflect current research trends in academia. In the future, VR technology is expected to be further integrated with clinical applications, which will enrich and improve the research in this subject field.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

SCIE: Science Citation Index Expanded
VR: virtual reality
WSCC: Web of Science Core Collection

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Original Paper

The Effects of Exergaming on Attention in Children With Attention Deficit/Hyperactivity Disorder: Randomized Controlled Trial

HongQing Ji[1,2], PhD; Shanshan Wu[1,2], PhD; Junyeon Won[3], PhD; Shiyang Weng[1], MSPE; Sujin Lee[2], MEd; Sangmin Seo[4], MD; Jung-Jun Park[2], PhD

[1]School of Physical Education & Health, Wenzhou University, Wenzhou, China

[2]Division of Sport Science, Pusan National University, Busan, Republic of Korea

[3]Institute for Exercise and Environmental Medicine, Texas Health Presbyterian Hospital, Dallas, TX, United States

[4]Busan Children's Mind Clinic, Busan, Republic of Korea

Corresponding Author:
Jung-Jun Park, PhD
Division of Sport Science
Pusan National University
63 beon-gil 2 Busandaehak-ro
Geumjeong-gu
Busan, 46241
Republic of Korea
Phone: 82 051 510 2713
Fax: 82 051 510 3746
Email: jjparkpnu@pusan.ac.kr

Abstract

Background: Despite growing evidence showing the effects of exercise and cognitive trainings on enhancing attention, little is known about the combined effects of exergame on attention in children with attention deficit/hyperactivity disorder (ADHD). Exergame, a form of exercise using a video game, has both cognitive stimulation and physical activity components and has been shown to improve cognitive function in children.

Objective: The purpose of this study was to investigate the effect of exergaming on attention and to compare the effect induced by exergaming with the effect of aerobic exercise on attention in children with ADHD.

Methods: In all, 30 children with ADHD, aged 8-12 years, were randomly divided into an exergaming group (EXG; n=16) or a bicycle exercise group (BEG; n=14). Before and after the 4-week intervention, the *Frankfurter Aufmerksamkeits-Inventar* (FAIR; Frankfurt Attention Inventory) test was administrated, and event-related potentials during the Go/No-go task was measured to assess attention.

Results: After intervention, both the EXG and BEG had significantly increased selective attention and continuous attention (all *P*<.001), as well as self-control on the FAIR test (EXG: *P*=.02 and BEG: *P*=.005). Similarly, both the EXG and BEG had significantly reduced response time on the Go/No-go test (all *P*<.001). For the Go response, the N2 amplitude (frontocentral maximal negativity) was significantly increased in Fz (midfrontal line) in the EXG (*P*=.003) but was not changed in the BEG (*P*=.97). Importantly, the N2 amplitude in Fz was significantly greater in the EXG compared to the BEG (Go: *P*=.001 and No-go: *P*=.008).

Conclusions: Exergaming has the comparable effects to bicycle exercise to enhance attention in children with ADHD, suggesting that exergaming can be used as an alternative treatment for children with ADHD.

Trial Registration: Clinical Research Information Service KCT0008239; https://tinyurl.com/57e4jtnb

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KEYWORDS

exergame; N2 amplitude; attention function; response time; attention deficit/hyperactivity disorder; ADHD

Introduction

Attention deficit/hyperactivity disorder (ADHD) is a neurodevelopmental disorder that is characterized by inattention, hyperactivity and impulsivity, or both [1]. Approximately 3% to 5% of the school-age population are living with ADHD [2,3]. Among symptoms of ADHD, hyperactivity tends to improve during adolescence, but carelessness and impulsiveness may persist into adulthood [4]. The impaired attention and executive function in children with ADHD lead to reduced inhibitory ability, working memory, and task shift due to an imbalance of neurotransmitters such as dopamine and norepinephrine [5-7]. The abnormal neuropsychological activities caused by these symptoms may disrupt the patients' learning ability, daily activities, professional activities, and social functions [8,9].

In children with ADHD (aged >8 years), dysfunctions in neuronal networks associated with attentional processes and cognitive control have been well documented using event-related potentials (ERPs) [10-13]. ERP studies used tasks (eg, Eriksen flanker and Go/No-go tasks) to assess both behavioral and neurophysiological perspectives of ADHD [14]. For example, behavioral performance (eg, response time [RT]) is commonly used to determine processing speed [15], and neurophysiological technology has been used to measure selective attention capacity and skills [16]. The No-go N2 components have been reported to be abnormally lower in children with ADHD than those in children with other neurodevelopmental disorders [17,18]. The N2 amplitude occurs for about 170-350 milliseconds and is related to attention and cognitive control, specifically an inhibitory control response [16,19,20]. Particularly, the amplitude of the N2 is an indication of the intensity of information processing required for the discrimination of stimuli, and the latent phase of the N2 reflects the time of the cognitive processing that distinguishes sensory stimuli [21].

Exercise has been known to enhance attention, executive function, impulsivity, and hyperactivity in children with ADHD by promoting the secretion of neurotransmitters (eg, dopamine and norepinephrine) in the brain, thereby inducing positive responses on the main symptoms of ADHD [22,23]. Although most of the evidence has focused on the acute effects of aerobic exercise on RT and P3 components of children with ADHD, N2 components have received comparatively little attention. Furthermore, there are mixed results in the study of exercise and N2 in normal young adults and preadolescent children [24-26]. For example, Ligeza et al [24] reported that acute moderate intensity exercise increased the conflict effect of N2 amplitude in young people, which suggested improvement in inhibition after a single session of moderate exercise compared to high-intensity interval exercise and seated rest condition. In another study, acute moderate-intensity exercise led to reduced N2 amplitude in preadolescent children and young adults, suggesting that acute exercise might have a general effect on the conflict detection process [25,26]. Therefore, further studies are needed to explore whether exercise can improve the N2 components of children with ADHD.

However, previous studies reported that cognitively engaging physical exercise leads to benefits for cognitive performance [27,28]. For example, a combination of physical activity and cognitive stimulation improved reaction times in inhibition and switching neural efficiency [27,28]. Exergaming is a video game that requires body movement and provides active gaming experience as a form of physical activity [29]. Due to motivational issues and a low level of positive reinforcement, traditional (cognitive) training programs are often uninteresting and fatiguing for children with ADHD [30]. Exergaming helps combine physical and cognitive training through an intriguing game. Recently, exergaming has attracted great attention because of their growing popularity among children, adolescents, and older adults [31-35] due to its effectiveness in motivating participants to engage in intervention [36].

Recent studies revealed that exergaming improves the executive function in healthy adolescents by increasing cognitive stimulation [31]. Exergaming has also been reported to enhance executive function in children with ADHD compared to the control group [37,38]. However, it is currently in question whether these effects are caused by games or exercise. Moreover, there is, to date, only one study that has measured the effects of exergaming on N2 amplitude. This study showed that exergaming led to greater aerobic capacity and larger N2 amplitude, an indication of improved selective attention in patients with metabolic syndrome [39]. Despite the evidence regarding the effects of exergaming on cognitive function, how the neural processing of N2 components is altered in children with ADHD after an exergaming intervention remains unclear. Moreover, it remains inconclusive if exergaming improves attention in children with ADHD and whether exergaming has additional benefits compared to traditional form of aerobic exercise. Therefore, the purpose of this study was to investigate the effect of exergaming on attention and to compare the effect induced by exergaming with the effect of aerobic exercise on attention in children with ADHD. Our first hypothesis was that exergaming will result in improved Go/No-go task performance and increased N2 amplitude in children with ADHD. Second, we hypothesized that the improvement in Go/No-go task performance and N2 amplitude will be greater in exergaming compared to bicycle exercise.

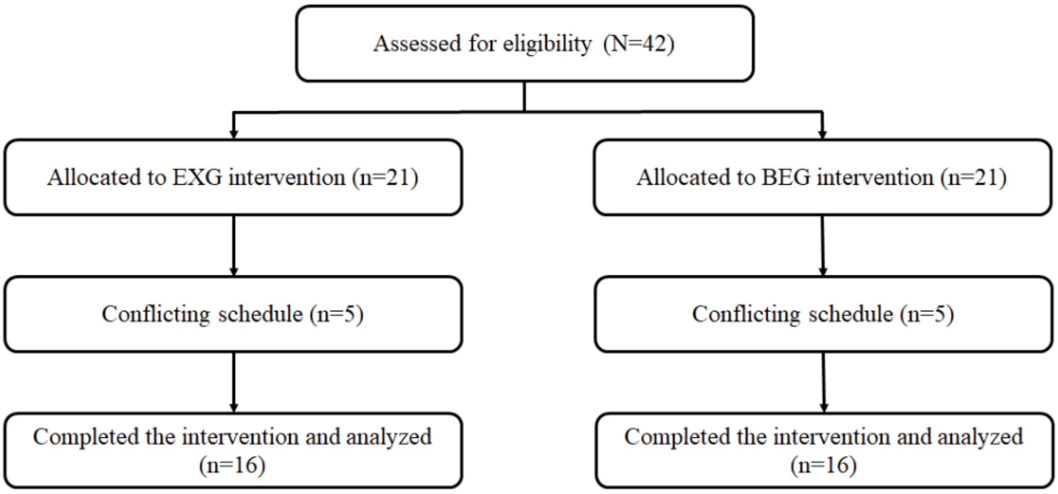
Methods

Study Design and Participants

We used a randomized controlled trial in which participants were randomly assigned to either the exergaming group (EXG) or the bicycle exercise group (BEG). Children with mild to moderate ADHD were recruited from the Children's Mental Health Medical Center in Busan, Republic of Korea. Participants who met the following criteria were included in the study: a Korean Attention-Deficit/Hyperactivity Disorder Diagnostic Scale score between 70-110, indicating a lack of attention; the absence of diseases other than ADHD; right-hand dominance; normal or corrected-to-normal vision; and the absence of physical impairment to perform exercise.

In all, 42 children (aged 8-12 years) with mild to moderate ADHD were recruited and then randomly assigned to either the EXG (n=21) or BEG (n=21). A total of 12 participants (5 for the EXG and 7 for the BEG) were withdrawn from the study, resulting in the final number of 30 participants in this study (16 in the EXG and 14 in the BEG; Figure 1). All participants maintained the same medication and dose during the exercise intervention.

Figure 1. Flowchart of participant eligibility, withdrawals, and the final sample included in the final analysis. BEG: bicycle exercise group; EXG: exergaming group.



Ethics Approval

Written informed consent was obtained from both the children and their parents or legal guardians. This study was approved by the Pusan National University Institutional Review Board in accordance with the Helsinki Declaration (PNU IRB/2018_30_HR).

Sample Size

The sample size was calculated using a sample size calculation software program (G*Power, version 3.1.9.2 for Windows), with an effect size of 0.58, statistical power of .80, and statistical level of significance of .05. The effect size was calculated from previous studies [40]. As a result, the sample size for each group was established at 15 patients, so we decided to recruit 42 patients for each group in consideration of a potential 30% dropout rate.

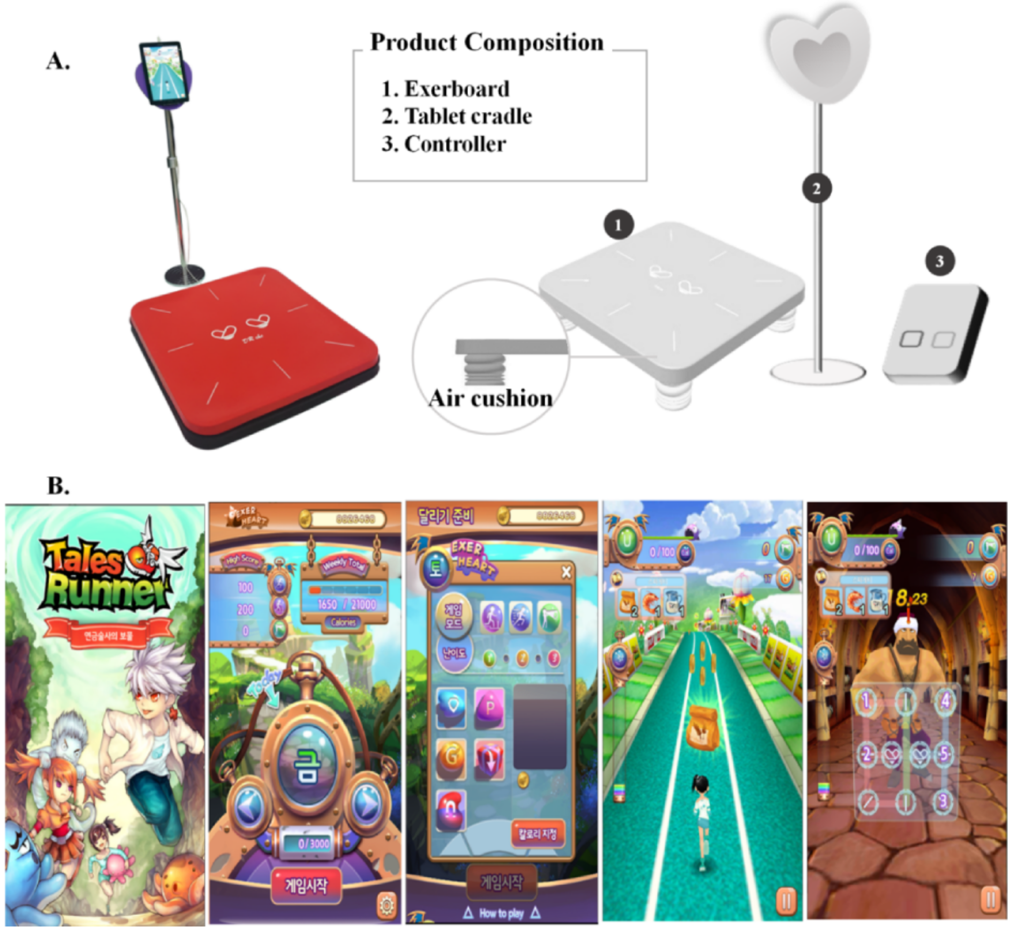
Exergaming and Bicycle Exercise Intervention

The EXG was administered using ExerHeart devices (D&J Humancare), which consisted of a running or jumping board (730-cm width × 730-cm depth × 130-cm height) and a screen connected to the board (Figure 2A). The exercise program called *Alchemist's Treasure* (D&J Humancare) was used for the EXG. In this game, participants run or jump in place with their avatars, using the front, back, left, and right sensors on the mat to avoid obstacles and acquire items (Figure 2B; Multimedia Appendix 1). The BEG performed stationary bike exercise using commercial Fit Elite-Whole body exerciser 1000, with resistance of 0.5~3 kiloponds.

Exercise session for both the EXG and BEG consisted of 3 days/week, 50 min/day, and 60% to 80% of heart rate (HR) reserve for 4 weeks. We monitored individual exercise intensity using an HR monitor (Polar RS400sd). Exercise intensity was determined by using the Karvonen target HR method: $[exercise\ intensity \times (HR_{max} - resting\ HR)] + resting\ HR$ [41]. Each exercise session consisted of 10 minutes of warm-up, 30 minutes of main exercise, and 10 minutes of cooldown. Exercise interventions were conducted at 2 separate child mental health care facilities so that the groups were not aware of the exercise program they were performing. Participants who did not complete more than 80% of the exercise sessions were excluded from the final analysis.

For both the EXG and BEG, all subjects' HRs during exercise were monitored using HR monitors (Polar RS400sd) to confirm that the values were within the target HR range.

Figure 2. (A) ExerHeart devices consisted of the Exerboard, a tablet cradle, and a controller. (B) Features of the video game Alchemist's Treasure.



Go/No-go Task

The Go/No-go task was used to measure the capacity to sustain attention and response control. We used the computerized Go/No-go task using a built-in software of the electroencephalography (EEG) analyzer (Telescan; LAXTHA). During the Go/No-go task, each participant was instructed to press a button for a frequent stimulus (ie, Go stimulus, 60% probability) or to withhold a response for an infrequent stimulus (ie, No-go stimulus, 40% probability). The stimulus was presented in the center of a 15-inch screen with a white background, and the size was 3 × 3 cm. In each trial, a signal consisting of an interstimulus interval was first presented for 1000 milliseconds to attract the participant's attention. This signal was followed by either the Go stimulus (ie, lion image), No-go stimulus (ie, tiger image), or Control stimulus (ie, leopard image) for 1500 milliseconds. Participants were instructed to press the left arrow keyboard for the Go stimulus and the right arrow keyboard for the No-go stimulus and not to respond to the Control stimulus. Participants underwent a familiarization session before starting the test. The number of practice trials was standardized (1 trial each) so that participants performed the same number of practice trials before each condition. The response time (milliseconds) and the accuracy rate (% correct) were recorded simultaneously from the start of the reaction. The entire task (including practice trials) lasted for 10 minutes.

EEG Measurements

EEG was measured from 31 Ag/Ag–CL electrodes, placed according to an augmented 10–20 International System. All EEG recordings were referenced to the average of the right and left mastoid, and the ground electrode was placed on the Fz electrode site. The electrooculogram activity was recorded from electrodes attached below and above the left eye and electrodes located at the outer canthi of both eyes. All electrodes were maintained at impedances <10 kΩ before data recording. After the completion of data collection, EEG signals were analyzed using software (Telescan; LAXTHA); the bandpass filter of the amplifier was 0.5-20 Hz, the sampling rate was 1000 Hz, and a notch filter was at 60 Hz.

The stimulus-locked epochs acquired for the Go/No-go test were extracted offline from 200 milliseconds before to 1500 milliseconds after the stimulus onset, and the period from –100 to 0 milliseconds before stimuli onset was used as the baseline. Peak amplitudes and latencies were measured automatically. The N2 peak amplitudes and latencies were measured in the difference waves of the attended condition. The N2 component was defined as the largest positive peak occurring between 170-320 milliseconds after stimuli. EEG data were collected before and after 8 weeks of the exercise intervention [42,43].

Frankfurter Aufmerksamkeits-Inventar

The *Frankfurter Aufmerksamkeits-Inventar* (FAIR; Frankfurt Attention Inventory) is a psychological test to assess attention and concentration [44]. The FAIR tests the ability to quickly distinguish correct signal among many other similar signals and to hide insignificant information (ie, external interference). Two different versions of the FAIR test were used for test reliability. A total of 640 test items were divided into tests 1 and 2. Each FAIR test paper was arranged in the shape of 20 horizontal and 16 vertical lines on a single sheet of paper, and there were a total of 320 test items. Participants were instructed to find 2 correct shapes, such as a "three-point circle" and "two-point square" among the 4 shapes and draw a line from left to right with a pencil on the test paper to mark them. The scoring was administered using the perspective of 3 attentional actions, and details are shown in Table 1. The ability index P is an index of the number of items related to attention during the test. The control index Q represents the proportional value of correct judgment as a result of attention among all responses. The persistence index C indicates how consistently the attention task was maintained.

Table 1. *Frankfurter Aufmerksamkeits-Inventar* inspection dimensions.

Test item	Related ability	Scoring method	Reliability
P[a]	Selective attention	$(T^b - EL^c) - 2(EO^d + EC^e)$	.944
Q[f]	Self-control	$P \div T$	.903
C[g]	Sustained attention	$P \times Q$	.941

[a]P: performance value.
[b]T: total number of items worked.
[c]EL: total number of line drawing errors.
[d]EO: total number of teeth not marked on a target item.
[e]EC: total number of teeth marked that are not a target item.
[f]Q: quality value.
[g]C: continuity value.

Statistical Analysis

The normality of Go/No-Go test performance was also tested using the Shapiro-Wilk test. Repeated measures ANOVA were used to compute the main effects of time (ie, before vs after intervention), group (ie, EXG vs BEG), and group × time interaction on the behavioral performance (ie, accuracy rate and reaction time), ERP (ie, N2 amplitude), and FAIR (ie, ability index P, control index Q, and persistence index C). If an interaction was identified, paired sample *t* test (2-tailed) was used to verify the direction of the interaction. Significance level was set at .05 for all analyses, effect sizes were assessed using partial eta squared (η^2_p), and all statistical analyses were performed using SPSS (version 24; IBM Corp).

Results

Participants

Of the 42 children who participated in this study, 5 in the EXG dropped out of the study due to conflicting schedule and 7 in the BEG dropped out of the study due to lost interest. Demographic and physical characteristics for all subjects are provided in Table 2.

Table 2. Summary of the participant demographic information.

	EXG[a] (n=16)	BEG[b] (n=14)
Age (years), mean (SD)	9.00 (1.46)	8.85 (1.63)
Male sex, n (%)	14 (88)	12 (86)
Height (cm), mean (SD)	129.38 (9.68)	134.69 (7.76)
Weight (kg), mean (SD)	31.66 (11.84)	35.31 (6.84)
BMI (kg/m^2), mean (SD)	18.5 (5.4)	19.3 (2.7)
K-ADHDDS[c] (index), mean (SD)	96.14 (19.16)	87.50 (13.17)

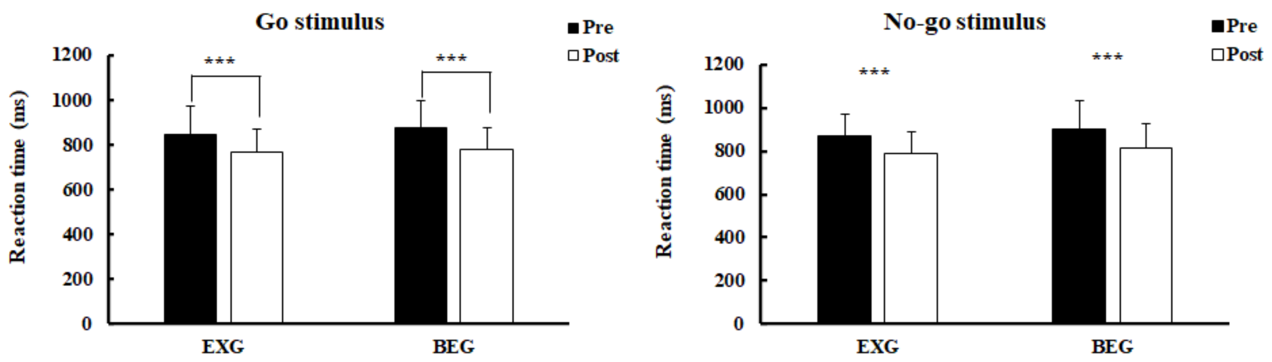
[a]EXG: exergaming group.
[b]BEG: bicycle exercise group.
[c]K-ADHDDS: Korean Attention-Deficit/Hyperactivity Disorder Diagnostic Scale.

Behavioral Indices

There was no significant group × time interaction on the changes in RT in response to Go and No-go stimulations before and after exercise intervention (*P*=.65 and *P*=.807, respectively). However, both groups significantly reduced RT for Go and No-go stimulations after exercise intervention (Figure 3). For Go stimulation, RT was significantly reduced in the EXG from 846.13 (SD 126.43) milliseconds to 764.56 (SD 107.05) milliseconds (P=.001; η^2_p=0.969) and in the BEG from 873.79 (SD 123.31) milliseconds to 780.79 (SD 96.41) milliseconds

(P=.001; η^2_p=1.267; Figure 3A). For No-go stimulation, RT was significantly reduced in the EXG from 872.25 (SD 96.53) milliseconds to 786.75 (SD 100.02) milliseconds (P=.001; η^2_p=1,211) and in the BEG from 903.71 (SD 130.78) milliseconds to 813.77 (SD 111.86) milliseconds (P=.001; η^2_p=1.114; Figure 3B).

Figure 3. Reaction time during Go/No-go task in the EXG and BEG before and after exercise intervention (A) Go stimulus, (B) No-go stimulus. BEG: bicycle exercise group; EXG: exergaming group. ***P<.001.



N2 Amplitude

There was a significant group × time interaction on the Go and No-go N2 amplitudes in the Fz region before and after exercise intervention (P=.049 and P=.047, respectively; Table 3). The EXG had significantly increased Go N2 amplitude in Fz after intervention (P=.003), whereas the BEG showed no significant changes (P=.97). Neither group showed changes in No-go stimulus after intervention. In the between-group comparison, the EXG consistently demonstrated greater N2 amplitudes on both Go and No-go stimulations. The waveforms of Go and No-go N2 amplitudes in Fz for the EXG and BEG before and after exercise are shown in Figure 4.

Table 3. Results of changes in Go/No-go N2 amplitude in Fz.

Effects and group	Preintervention	Postintervention	*t* test		*P* value			
			P value	η^2_p	G[a]	T[b]	G×T[c]	η^2_p
Go stimulus					.02	.054	.049	.08
EXG[d], mean (SD)	–3.92 (3.78)	–6.82 (4.49)	.003	1.791				
BEG[e], mean (SD)	–2.33 (2.15)	–2.30 (4.05)	.97	0.020				
***t* test**								
P value	.18	.008						
η^2_p	0.503	1.045						
No-go stimulus					.008	.68	.047	.08
EXG, mean (SD)	–4.64 (3.65)	–6.70 (3.85)	.09	0.911				
BEG, mean (SD)	–3.55 (3.91)	–2.18 (2.36)	.27	0.615				
***t* test**								
P value	.44	.001						
η^2_p	0.289	1.345						

[a]G: group effect.

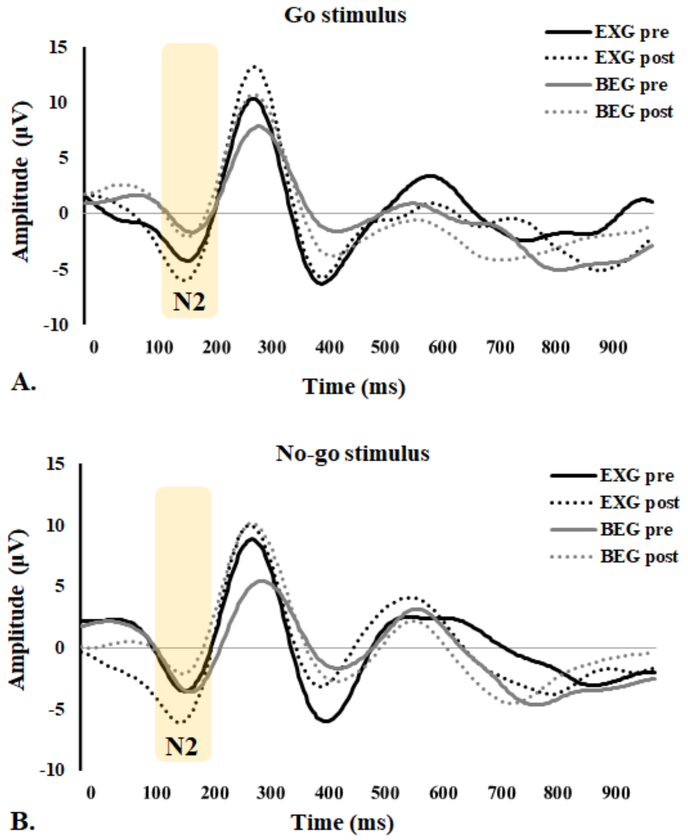
[b]T: time effect.

[c]G×T: interaction effect between group and time.

[d]EXG: exergaming group.

[e]BEG: bicycle exercise group.

Figure 4. Average event-related potential waveforms of Fz for mean N2 amplitudes during the Go/No-go test: (A) Go stimulus and (B) No-go stimulus in the exergame group (EXG) and bicycle exercise group (BEG) before and after the exercise intervention.



Aufmerksamkeits-Inventar Data

There was no significant group × time interaction on the ability index P (selective attention) before and after exercise intervention (*P*=.79). However, both groups significantly increased ability index P after exercise intervention (both *P*<.001). Similarly, although there was no significant interaction between the EXG and BEG on the on the changes in ability index Q (self-control; *P*=.68), both the EXG and BEG significantly increased control index Q following intervention (EXG: *P*=.02 and BEG: *P*=.005). Lastly, there was also no significant interaction between the EXG and BEG on the on the changes in ability index C (persistent attention; *P*=.66), but both groups significantly increased index C in response to exercise intervention (both *P*<.001; Table 4).

Table 4. Results of changes in *Frankfurter Aufmerksamkeits-Inventar* (FAIR).

Effects and group	Preintervention	Postintervention	*t* test		*P* value			
			P value	η^2_p	G[a]	T[b]	G×T[c]	η^2_p
Performance value (P; score)					.19	.001	.79	.10
EXG[d], mean (SD)	190.44 (47.85)	269.06 (92.13)	.001	2.070				
BEG[e], mean (SD)	231.15 (71.44)	303.92 (101.78)	.001	2.308				
***t* test**								
P value	.08	.34						
η^2_p	0.670	0.354						
Quality value (Q; ratio)					.19	.001	.68	<.001
EXG, mean (SD)	0.90 (0.08)	0.95 (0.005)	.02	1.339				
BEG, mean (SD)	0.92 (0.06)	0.97 (0.02)	.005	1.833				
***t* test**								
P value	.31	.23						
η^2_p	0.381	0.451						
Continuity value (C; score)					.20	.001	.66	.17
EXG, mean (SD)	171.33 (48.30)	262.44 (98.58)	.001	2.070				
BEG, mean (SD)	214.66 (76.67)	294.70 (10(3.07)	.001	2.308				
***t* test**								
P value	.07	.40						
η^2_p	0.679	0.314						

[a]G: group effect.

[b]T: time effect.

[c]G×T: interaction effect between group and time.

[d]EXG: exergaming group.

[e]BEG: bicycle exercise group.

Discussion

Principal Findings

The purpose of this study was to examine the effects of exergaming on attention in children with ADHD and whether these effects were driven by games or exercise by comparing the effects of exergaming and bicycle exercise. Through an examination of the behavioral performance and ERP during the Go/No-go task and FAIR test, our results may suggest that both exergaming and bicycle exercise elicited shorter RT during the Go/No-go task and improved selective attention, self-control, and persistent attention. Notably, larger N2 amplitudes were observed following exergaming compared to the bicycle exercise.

Our results are in agreement with prior findings that showed improved processing speed in children with ADHD after exercise. For example, acute aerobic exercise engendered significantly faster processing speed during the Stroop and flanker tasks compared to the control group [45]. In another study, an 8-week yoga program enhanced attention and processing speed in children with ADHD [46]. Research shows that exercise facilitates the upregulation of cerebral blood flow (CBF) [47] and that an exercise-induced increase in CBF promotes information processing speed [48]. Further, a possible neurophysiological mechanism underpinning the beneficial effects of exercise training on attention in children with ADHD was the exercise-induced secretion of catecholamine [49]. Therefore, in this study, it may be that both exergaming and bicycle exercise stimulate CBF increase and catecholamine secretion, thereby promoting the allocation of attention resources and improvement of processing speed in children with ADHD. However, since this study did not measure CBF and catecholamines levels, this interpretation should be viewed with caution, and the potential neurophysiological mechanism underpinning exergaming and attention should be further investigated in the future.

Novel to this investigation is that there was an interaction effect of exercise modes on changes in the N2 amplitude during the Go/No-go task after intervention, such that the improvements in the N2 amplitude were only manifested in exergaming while the intervention effects were not observed in the bicycle exercise. The N2 components provide important information through the amplitude and latent phase because it is an indication of attentional assignment of the anterior cingulate cortex (ACC) when performing cognitive tasks [50,51]. Baker and Holroyd [52] suggested that task demands involving high conflict and working memory loads should strongly activate the ACC, giving rise to increased N2 amplitudes. No-go stimulation activates the prefrontal cortex and can affect cognitive regulation and inhibition processes [53]. Previous studies have reported that the N2 amplitude reflects the neural changes associated with the task [54] and that the N2 amplitude increases with greater attention [51]. Drollette et al [25] reported that the N2 amplitude decreased after running on the treadmill for 20 minutes, but another study showed that the N2 amplitude remained unchanged after an acute exercise [55]. Additionally, Stroth et al [56] pointed out that greater physical fitness is associated with better task preparation as well as decreased amplitudes in N2 amplitude, indexing more efficient executive control processes. In our previous study, both exergaming and treadmill exercise improved selective attention (N2) in patients with metabolic syndrome [39]. The results indicated that exergaming facilitated visual perceptual stimulation in the virtual environment to enhance the selective attention activity within with the cerebral cortex, brain regions associated with executive function, which was not changed by normal aerobic exercise.

In light of our N2 amplitude findings, exergaming is likely to better regulate the activity of ACC in the ventral prefrontal cortex than traditional form of aerobic exercise and effectively increase attention. It is hypothesized that ACC activation may have been reduced due to less-engaging exercise environment, which engendered no beneficial effect on attention after bicycle exercise. This may also be associated with the fact that all participants who dropped out from the BEG (n=7) were due to lost interest, whereas all participants who dropped out from the EXG (n=5) were due to conflicting schedule. This obvious discrepancy between the groups in the dropout reasons occurred even though the interventions were administered in 2 separate child mental health care facilities, which was intended to avoid environmental factors that could influence the participants' motivation. Thus, the ACC is likely to be more actively stimulated during complex exercise that involves multiple aspects of environment (eg, exergaming) than monotonous exercise environment (eg, cycling). Performing exergaming requires a process of directional judgment (eg, front or back and left or right); thus, attention and cognitive control ability needs to be executed to successfully perform the task. However, further translational evidence is needed to clarify this hypothesis.

Interestingly, aerobic exercise has a faster judgment of response times when it comes to information processing, but cash realization during neuroelectrical activity has a different effect. It may be that in the applied exergaming, the inhibition and switching components are needed to a greater extent than updating for successful task performance [37]. The Alchemist's Treasure training program primarily includes strength training; coordination (and endurance); sensitivity training; as well as demands on cognitive functions such as inhibition, switching, updating, attention, and rapid action execution. Prior research has demonstrated that cognitively demanding physical activities (exergaming), such as coordination exercises, preferentially activate brain regions used to control higher-order cognitive processes, leading to improved performance [31,37]. In conclusion, exergaming has the characteristics of aerobic exercise, so it has the ability to judge reaction time quickly. Meanwhile, the brain area is stimulated by the corresponding stimulation more favorable to neuroelectrical activity than general aerobic exercise.

For the FAIR results, we found improved selective attention, self-control, and persistent attention following exergaming and bicycle exercise. The results of Medina et al [57] showed that physical activity increases the release of serotonin, dopamine, and norepinephrine, and it is assumed that the attention of the participants with ADHD is improved because of the release of these neurotransmitters. According to a previous investigation, tai chi training was conducted to investigate the attentional in children and adolescents with ADHD [58]. The results showed that continuous tai chi performance at a stable speed significantly enhanced the ability of selective attention and continuous attention. Studies in adolescents with ADHD have shown that exercise-based game intervention confers maximal benefits for selective attention, self-control, and persistent attention [59,60].

We surmise that 3 components of executive function (ie, selective attention, self-control, and persistent attention) have been facilitated during exergaming performance. First, selective attention is the process of stimulating specific consciousness. During exergaming, participants had to quickly avoid the obstacles that appear on the screen; thus, participants had to maintain their selective attention throughout the game. The second component is cognitive control, which is necessary to complete tasks within a certain period of time and is expected to be facilitated while pressing the displayed number on the screen quickly and accurately during exergaming. Lastly, sustained attention is the duration of concentration related to the duration of correct concentration. In this study, exergaming characters were controlled by the user's movement. To control the game character's movement accurately and quickly, participants had to maintain their attention throughout the game. Therefore, because exergaming contains general aerobic exercise elements as well as additional components to stimulate selective attention, self-control, and continuous attention, it may have had significant impacts on the attention and attention of children with ADHD.

Limitations

Our study is not without limitations. First, this study is subject to the limitation of lacking a nonexercise (or active) control group, warranting some caution in interpreting the results until they can be replicated in a larger randomized controlled trial. Second, this study is also limited by a relatively small sample size (n=30) and homogeneous characteristics of participants (ie, all Asian and 26/30, 87% male), so the results may not be generalizable to the entire population of children with ADHD. Third, only one type of game device was used in this study; thus, future studies also need to examine the effects of multiple exergaming devices and games on ADHD attention. Fourth, the relationship between game scores and attention was not considered in this study, which should be examined in future studies.

Conclusions

Our results showed that both exergaming and bicycle exercise training enhanced attention in children with ADHD, but the benefits induced by exergaming may be somewhat greater than those from bicycle exercise. These findings suggest that, through complex and stimulating environment during the training, exergaming may stimulate the frontal lobes of the brain and has a significant impact on attention, processing speed, and cognitive control function, thereby improving attention in children with ADHD symptoms. Therefore, this study may hold an important public health implication that exergaming could be used as a new exercise therapy for children with ADHD in the future.

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Conflicts of Interest

None declared.

Editorial Notice

This randomized study was only retrospectively registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
Participants played the video game with ExerHeart.
[MP4 File (MP4 Video), 2747 KB - games_v11i1e40438_app1.mp4]

Multimedia Appendix 2
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1352 KB - games_v11i1e40438_app2.pdf]

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Abbreviations

ACC: anterior cingulate cortex
ADHD: attention deficit/hyperactivity disorder
BEG: bicycle exercise group
CBF: cerebral blood flow
EEG: electroencephalography
ERP: event-related potential
EXG: exergaming group
FAIR: Frankfurter Aufmerksamkeits-Inventar (Frankfurt Attention Inventory)
HR: heart rate
RT: response time

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Original Paper

The Change in Exergaming From Before to During the COVID-19 Pandemic Among Young Adults: Longitudinal Study

Erin K O'Loughlin[1,2], PhD; Catherine M Sabiston[2], PhD; Roxy H O'Rourke[2], MSc; Mathieu Bélanger[3,4], PhD; Marie-Pierre Sylvestre[1,5], PhD; Jennifer L O'Loughlin[1,5], PhD

[1]Department of Social and Preventive Medicine, Centre de recherche du centre hospitalier de l'Université de Montréal, Montreal, QC, Canada
[2]Faculty of Kinesiology and Physical Education, University of Toronto, Toronto, ON, Canada
[3]Department of Family and Emergency Medicine, Université de Sherbrooke, Moncton, NB, Canada
[4]Department of Family and Emergency Medicine, Centre de formation médicale du Nouveau-Brunswick, Moncton, NB, Canada
[5]School of Public Health, Université de Montréal, Montreal, QC, Canada

Corresponding Author:
Erin K O'Loughlin, PhD
Department of Social and Preventive Medicine
Centre de recherche du centre hospitalier de l'Université de Montréal
900 Saint Denis St
Montreal, QC, H2X 0A9
Canada
Phone: 1 514 890 8000 ext 31473
Email: erin_oloughlin@hotmail.com

Abstract

Background: Exergaming may be an important option to support an active lifestyle, especially during pandemics.

Objective: Our objectives were (1) to explore whether change in exergaming status (stopped, started or sustained exergaming, or never exergamed) from before to during the COVID-19 pandemic was related to changes in walking, moderate-to-vigorous physical activity (MVPA) or meeting MVPA guidelines and (2) to describe changes among past-year exergamers in minutes per week exergaming from before to during the pandemic.

Methods: A total of 681 participants (mean age 33.6; SD 0.5 years; n=280, 41% male) from the 22-year Nicotine Dependence in Teens (NDIT) study provided data on walking, MVPA, and exergaming before (2017 to 2020) and during (2021) the COVID-19 pandemic. Physical activity (PA) change scores were described by change in exergaming status.

Results: We found that 62.4% (n=425) of the 681 participants never exergamed, 8.2% (n=56) started exergaming during the pandemic, 19.7% (n=134) stopped exergaming, and 9.7% (n=66) sustained exergaming. Declines were observed in all 3 PA indicators in all 4 exergaming groups. The more salient findings were that (1) participants who started exergaming during COVID-19 reported the highest MVPA levels before and during the pandemic and declined the least (mean –35 minutes/week), (2) sustained exergamers reported the lowest MVPA levels during the pandemic (median 66 minutes/week) and declined the most in MVPA (mean change of –92 minutes/week) and in meeting MVPA guidelines (–23.6%). During the pandemic, starting exergamers reported 85 minutes of exergaming per week and sustained exergamers increased exergaming by a median 60 minutes per week.

Conclusions: Although starting and sustaining exergaming did not appear to help exergamers maintain prepandemic PA levels, exergaming can contribute a substantial proportion of total PA in young adults and may still represent a useful option to promote PA during pandemics.

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KEYWORDS

exergaming; active video games; longitudinal study; COVID-19 pandemic; physical activity; serious game; youth; young adult; health promotion; digital health intervention; exergame

Introduction

Many studies conducted early on during the COVID-19 pandemic suggest widespread decreases in physical activity (PA) related to public health lockdowns and restrictions [1-5]. Specifically, working from home was associated with declines in active transport, and the closure of gyms and recreational centers limited access to and opportunities for PA [1-5]. Conversely, some pandemic-related changes may have facilitated PA [6]. With less time needed for commuting to and from work, leisure time may have increased for some, thus affording more time to engage in PA [6].

A review on PA during COVID-19 suggested that "positive technology" (defined as a "scientific and applied approach to the use of technology for improving the quality of our personal experience") [7,8] represented a popular option to support or maintain an active lifestyle during the pandemic [9,10]. Use of technology has been suggested by the World Health Organization (WHO) as one alternative to stay physically active during confinements [11], and many appear to have turned to positive technology during the COVID-19 outbreak to maintain or increase PA [7,9].

Exergaming (or active video gaming), one form of positive technology that engages users in PA, can be played using gaming consoles, mobile devices, virtual reality, personal computers, and specific types of exercise equipment (eg, stationary bikes and treadmills with interactive screens) [7,10,12]. It offers a PA option that is both enjoyable and motivating because of self-monitoring options, gamification, and user interface technology [7,13]. Pokémon Go, for example, is a notably popular exergame that increased PA in both men and women of all ages and weights, even reaching low-activity populations [12]. Exergaming offers personalized, convenient activity options, as well as the possibility of playing with other users online, which, in addition to decreasing sedentary time, may decrease feelings of social isolation during pandemic-related restrictions [13-15]. Exergaming can help people cope with mental health issues such as anxiety [9,16,17], and it can support those with chronic disease, such as Parkinson diseases [17,18], poststroke sequelae [19], arthritis [20], and brain injuries [21], in maintaining PA levels in home-based rehabilitation situations during pandemics.

Before the COVID-19 pandemic, the prevalence of weekly exergaming among adolescents and young adults ranged from 18% to 43% in Canada [22-25]. However, it is not clear whether the prevalence changed during the COVID-19 pandemic. Further, no longitudinal studies have assessed whether exergaming was associated with changes in PA levels during the pandemic. Because future pandemics are possible, understanding exergaming behavior during the COVID-19 pandemic could shed light on potential benefits and challenges of using technology to encourage PA during lockdowns. Further, stressful times can encourage positive behavior change (eg, taking up exergaming) that may endure postpandemic [13,17,26]. Therefore, building the evidence base in this realm could inform public health decisions related to promoting PA during a pandemic.

The objectives of this study were to (1) explore whether a change in exergaming status (stopped, started or sustained exergaming, or never exergamed) from before to during the COVID-19 pandemic related to changes in walking, minutes of moderate-to-vigorous physical activity (MVPA), and meeting MVPA guidelines. We were particularly interested in ascertaining whether starting to exergame or sustaining exergaming were associated with maintaining pre–COVID-19 PA levels of walking, MVPA, or meeting MVPA guidelines. We also aimed to (2) describe changes in minutes of exergaming per week among past-year exergamers from before to during the COVID-19 pandemic.

Methods

Study Sample

Data were drawn from the Nicotine Dependence in Teens (NDIT) study [27], an ongoing 23-year longitudinal study that aims to describe the natural course of nicotine dependence in youth, but also collects data on a wide range of sociodemographic, substance use, psychosocial, lifestyle, and health-related variables. A detailed description of the NDIT study methods has been published previously [27]. Relevant to this study, data for 799 participants were collected in cycle 23 between January 2017 to March 2020 (n=551, 69% of participants completed the questionnaire in 2017; n=152, 19% in 2018; n=88, 11% in 2019; and n=8, 0.8% in 2020). Data were available for 722 participants in cycle 24, which was conducted online during the COVID-19 pandemic, from December 2020 to February 2021. Participants could use their mobile phone, tablet, or personal computer to complete the questionnaire. A total of 681 participants in cycle 23 (85%) also provided data in cycle 24 and were retained for this analysis. Participants received a CAD $50 (US $36.97) gift card or e-transfer in each cycle to cover any costs associated with their participation.

Ethical Approval

The study procedures were approved by the Montreal Department of Public Health Ethics Review Committee (2007–2384), the McGill University Faculty of Medicine Institutional Review Board (2017–6895), and the Ethics Research Committee of the Centre de Recherche du Centre Hospitalier de l'Université de Montréal (2021-9385, 20.278-YP). Parental consent was obtained at NDIT inception. Participants could legally provide consent in the post–high school data collections because they had all attained the age of 18 years.

Study Variables

PA Variables

Data on number of minutes per week walking, moderate physical activity, and vigorous physical activity were collected using the short form of the International Physical Activity Questionnaire (IPAQ-SF) [28,29]. The IPAQ-SF is used in cross-national monitoring of PA and demonstrates low to moderate reliability and validity against device-based PA measures [30]. Participants reported the number of days on which they had engaged in each type of PA over the past week and the average number of minutes per bout. The recommended truncation protocol [29] was used to exclude unrealistic values and reduce improbable

PA scores. Number of minutes walking per week was calculated as the number of days walking per week multiplied by the number of minutes per bout. Number of moderate PA minutes per week was computed as the number of days of moderate PA per week multiplied by the number of minutes per bout, and the number of vigorous PA minutes per week was computed as the number of days of vigorous PA per week multiplied by the number of minutes per bout.

Calculation of MVPA

Number of MVPA minutes per week was calculated by adding the number of moderate PA minutes per week and number of vigorous PA minutes per week.

Meeting MVPA Guidelines

Participants were categorized as meeting MVPA guidelines (yes or no) if they had engaged in MVPA for ≥150 minutes per week [31].

Exergaming Status

Using data from cycles 23 and 24, participants were categorized into 4 groups based on their exergaming behavior over time using the following item: "In the past 12 months, how often did you exergame using consoles, or using your cellphone and/or a mobile app?" Response choices included never, less than once a month, 1 to 3 times a month, 1 to 6 times per week, and every day. In both cycles 23 and 24, participants were categorized as exergamers if they chose any response option other than "never." The four groups included (1) never-exergamers (ie, participants who did not report exergaming in cycles 23 or 24); (2) stopping exergamers (ie, participants who reported exergaming in cycle 23 but not in cycle 24); (3) starting exergamers (ie, participants who reported exergaming in cycle 24 but not in cycle 23); and (4) sustaining exergamers (ie, participants who exergamed in both cycles 23 and 24).

Minutes Exergaming per Week

Items measuring the number of minutes exergaming per week were modeled on the IPAQ-SF [22,23,25]. Participants who reported past-year exergaming were asked: "Did you exergame using consoles such as Nintendo Wii, XBOX ONE Kinect, Sony Play Station Move, Sony Eye Toy: Kinetic, or using your cellphone and/or a mobile app in the past 30 days? (ex. ZOMBIES, RUN!, Nike+ Running App, Fit Freeway, Pokémon Go)?" Response options were yes or no. Participants who responded no were assigned a score of 0 for minutes exergaming per week. Those who responded yes were asked how many days per week they exergamed (the response option was from 1 to 7 days) and how many minutes they played on average during each bout in the past month (responses were open-ended). The total number of minutes exergaming per week was calculated as the number of days exergaming per week multiplied by the average number of minutes per bout.

Exergaming Intensity

Usual intensity of exergaming was measured by the following question: "What was your usual physical effort during play?" Response choices included light, moderate, and vigorous.

Sociodemographic Characteristics

Sociodemographic characteristics included age, sex, whether the participant was university educated (yes or no), whether their mother was university educated (yes or no), and whether they were French speaking (yes or no), were born in Canada (yes or no), had an annual household income <CAN $50,000 (US $36,966; yes or no), lived alone (yes or no), lived with children (yes or no), and were employed (yes or no).

Data Analyses

Descriptive statistics were used to compare sociodemographic and PA-related characteristics (ie, walking, MVPA, and exergaming) of participants retained in the analytic sample (ie, those who provided data in cycles 23 and 24) versus not retained (ie, those who provided data in cycle 23 but not cycle 24). Based on skewness and kurtosis, walking, MVPA, and exergaming minutes per week were not normally distributed. Therefore, the median (IQR) is reported for these variables. The proportion of participants that met MVPA guidelines is reported as a percentage.

Change scores were computed by subtracting number of minutes per week for each PA indicator (including exergaming) in cycle 23 from minutes per week in cycle 24. Because the distributions for the change scores were relatively normal in each of the 4 groups defined by exergaming status as well as in the sample overall, we report mean (SD) change scores. We report the median (IQR) for the change in minutes exergaming per week because the data were not normally distributed. Data were analyzed using SPSS (version 20.0; IBM Corp).

Results

Participants Retained Versus Not Retained

Table 1 compares the sociodemographic and PA-related characteristics of participants retained and not retained (ie, as measured in cycle 23). Lower proportions of those retained were male and French speaking. In addition, they reported fewer minutes per week walking and engaging in MVPA than participants who were not retained.

The mean age of the 681 participants retained for analysis was 33.6 (SD 0.5) years in cycle 24; 41% (n=280) were male, 95% (n=647) were born in Canada, 33% (n=225) were French speaking, 21% (n=143) had an annual household income of <CAN $50,000 (US $36,966), 15% (n=102) lived alone, 51% (n=347) lived with children, 83% (n=565) reported being employed, and 36% (n=245) met MVPA guidelines. The median (IQR) minutes per week during COVID-19 was 120 (45-240) for walking and 80 (0-240) for MVPA. Participants who exergamed during COVID-19 (n=122) reported a median (IQR) of 80 (9-240) minutes of exergaming per week.

Of 681 participants retained for analysis, 425 (62.4%) were never-exergamers, 56 (8.2%) started exergaming in cycle 24 (during the pandemic), 134 (19.7%) stopped exergaming in cycle 24, and 66 (9.7%) sustained exergaming. Among the 200 exergamers in cycle 23, 66 (33%) sustained exergaming in cycle 24, and 134 (67%) stopped exergaming.

Table 2 reports the median number of minutes walking per week, median number of minutes engaged in MVPA per week, and the percentage of participants who met MVPA guidelines before and during the COVID-19 pandemic. In addition to reporting values for the sample overall, data are provided for the 4 groups defined by exergaming behavior over time.

The data suggest declines over time in all 3 PA indicators in the sample overall (Table 2). Median minutes walking per week declined from 175 before COVID-19 to 120 during COVID-19, with a mean decline of 58 minutes per week. MVPA declined from a median 130 to 80 minutes per week among the participants overall, with a mean decline of 49 minutes per week. The proportion of participants that met MVPA guidelines declined from 48.3% (n=326) before the pandemic to 36% (n=245) during the pandemic, an absolute decline of 12.3%.

Table 1. Characteristics of participants retained and not retained for analysis from the Nicotine Dependence in Teens study (Montreal, Quebec, 2017-2021). Data were drawn from cycle 23[a].

Characteristics[b]	Total (n=799)	Retained in cycle 24 (n=681)	Not retained in cycle 24 (n=118)
Age (years), mean (SD)	30.6 (1.0)	30.5 (1.0)	31.0 (1.1)
Male, n (%)	351 (43.9)	280 (41.1)	71 (60.2)
Born in Canada, n (%)	799 (93.7)	642 (94.3)	107 (90.7)
Mother is university educated, n (%)	332 (46.2)	283 (45.6)	49 (50)
French speaking, n (%)	245 (30.7)	199 (29.2)	46 (39)
Walking (minutes/week), median (IQR)	175(60-350)	175 (60-350)	200 (70-420)
MVPA[c] (minutes/week), median (IQR)	135 (0-330)	135 (0-303)	180 (20-450)
Met MVPA guidelines, n (%)	387 (49.5)	326 (48.9)	61 (53)
Exergaming (minutes/week), median (IQR)[c]	0 (0-0)	0 (0-0)	0 (0-83)

[a]Totals may differ due to missing data.

[b]Includes only past-year exergamers.

[c]MVPA: moderate-to-vigorous physical activity.

Table 2. Number of minutes walking per week, number of minutes engaged in moderate-to-vigorous physical activity per week, and percentage of participants who met moderate-to-vigorous physical activity guidelines from before to during the COVID-19 pandemic in 4 groups defined by consistency in exergaming behavior over time (Nicotine Dependence in Teens study, Montreal, Canada, 2017-2021)[a].

	Before COVID-19 (cycle 23[b])	During COVID-19 (cycle 24[c])	Change between cycles 23 and 24
Walking (minutes/week), median (IQR)			
Overall (n=681)	175 (60-350)	120 (45-240)	–58 (310)[d]
Never exergamed (n=424)	175 (60-315)	120 (45-240)	–48 (298)[d]
Started exergaming (n=56)	163 (90-420)	195 (40-420)	–38 (372)[d]
Stopped exergaming (n=134)	178 (88-420)	120 (60-210)	–97 (279)[d]
Sustained exergaming (n=66)	140 (30-258)	90 (40-188)	–56 (380)[d]
MVPA[e] (minutes/week), median (IQR)			
Overall (n=681)	130 (0-310)	80 (0-240)	–49 (342)[d]
Never exergamed (n=424)	120 (0-300)	80 (0-240)	–41 (336)[d]
Started exergaming (n=56)	210 (40-420)	90 (4-394)	–35 (395)[d]
Stopped exergaming (n=134)	180 (41-360)	80 (0-275)	–58 (306)[d]
Sustained exergaming (n=66)	180 (0-360)	66 (0-221)	–92 (405)[d]
Met MVPA guidelines, n (%)			
Overall (n=681)	326 (48.3)	245 (36)	–12.3[f]
Never exergamed (n=424)	186 (44.8)	155 (36.6)	–8.2[f]
Started exergaming (n=56)	31 (57.1)	21 (37.5)	–19.6[f]
Stopped exergaming (n=134)	74 (55.6)	48 (35.8)	–19.8[f]
Sustained exergaming (n=66)	35 (55.4)	21 (31.8)	–23.6[f]

[a]Totals may differ due to missing data.
[b]Data were collected from January 2017 to March 2020 (mean age 30.6 years).
[c]Data were collected from December 2020 to June 2021 (mean age 33.6 years).
[d]These values are the mean (SD), since the change scores were normally distributed.
[e]MVPA: moderate-to-vigorous physical activity.
[f]These values represent the absolute decline in percentage.

Change in Walking Across Exergaming Groups

Among the 4 groups defined by exergaming status, patterns of interest in walking from before to during COVID-19 (Table 2) show that those who started exergaming reported the highest level of walking during the pandemic (a median 195 minutes per week), and in addition, they declined the least (they had a mean decline of 38 minutes per week, compared to 58 minutes among all participants). Those who stopped exergaming had the highest level of walking before COVID-19 (median 178 minutes per week) and declined the most (their mean minutes walking per week declined by 97 minutes). Finally, sustained exergamers reported the lowest median levels of walking both before and during the pandemic; the mean decline in minutes walking per week in this group (–56 minutes per week) was similar to the mean decline among participants overall (–58 minutes per week).

Change in MVPA Across Exergaming Groups

Patterns of interest in MVPA in the 4 exergaming status groups (Table 2) show that never-exergamers reported the lowest MVPA levels before the COVID-19 pandemic (a median 120 minutes per week). Participants who started exergaming during the pandemic reported the highest MVPA levels both before and during the COVID-19 pandemic, and they declined the least (Table 2). Their mean MVPA change score was –35 minutes MVPA per week compared to –49 minutes among participants overall. Finally, sustained exergamers reported the lowest MVPA levels during the pandemic (a median 66 minutes per week) and they declined the most. Their mean MVPA change score was –92 minutes per week.

Change in Meeting MVPA Guidelines Across Exergaming Groups

Compared to the other 3 groups, a higher proportion of participants who started to exergame during the COVID-19 pandemic met MVPA guidelines both before and during the COVID-19 pandemic. Although the proportion of sustained exergamers that met MVPA guidelines was similar to the other 2 exergaming groups before COVID-19, this group reported the lowest proportion during COVID-19 and the largest decline over time (–23.6%). The proportion of participants that met MVPA guidelines was lowest among never-exergamers before COVID-19 (186/424, 44.8%), and this group had the lowest decline over time (–8.2%).

Change in Minutes Exergaming Among Exergamers

Table 3 reports change in exergaming minutes per week among sustained exergamers, participants who started exergaming, and participants who stopped exergaming. Participants who started exergaming reported a median of 85 minutes of exergaming per week during the COVID-19 pandemic. Sustained exergamers also increased exergaming by a mean 90.5 minutes per week (Table 3). Light intensity exergaming was reported by 65% (47/72) of exergamers in cycle 23 and 59% (55/94) of exergamers in cycle 24. Moderate or vigorous exergaming was reported by 35% (25/72) of exergamers in cycle 23 and 42% (39/94) in cycle 24.

Table 3. Number of minutes per week engaged in exergaming before and during the COVID-19 pandemic in groups defined by consistency in exergaming behavior over time (Nicotine Dependence in Teens study, Montreal, Quebec, 2017-2021).

	Exergaming (minutes/week), median (IQR)		
	Before COVID-19 (cycle 23[a])	During COVID-19 (cycle 24[b])	Change between cycles 23 and 24
Started exergaming (n=56)	0 (0 to 0)	85 (0 to 240)	85 (0 to 240)
Stopped exergaming (n=134)	0 (0 to 0)[c]	0 (0 to 0)	0 (0 to 0)
Sustained exergaming (n=66)	0 (0 to 63)[c]	68 (14 to 229)	60 (–4 to 188)

[a]Data were collected from January 2017 to March 2020 (mean age 30.6 years).

[b]Data were collected from December 2020 to June 2021 (mean age 33.6 years).

[c]Participants who reported past-year exergaming but 0 minutes exergaming in the past 30 days were assigned a score of 0 minutes exergaming per week.

Discussion

Overall Findings

Overall, the percentage of participants meeting MVPA guidelines, the number of minutes walked, and the number of minutes engaged in MVPA per week declined from before to during the pandemic regardless of exergaming status [6]. Our data suggest that sustained exergamers were not more active than never-exergamers during the COVID-19 pandemic and, in fact, appeared to be less active. In contrast, those who started exergaming reported the highest levels of walking and MVPA during COVID-19, although, as in all groups, the change scores suggest declines on average in both activities. Thus, it appears that even if exergaming encourages PA during periods of confinement, in and of itself exergaming may not be sufficient to help exergamers maintain prepandemic PA levels. It is possible, however, that without exergaming the declines observed among sustained exergamers could have been steeper.

Never-Exergamers

Never-exergamers reported declines of 48 minutes per week in walking and 41 minutes per week in MVPA from before to during the COVID-19 pandemic. Of the 4 exergaming groups studied, never-exergamers reported the lowest levels of MVPA and were least likely to meet MVPA guidelines before the pandemic. The relatively minor changes in PA in this group during COVID-19 may reflect a general disinterest in PA (so that closure of gyms and recreational centers during the pandemic made little difference to their PA levels). It is possible that level of motivation for PA remained low among these individuals during the pandemic, such that they did not benefit from any increases in time available for PA due to containment measures. It is also possible that this group had established (lower) PA levels and patterns that they were content with and that they felt little need to explore different ways of building PA into their routines, regardless of the pandemic context.

Stopped Exergaming

Among the 4 groups defined by exergaming status, those who stopped exergaming declined the most in walking (–97 minutes/week) from before to during the COVID-19 pandemic. Although stopping exergaming in this group was possibly related to COVID-19, the middle to early 30s is often a turbulent time during the life course marked by numerous important transitions as people complete their education, enter the workforce, and begin their own families [32]. Rather than being a consequence of the COVID-19 pandemic, exergaming may be a form of PA that is dropped during these life transitions to make way for engaging in new roles and activities. Alternatively, exergaming could be an intermittent activity [32] linked to the release of new games or consoles, and the lack of new releases during the pandemic could be among the reasons that participants stopped exergaming. Exergaming may also be a "transferable" PA, such that it is used to experiment with a new PA (eg, to begin jogging), which is then continued independently of the exergaming component. Finally, frustration with technical glitches, concerns with online privacy [33], reduction in enjoyment and game immersion (ie, how a videogame draws a player into the game) [33,34], and price have also been cited as reasons for stopping exergaming [33,34]. Qualitative studies may be helpful in identifying the reasons why exergamers in their 30s choose to stop exergaming during pandemics.

Sustained Exergaming

Of the 4 exergaming groups, sustained exergamers reported the lowest levels of walking both before and during the pandemic and the lowest levels of MVPA during the pandemic. Previous research suggests that although exergamers do not necessarily have higher PA levels than never-exergamers and may not be interested in traditional PA, they do understand the importance of movement and turn to exergaming for their PA [22,25,35]. Sustained exergamers may have continued to play games such as Pokémon Go during the COVID-19 pandemic. There is evidence that 2020 was the most profitable year ever for the Pokémon Go enterprise [36], suggesting that many exergamers continued to play this outdoor game during COVID-19. Zombies, Run! also had an increase of 2 million users during COVID-19 [37]. Further, Ellis et al [38] reported that among 2004 young adult gamers (aged 30.5 years on average), Pokémon Go and Harry Potter: Wizards Unite were played frequently during the pandemic to maintain exercise levels and for social connection. Many participants reported that Pokémon Go was "the one thing that keeps me going outdoors and moving each day" [34]. Ellis et al [38] also reported that those who exergamed during the COVID-19 pandemic did so to distract themselves, escape from reality for a short period of time, occupy themselves, and manage their mental health.

Sustained exergamers reported a median of 68 minutes per week of exergaming, an important contribution to overall PA. Exergaming is not usually dependent on fitness or recreational facilities outside the home; therefore, this group may not have been overly affected by pandemic-related lockdowns. While the change in walking levels among sustained exergamers was not as marked as among those who stopped exergaming, their decline in MVPA was substantial (–92 minutes per week). It is possible that sustained exergamers participated in other modes of PA before the pandemic that were not replaced during the pandemic. Minutes exergaming per week among sustained exergamers did increase (as also reported in the Ellis et al study), but this was not enough to replace MVPA lost in other PA modes.

Started Exergaming

Of the 4 exergaming groups, those who started exergaming during the pandemic reported the highest MVPA levels before the pandemic (210 minutes/week) and the smallest decrease in MVPA (–35 minutes/week) during the pandemic. This group may have started using exergaming to compensate for activities they could no longer participate in during COVID-19. In addition to compensating for the loss of PA during the pandemic, video games may have helped with the loss of social interactions, which might have been a particularly salient loss in this group [7,14,38,39]. Whatever the underpinning, starting exergaming during the pandemic likely reflects relatively high levels of "physical literacy," which represents the motivation and financial resources to search out new forms of accessible PA [40]. Alternatively, or in addition, this group may also have been particularly sensitive to public health messaging that recommended maintaining PA levels during the pandemic.

Future Research

More research is needed to examine fluctuations in exergaming behaviors over time, especially during such challenging times as COVID-19. Qualitative research may help identify reasons for stopping, starting, or continuing to exergame during pandemics. This study did not identify types of exergaming engaged in, who participants exergamed with, or the context (ie, indoors or outdoors) in which they exergamed. These areas could be important avenues to explore to better inform recommendations for starting exergaming or for maintaining previous levels of exergaming during pandemics, as well as in general.

Limitations

Limitations of this study include that self-report IPAQ-SF data are subject to overreporting, although Lee et al [28] suggest that because of its established reliability, the IPAQ-SF can be used with care in repeated-measures studies. There was loss to follow-up between cycle 23 and cycle 24, which may relate to competing interests in the busy lives of young people in emerging adulthood. Selection bias related to this loss to follow-up could have attenuated our estimates, although the small number of sociodemographic differences between those retained and not retained for analysis mitigates this concern somewhat. Use of a purposive sample of schools in the NDIT study may limit the generalizability of the findings. Finally, we were unable to categorize exergamers according to more refined categories of exergaming intensity and frequency, and this may have led to misclassification of some exergamers. Future studies should use more refined measures of exergaming to enable more accurate categorization of exergamers.

Conclusion

Although it may support PA at home during periods of confinement, starting or sustaining exergaming did not appear to be enough to maintain prepandemic PA levels in this population-based sample of young adults. However, the data suggest that exergaming can contribute a substantial proportion of total PA in young adults and may still represent a useful option to promote PA during pandemics.

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Authors' Contributions

EKO is the first author of the manuscript and conducted all analyses and data verifications. EKO, CMS, RHO, MB, MPS, and JLO drafted and revised the manuscript. JLO designed and acquired the funding for the Nicotine Dependence in Teens study, and JLO, MPS, and MB acquired the funding for the COVID-19 data collection. All authors contributed to the interpretation of results and read and approved the final manuscript. EKO holds a postdoctoral salary award from the Fonds de Recherche du Québec-Santé (FRQ-S). CS holds a Canada Research Chair in physical activity and mental health. MPS holds a J2 Salary award from the FRQ-S. JLO held a Canada Research Chair in the Early Determinants of Adult Chronic Disease from 2004 to 2021.

Conflicts of Interest

None declared.

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Abbreviations

IPAQ-SF: International Physical Activity Questionnaire–Short Form
MVPA: moderate-to-vigorous physical activity
NDIT: Nicotine Dependence in Teens
PA: physical activity
WHO: World Health Organization

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Original Paper

Effects of Virtual Reality Pilates Training on Duration of Posture Maintenance and Flow in Young, Healthy Individuals: Randomized Crossover Trial

Sung Je Park[1], PhD; Jea Woog Lee[2], PhD

[1]College of Sport, Chung-Ang University, Anseong-si, Republic of Korea

[2]Intelligence Information Processing Lab, Chung-Ang University, Seoul, Republic of Korea

Corresponding Author:
Jea Woog Lee, PhD
Intelligence Information Processing Lab
Chung-Ang University
84, Heukseok-ro, Dongjak-gu
Seoul, 06974
Republic of Korea
Phone: 82 010 5426 7318
Email: yyizeuks@cau.ac.kr

Abstract

Background: This study explored the use of virtual reality (VR) technology to enhance the effectiveness and duration of low-intensity movements and postures in Pilates-derived exercises. We postulate that by leveraging the flow state in VR, individuals can engage in these exercises for longer periods while maintaining a high level of flow.

Objective: The purpose of this study was to compare differences in posture maintenance and flow between VR Pilates training and conventional Pilates training, and the correlation between the 2 factors.

Methods: The 18 participants in each group received either VR training or conventional training and were switched to the other training type after a 2-day wash-out period. Each group performed Pilates movements in a VR environment and a conventional environment, divided into 4 types. After training sessions, participants were evaluated for flow using a self-report questionnaire. In addition, a sports video analysis program was used to measure the duration of posture maintenance in 2 video-recorded sessions. Repeated-measures ANOVA and correlation analysis were performed on the measured duration of posture maintenance and flow scores. In all cases, the statistical significance level was set at $P<.05$.

Results: Results for the duration of posture maintenance verification by type showed that simple behavior ($F_{1,16}=17.631$; $P<.001$), upper body–arm coordination behavior ($F_{1,16}=6.083$; $P=.04$), upper body–leg coordination behavior ($F_{1,16}=8.359$; $P<.001$), and whole-body coordination behavior ($F_{1,16}=8.426$; $P<.001$) all showed an interaction effect at $P<.05$. Flow ($F_{1,16}=15.250$; $P<.001$) also showed an interaction effect. In addition, significant correlations were determined between duration of all types of posture maintenance and flow in the VR training group at $P<.05$.

Conclusions: Our results indicate that VR Pilates training may be more useful than conventional Pilates training in improving the duration of posture maintenance and that it promotes a significantly higher degree of flow when compared with conventional Pilates training.

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KEYWORDS

virtual reality; Pilates; exercise program; flow; duration of posture maintenance; sport video data analytics; video; data analytics; sport; sports; exercise; physical activity; posture; VR; balance; movement; self-reported; patient reported

Introduction

Virtual reality (VR) technology provides a virtual environment using virtually created graphics or images [1]. VR was previously seen as encompassing the implementation of virtual graphics—including 2D or 3D graphics—to simulate the real world, irrespective of the type of VR device used [2]. Currently, however, VR has come to be defined as a technology that induces users to enter a virtual world while wearing a head-mounted display (HMD) that completely blocks the wearer's visual senses [3]. This flow eventually digitizes the positions and directions of the real world (and those who live in it) while providing the wearer with 3D images, thereby affecting their movements [4].

Previous studies have emphasized the potential benefits of VR technology in certain specialty areas—such as education, training, and entertainment—with its usefulness further expanded to other disciplines [5]. The application of VR technology in sports is an innovative development for overcoming barriers through effective training methods [6,7]. This justifies the great academic interest in the applicability of VR technology to sports. Specifically, VR-based fitness effectively promotes muscle growth and aerobic capacity [8]. Moreover, VR technology is effective at improving physical activity in sports and military training [9]. A VR-based exercise rehabilitation program was effective in improving the physical strength of patients undergoing hemodialysis and in improving psychological outcomes—such as quality of life, depression, and anxiety—in those with cardiovascular diseases [10-12].

Previous studies have examined the effects of sports participation in VR environments on motivation and enjoyment. This was followed by studies showing that a high degree of flow is closely associated with VR sports games. Thus, these studies have demonstrated the effects of psychological factors [13,14]. Furthermore, mind-body physical activities—such as yoga or Pilates—conducted in a VR environment can simulate real situations [15].

Flow is defined as the degree to which individuals concentrate on an object in response to specific stimuli and can be expressed as a holistic sensation that individuals perceive while acting holistically. Moreover, flow is an inherently valuable concept closely associated with motivation, as it induces individuals to be fully engaged in an activity, experience it as intrinsically rewarding, and pursue it even without achieving an ultimate goal [16,17]. A recent study highlighted the impact of flow in the context of physical exercise; it showed that flow is closely associated with intention for sustainable use of Wii Fit or smartphone-based fitness apps [17].

Previous studies have shown that VR technology is effective in creating a state of flow because of its flow sensory and physical affordances [13,18,19]. Along the continuum of these previously published studies, we hypothesize that flow might be involved in the duration of posture maintenance in the context of VR Pilates. Therefore, we have conducted this study to assess the efficacy of VR Pilates in improving the duration of posture maintenance and its ability to promote a significantly higher degree of flow compared to traditional Pilates among typical healthy adults.

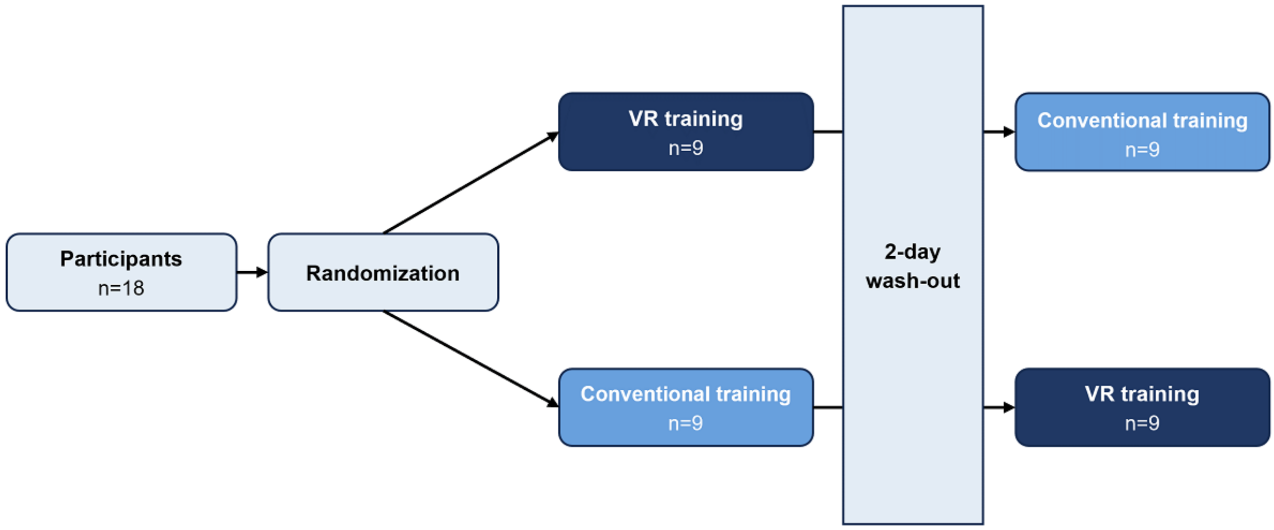
Methods

Study Design and Participants

Recruitment was conducted through an advertisement posted on the internet board of the College of Sport of Chung-Ang University. Participants were instructed to send a message of intent to participate to the researcher's messenger address posted in the advertisement. The recruitment period was from February 2021 to April 2021. Participants were included if they were male Korean nationals aged ≥20 years attending university with a major in physical education; participants' physical health, along with confirmation of an absence of mental illness, was confirmed by a health check-up program at a university-affiliated hospital. Participants were excluded if they had a history of head trauma; abused substances such as alcohol, tobacco, or drugs; were unable to understand the study and consent procedures; or had a confirmed diagnosis of a mental or psychiatric disorder [20]. For this study, we estimated the sample size using G* Power (Heinrich-Heine-Universität). To do this, we performed a repeated-measures ANOVA and used a type I error of .05, an effect size of 0.25, a statistical power of 0.9, and a drop-out rate of 10%; we also conservatively set the correlation between the repeated measures at 0. Therefore, we estimated the sample size to be a minimum of 18, and we enrolled 18 participants in this prospective, randomized, crossover trial. All 18 participants completed the trial; their age, height, and weight were measured as 24.17 (SD 2.81) years, 177.06 (SD 3.65) cm, and 75.21 (SD 9.49) kg, respectively. In this study, no participants presented with symptoms of motion sickness.

The participants were divided equally into 2 groups. Participants from each group received either 11 minutes of VR training or 11 minutes of conventional training and were switched to the other group after a 2-day wash-out period. Each session comprised a 3-minute warm-up, 5-minute main training session, and 3-minute cooldown session. The participants performed all the movements that were recorded on the video. Subsequently, the participants were evaluated for flow using a self-reported questionnaire. The study design is schematically illustrated in Figure 1.

Figure 1. Study design. VR: virtual reality.



Ethics Approval

This study was approved by the Institutional Bioethics Committee of Chung-Ang University (1041078-201908-HRSB-231-01), and the experiment and research were conducted with written consent from all participants.

Training Protocol

At baseline, the participants were evaluated for the possible onset of motion sickness or epilepsy after wearing an HMD (Vive Cosmos Elite; High Tech Computer Corp). The training protocol consisted of 40 types of Pilates movements. These included 8 types of simple behaviors, 12 types of 2 complex behaviors, and 16 types of 3 complex behaviors. The participants in each group were instructed to perform 40 Pilates movements using a voice-recorded file, supervised by a female expert instructor (Figure 2).

Figure 2. Virtual reality training and conventional training. Left: Participant receiving virtual reality training. Right: Participant receiving conventional training supervised by a female instructor.

Participants were allowed to interact with the VR environment using a Google Maps–based VR system (Vive Cosmos Elite). They were provided with views of tall mountains and the sky in a 3D video. They then felt as if they were flying through the valleys and sky while performing Pilates movements. Participants also performed Pilates movements under the guidance of a female expert instructor while listening to a voice recording.

Study Procedure

Throughout this trial, the participants' compliance and safety were meticulously monitored. At baseline, the participants were instructed to immediately quit Pilates movements as soon as they experienced nausea or dizziness while receiving VR-based training. They were instructed to wear the VR HMDs and a TheraBand (Hygenic Corp). However, in order to differentiate between the male participants and the female instructor, we used TheraBands with different colors. Subsequently, participants stood in a designated position. When participants sequentially performed all 40 Pilates movements in the VR environment, they received a response from the VR images.

Measurements

Measurement of the Duration of Posture Maintenance

The duration of posture maintenance for the 40 Pilates movements was measured using sports video analysis (Figure 3). To simplify video recording, participants were instructed to perform the movements in a location where footprints were marked before starting the session. During the session, all movements were video-recorded using an Apple iPhone 11. Then, the duration of posture maintenance was measured (in seconds) using a sports video analysis program, Dartfish (Dartfish SA).

Figure 3. Measurement of the duration of posture maintenance through video analysis.

Measurement of Flow

After completing both sessions, participants filled out a flow questionnaire to identify the challenges, behaviors, goals, feedback, concentration, and control that they experienced while performing the Pilates movements. Measurements of reliability and validity have confirmed the acceptability of the flow scale as a single factor, thus indicating that it is useful across diverse samples of physical activity [21]. The applicability of the single factor of 10 items to various environments, such as volleyball, swimming, golf, dynamic sports, and static sports, is well documented in the literature [22-25].

Data Analysis

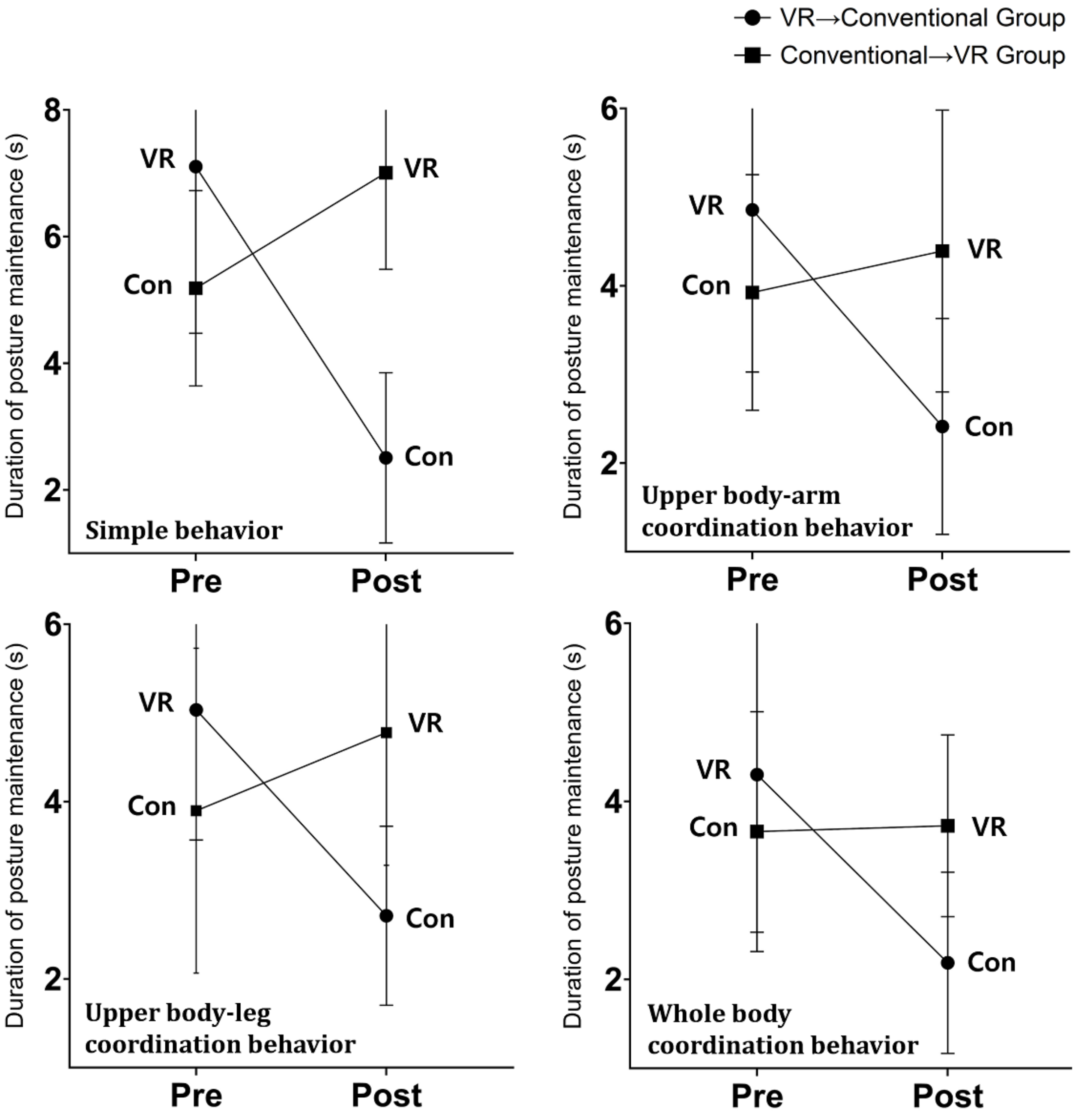
Data were analyzed using GraphPad Prism (version 9.0; GraphPad Software) and SPSS Statistics (version 25.0; IBM Corp). First, a repeated-measures ANOVA (period × group) was performed to compare the duration of posture maintenance between the VR training and conventional training sessions. Second, a Pearson correlation analysis was performed to confirm the relationship between flow and the duration of posture maintenance. In all cases, the statistical significance level was set at $P<.05$.

Results

Verification of Difference in Duration of Posture Maintenance by Type According to Group and Time

Results for the duration of posture maintenance by type showed that simple behavior ($F_{1,16}$=17.631; $P<.001$), upper body–arm coordination behavior ($F_{1,16}$=6.083; P=.04), upper body–leg coordination behavior ($F_{1,16}$=8.359; $P<.001$), and whole-body coordination behavior ($F_{1,16}$=8.426; $P<.001$) all had an interaction effect. All groups had high posture maintenance in the VR sessions both pre- and postintervention compared to the conventional session; the group where the VR session was performed first had reduced posture maintenance during the conventional session, and the group where the conventional session was performed first had increased posture maintenance during the VR session (Figure 4).

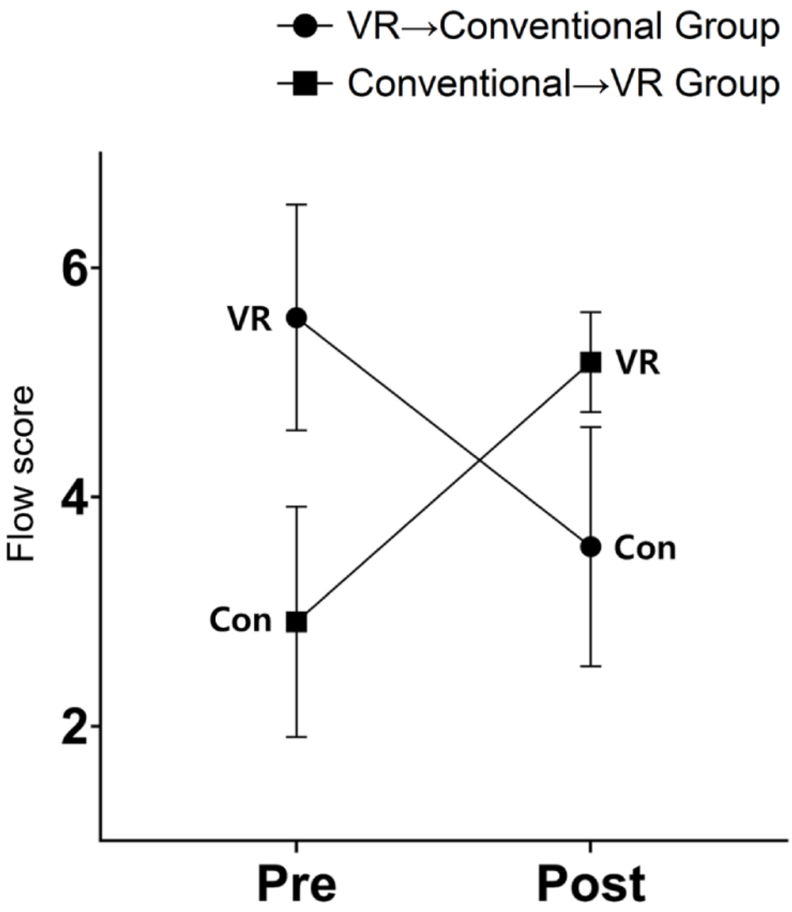
Figure 4. Interaction effects for all types of duration of posture maintenance among participants in a VR training session followed by a conventional session or vice versa. Con: conventional; VR: virtual reality.



Verification of Difference in Flow by Type According to Group and Time

Flow ($F_{1,16}$=15.250; P<.001) showed an interaction effect. All groups had a higher degree of flow in the VR sessions, both pre- and postintervention, compared with conventional sessions. The group in which the VR session was performed first had reduced flow during the conventional session, whereas the group in which the conventional session was performed first had increased flow during the VR session (Figure 5).

Figure 5. Interaction effects for flow among participants in a VR training session followed by a conventional session or vice versa. Con: conventional; VR: virtual reality.



Correlation Between the Duration of Posture Maintenance and Flow

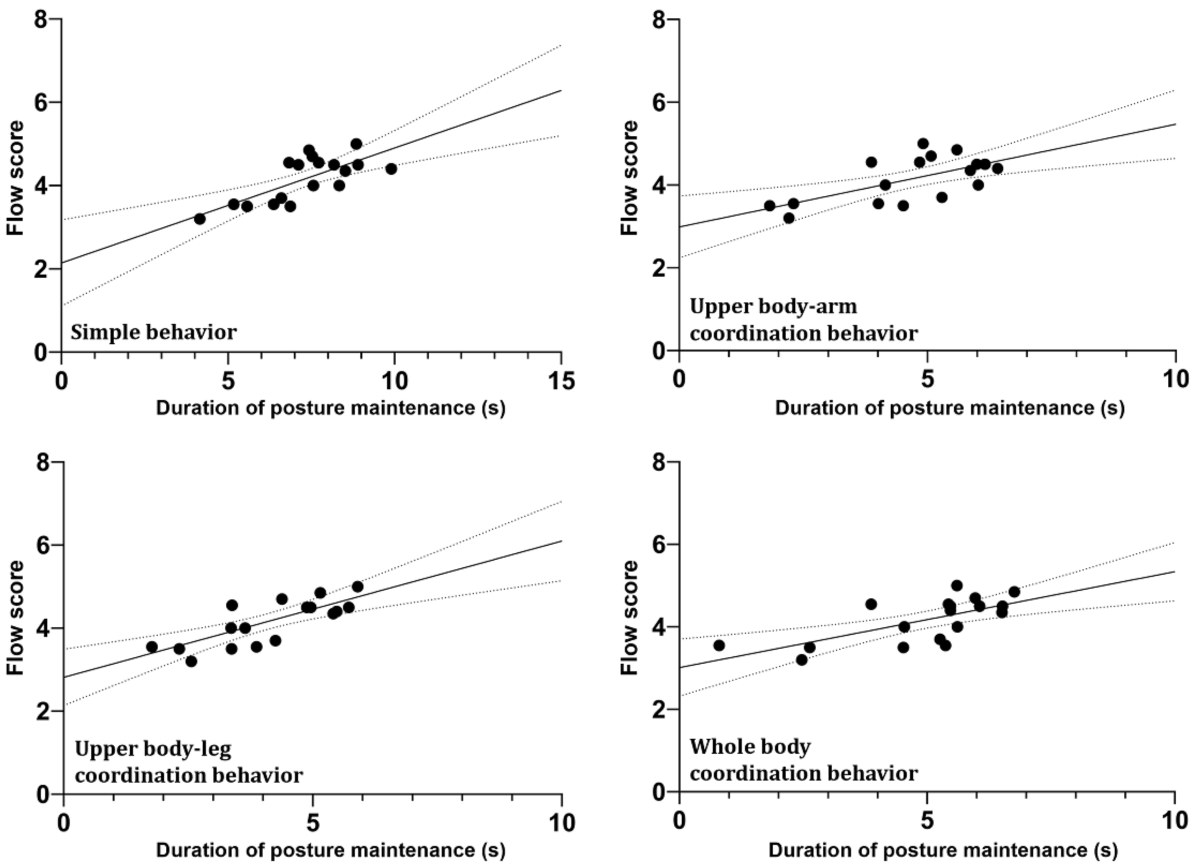
There were significant correlations between the duration of posture maintenance and flow in the VR training group. In detail, simple behavior was positively correlated with flow (r=0.49; *P*=.04), upper body–arm coordination behavior was positively correlated with flow (r=0.56; *P*<.001), upper body–leg coordination behavior was positively correlated with flow (r=0.70; *P*<.001), and whole-body coordination behavior was positively correlated with flow (r=0.60; *P*<.001). However, this was not observed in the conventional training group (Table 1 and Figure 6).

Table 1. Correlations between the duration of posture maintenance and flow (N=18).

Variable	*r*	*P* value
Simple behavior and flow		
VR[a] training	0.492	.04
Conventional training	0.153	.32
Upper body–arm coordination behavior and flow		
VR training	0.557	<.001
Conventional training	0.342	.10
Upper body–leg coordination behavior and flow		
VR training	0.702	<.001
Conventional training	0.372	.09
Whole-body coordination behavior and flow		
VR training	0.606	<.001
Conventional training	0.436	.05

[a]VR: virtual reality.

Figure 6. The results of Pearson correlation analysis for virtual reality training. There was a significant correlation between the duration of posture maintenance and flow in the virtual reality training group. Flow was positively correlated with simple behavior (r=0.49; *P*=.04), upper body–arm coordination behavior (r=0.56; *P*<.001), upper body–leg coordination behavior (r=0.70; *P*<.001), and whole-body coordination behavior (r=0.60; *P*<.001).



Discussion

Principal Findings

Participants in each group received either VR training or conventional training followed by a 2-day washout period before switching to the other type of training. Each group performed 4 different types of Pilates movements in a VR environment and a conventional environment. After the session, participants then evaluated the flow of the exercise using a self-report questionnaire. In all filmed sessions, duration of posture maintenance was measured using a sports video analysis program. Repeated measures were used to compare duration of posture maintenance and flow between VR and conventional sessions. Pearson correlation analysis was then performed to determine the relationship between flow and duration of posture maintenance. The results show that training in a VR environment improves balance and postural stability, which in turn increases the amount of time a person can hold a particular position steady. Participants also experienced higher levels of flow in VR training and found that the VR environment increased their focus on the exercise and induced a higher level of flow state. Third, we found a correlation between flow and exercise duration during VR training, suggesting that the higher flow that occurs in the VR environment induces improvements in postural stability and holding time.

Comparison to Prior Work

Movement duration was significantly different between the VR and conventional training sessions. A number of related studies have suggested 2 possible explanations for these results: improved posture and reduced resistance through VR. VR interventions have been shown to naturally promote exercise-specific behaviors through events presented in a virtual environment [26]. Furthermore, Lee and Kim [8] reported that sports VR training significantly influenced coordination related to balance and postural stability. In addition to this, various studies have found that VR simulation–based exercise increases body stability [27-29]. In other words, we can predict the mechanism by which VR increases action duration, as seen in this study: a sense of balance can enhance the stable continuation of a certain posture. On the other hand, Bryanton et al [30] reported that when children performed ankle flexion exercises in a VR environment for ankle joint rehabilitation, the duration of the dorsiflexion posture was enhanced compared to other environments, which may explain why the endurance required to fix and maintain a specific body pose for a long period of time is associated with training in the VR environment. Furthermore, previous studies showing that VR reduces the fatigue felt during isometric exercise may be related to the sustained effect of a similar mechanism in the static posture–holding movements performed in this study [31]. These findings suggest that VR environments may be useful in overcoming the negative sensations associated with exercise in a static position and modestly enhance performance potential. However, further studies that directly measure factors such as endurance and perceived resistance will be needed to prove this effect.

This study investigated whether VR environments provide an experience with high flow. After each session, participants reported that they felt more immersed in the VR training. Results from a randomized controlled trial evaluating a VR program for children with cerebral palsy highlighted maximizing engagement through flow in the VR environment as one of the strongest predictors of successful learning [32,33]. Vahle and Tomasik [34] reported that physical exercise in a VR environment led to a greater degree of flow as compared with a real-world environment, without respect to age. Moreover, according to Burt and Louw [35], VR technology was efficient in inducing a relatively higher level of flow. Virtual exercise environments can be characterized by a fundamental shift in focus from exercise to flow activity participation. While participants may perform physical movements of their own volition, the phenomenon of performing naturally guided behaviors in response to the interface provided by VR can also be explained. In this study, participants experienced flow states while performing the exercises, so it can be assumed that they adapted to the difficulty of the challenge and felt a sense of mastery. This is supported by research that suggests that flow is related to the balance between an individual's athletic and psychological abilities [36].

We conducted a correlation analysis to determine whether the participants adapted to the difficulty of the challenge and felt a sense of mastery over the duration of posture maintenance during training in the VR environment. The analysis confirmed a correlation between duration of posture maintenance and flow during VR training sessions. Virtual environments have been shown to induce psychological changes that engage participants in exercise [37] and enhance motor learning, including balance and posture [38]. These findings can be interpreted to suggest that performing physical activities while watching videos provided by VR devices increases motor focus. Specifically, participants experienced the possibilities and benefits of flow during physical activity combining Pilates and exergames in a virtual environment while performing naturally guided behaviors to respond to the videos provided in the game. VR exercise environments add virtual elements to real-world sensory elements and graphics to provide new challenges during real-world exercise [39,40]. Therefore, the findings of this study support the notion that VR training can provide seamless control over movement, as it allows for a gradual progression of the exercise protocol while maintaining the participant's attention. Furthermore, Mouatt et al [41] reported that VR-based flow engagement can have dramatic effects, especially for low-intensity exercise, by providing a virtual exercise environment for both able-bodied and disabled participants. In another study, an 8-week VR exergame training program designed to improve physical conditioning and increase performance yielded similar results to this study [42]. Virtual environments have also been proven to provide more intense visual stimulation than conventional physical activity, inducing changes in brain mechanisms responsible for high levels of concentration, thereby improving motor learning and body control, which are necessary for balance [43]. In another study, the authors interviewed users of a VR exercise program to gain insight into their experiences [44]. The participants expressed feelings of being in the environment as if they were floating in the air, able to observe the landscape in 360 degrees, and a sense of accomplishment after achieving what they wanted through postural control. The results of this study and various previous studies suggest that participants' flow responses are associated with increased playtime and improved performance in the long run. The psychological mechanisms of flow can be applied to dynamic and challenging exercises, physical activities, and even static, near-isometric movements in VR environments.

Strengths and Limitations

The VR environment's ability to improve an individual's stability in maintaining posture can be considered a major contribution to Pilates and physical activity. Traditionally, research avenues exploring physical activity and sports within VR realms have predominantly focused on the effects and efficiencies concerning dynamic performance parameters, such as strength enhancement and aerobic capacity. Nonetheless, this study ventured beyond the conventional boundaries by elucidating the efficacy of VR training methodologies specifically tailored for low-intensity, static movements and activities, wherein the core focus is balance retention and maintenance. Thus, this study not only corroborated the increasing importance of VR's flow environment but also exemplified its potential to enhance the quality of physical activities through improved postural stability and maintenance mechanisms.

There are several limitations to this study. First, it involved a small number of participants, which makes it difficult to generalize to the entire population. Therefore, a larger study that randomizes men and women in equal proportions and includes participants of different ages is necessary to generalize the findings. Second, this study focused on demonstrating the effect on duration of posture maintenance of a VR environment in relation to flow. Future research should expand the factors measured and types of physical activity to demonstrate the strengths of VR in improving postural stability and increasing duration from a variety of perspectives. Third, this study evaluated the effectiveness of VR training in the short term, so further research is needed to identify any adverse effects and obtain new insights that may have been difficult to detect in a short-term intervention when applied in the long term.

Conclusion

In conclusion, the findings of this study cautiously suggest that VR Pilates training might be more effective in improving duration of posture maintenance and inducing higher flow than conventional Pilates training. However, careful judgment is needed when asserting that physical activities in a VR environment are absolutely more beneficial than conventional training. Nonetheless, it suggests the possibility that a VR environment can enable effective performance even with different types of movement and when the difficulty of the applied movements increases in physical activity. In the future, there remains the challenging task of minimizing chronic stressors such as motion sickness and the weight of the device. Moreover, there is a need to develop distinct physical activities and exercise programs to overcome these challenges. We cautiously predict that if such efforts persist, useful VR environment training could be realized.

Acknowledgments

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Data Availability

The data sets generated and analyzed during this study are not publicly available for privacy and ethical reasons but are available from the corresponding author upon reasonable request.

Authors' Contributions

All authors conceptualized and designed the study. JWL conducted the data collection. SJP carried out the data management, analysis, and synthesis of data. All authors wrote the study. All authors critically reviewed, read, and approved the final version of the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist.
[PDF File (Adobe PDF File), 82 KB - games_v11i1e49080_app1.pdf]

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Abbreviations

HMD: head-mounted display
VR: virtual reality

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Original Paper

An Internet- and Kinect-Based Multiple Sclerosis Fitness Intervention Training With Pilates Exercises: Development and Usability Study

Andrea Tacchino[1], PhD; Michela Ponzio[1], PhD; Paolo Confalonieri[2], MD; Letizia Leocani[3], MD, PhD; Matilde Inglese[4,5], MD, PhD; Diego Centonze[6], MD, PhD; Eleonora Cocco[7], MD; Paolo Gallo[8], MD, PhD; Damiano Paolicelli[9], MD, PhD; Marco Rovaris[10], MD, PhD; Loredana Sabattini[11], MD; Gioacchino Tedeschi[12], MD; Luca Prosperini[13], MD, PhD; Francesco Patti[14], MD; Placido Bramanti[15], MD; Elisabetta Pedrazzoli[16], MD; Mario Alberto Battaglia[17], MD; Giampaolo Brichetto[1,18], MD, PhD

[1]Scientific Research Area, Italian Multiple Sclerosis Foundation, Genoa, Italy
[2]Multiple Sclerosis Center, IRCCS Foundation "Carlo Besta" Neurological Institute, Milan, Italy
[3]Vita-Salute University & Hospital San Raffaele, Milan, Italy
[4]Department of Neuroscience, Rehabilitation, Ophthalmology, Genetics, Maternal and Child Health, University of Genoa, Genoa, Italy
[5]IRCCS San Martino Hospital, Genoa, Italy
[6]Neurology Unit, IRCCS Neuromed, Pozzilli, Italy
[7]Department of Medical Science and Public health, University of Cagliari, Cagliari, Italy
[8]Department of Neuroscience, University of Padua, Padua, Italy
[9]Department of Basic Medical Sciences, Neuroscience and Sense Organs, University of Bari, Bari, Italy
[10]Multiple Sclerosis Center, IRCCS Don Carlo Gnocchi Foundation, Milan, Italy
[11]Uosi Multiple Sclerosis Rehabilitation, IRCCS Istituto delle Scienze Neurologiche of Bologna, Bologna, Italy
[12]Department of Advanced Medical and Surgical Sciences, University of Campania Luigi Vanvitelli, Naples, Italy
[13]Department of Neurosciences, S. Camillo-Forlanini Hospital, Rome, Italy
[14]Department of Medical and Surgical Sciences and Advanced Technologies, University of Catania, Catania, Italy
[15]IRCCS Centro Neurolesi "Bonino-Pulejo", Messina, Italy
[16]Rehabilitation Service of Padua, Italian Multiple Sclerosis Society, Padua, Italy
[17]Department of Life Science, University of Siena, Siena, Italy
[18]Rehabilitation Service of Genoa, Italian Multiple Sclerosis Society, Genoa, Italy

Corresponding Author:
Andrea Tacchino, PhD
Scientific Research Area
Italian Multiple Sclerosis Foundation
Via Operai 40
Genoa, 16149
Italy
Phone: 39 0102713812
Email: andrea.tacchino@aism.it

Abstract

Background: Balance impairments are common in people with multiple sclerosis (MS), with reduced ability to maintain position and delayed responses to postural adjustments. Pilates is a popular alternative method for balance training that may reduce the rapid worsening of symptoms and the increased risk of secondary conditions (eg, depression) that are frequently associated with physical inactivity.

Objective: In this paper, we aimed to describe the design, development, and usability testing of MS Fitness Intervention Training (MS-FIT), a Kinect-based tool implementing Pilates exercises customized for MS.

Methods: MS-FIT has been developed using a user-centered design approach (design, prototype, user feedback, and analysis) to gain the target user's perspective. A team composed of 1 physical therapist, 2 game programmers, and 1 game designer developed the first version of MS-FIT that integrated the knowledge and experience of the team with MS literature findings related to Pilates exercises and balance interventions based on exergames. MS-FIT, developed by using the Unity 3D (Unity Technologies) game engine software with Kinect Sensor V2 for Windows, implements exercises for breathing, posture, and balance. Feedback from an Italian panel of experts in MS rehabilitation (neurologists, physiatrists, physical therapists, 1 statistician, and 1 bioengineer) and people with MS was collected to customize the tool for use in MS. The context of MS-FIT is traveling around the world to visit some of the most important cities to learn the aspects of their culture through pictures and stories. At each stay of the travel, the avatar of a Pilates teacher shows the user the exercises to be performed. Overall, 9 people with MS (n=4, 44% women; mean age 42.89, SD 11.97 years; mean disease duration 10.19, SD 9.18 years; Expanded Disability Status Scale score 3.17, SD 0.75) were involved in 3 outpatient user test sessions of 30 minutes; MS-FIT's usability was assessed through an ad hoc questionnaire (maximum value=5; higher the score, higher the usability) evaluating easiness to use, playability, enjoyment, satisfaction, and acceptance.

Results: A user-centered design approach was used to develop an accessible and challenging tool for balance training. All people with MS (9/9, 100%) completed the user test sessions and answered the ad hoc questionnaire. The average score on each item ranged from 3.78 (SD 0.67) to 4.33 (SD 1.00), which indicated a high usability level. The feedback and suggestions provided by 64% (9/14) of people with MS and 36% (5/14) of therapists involved in the user test were implemented to refine the first prototype to release MS-FIT 2.0.

Conclusions: The participants reported that MS-FIT was a usable tool. It is a promising system for enhancing the motivation and engagement of people with MS in performing exercise with the aim of improving their physical status.

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KEYWORDS

exergame; Multiple Sclerosis Fitness Intervention Training; MS-FIT; Pilates; Kinect; multiple sclerosis; exercise; serious games; balance; mobile phone

Introduction

Background

Balance control impairments are common in people with multiple sclerosis (MS) [1] and may affect approximately 75% of people with MS during the course of the disease [1,2]. Weakness, spasticity, and fatigue are just some of the factors that cause balance disorders; moreover, central sensorimotor integration of visual, proprioceptive, and vestibular inputs is a critical aspect of balance control that may underlie dysfunction in static and dynamic balance [3,4]. Imbalance is usually characterized by the reduced ability to maintain position and to move toward the limits of stability and delayed responses to postural adjustments [1,4]. These abnormalities, together with other impairments and disabilities, often prevent people with MS from correctly and easily performing daily living activities and are considered as a primary fall risk in MS [5] with many adverse physical and psychological consequences (eg, injuries, fear of falling, and loss of autonomy) [6,7].

Mainly for these reasons, MS is associated with physical inactivity [8,9] that may lead to rapid symptom worsening and increased risk of secondary conditions (eg, fractures, high rates of depression, and fatigue). In turn, these may seriously affect participation in societal interactions and ultimately translate into reduced quality of life (QoL) [10]. Thus, balance exercises have increasingly been recommended in MS to control symptoms, enhance participation in daily activities, and improve QoL [11]. Balance exercises can be considered as the cornerstone of MS interventions [4].

Pilates is a popular alternative method for the maintenance and improvement of balance [12]. It is a precisely controlled form of exercise that uses stabilizing muscles of the body. Specifically, Pilates uses a holistic approach: concentration, control, centering, flowing movement, precision, and breathing are 6 fundamental principles; if correctly followed, they can improve flexibility, strength, core stability, muscle control, breathing, and posture and increase body awareness with less ground impact and joint stress [12,13]. These aspects and the possibility to perform exercises at the most convenient intensity levels (ie, difficulty adjusted to own level of conditioning) make Pilates an ideal approach to treat physical symptoms of MS [14]. More specifically, although high-quality studies are needed owing to the methodological flaw of most of the current literature, a recent meta-analysis showed that Pilates exercises might be an optional effective method to treat balance in people with MS [15].

In this context, the advancement of technology makes new alternatives available to deliver rehabilitative interventions in the form of internet- and game-based exercises (exergames) [16]. Playing exergames is a form of whole-body physical exercise delivered via commercial nonimmersive virtual reality [17] that requires users to complete the assigned tasks aimed at improving fitness and promoting an active lifestyle [18]. Exergames stimulate users to be more active, allowing repetitive practice and real-time interaction with feedback and tracking of progress, which enhance motivation, treatment adherence, and training outcomes [19-21]. Games that are specifically designed to address a problem or teach a certain ability have had a lot of success [22]. Researchers have demonstrated that exergames are comparable with traditional therapies and can be more fun and acceptable [23].

In the field of neurological diseases, a recent meta-analysis [24] explored the extent to which exergaming was superior to physical therapy or other forms of rehabilitation in improving balance dysfunction. Results were consistent with those of previously published meta-analyses and systematic reviews supporting the efficacy of exergames in the neurological setting [25-28]. A beneficial effect of exergames was found in stroke; Parkinson disease; and to a lesser extent, in MS, whereas conclusions on other conditions, such as mild cognitive impairment or Alzheimer disease, traumatic brain injuries, and myelopathies, were not possible. Furthermore, the effect size of exergames on balance significantly depended on the weekly frequency of sessions, single session duration, and overall intervention duration, whereas it was independent of the setting (supervised or home-based) and strategy (exclusive or add-on) of the intervention. Finally, exergames were found to be safe, with only mild to moderate musculoskeletal adverse events found in a minority of patients, with no significantly increased risk of falls [29].

Among the internet- and game-based technologies used for exercise training, the Kinect motion sensor (Microsoft Corp) constitutes a high-potential approach; it provides a precise markerless, full-body 3D motion tracker with real-time feedback about user performance and enables users to virtually interact hands-free with a computer system without needing a remote controller [30-35]. Lozano-Quilis et al [36] demonstrated the effectiveness of RemoviEM, a Kinect-based system offering people with MS an intuitive and motivating way to perform weight transfer and upper limb coordination exercises. Results showed great improvement in balance outcomes in the group using RemoviEM compared with the control group receiving the same types of exercises in a standard rehabilitative intervention. More recently, Molhemi et al [37] assessed the efficacy of a rehabilitative protocol including standing, walking, and weight shifting exercises delivered through a Kinect-based versus conventional training on the improvement of balance and mobility in people with MS. Both interventions improved balance and mobility; however, training with exergames was more efficacious in enhancing cognitive-motor function and reducing falls, whereas conventional exercises led to better directional control.

In the next years, new exergames will become available to the therapists, and it is hoped that these will allow for the integration in MS outpatient and at-home settings to optimize patient clinical outcomes and to ensure the continuity of care [38]. On the basis of the usability challenges faced by people with MS, programmers should develop user-friendly interfaces customized for people with MS, which is the main assumption for high acceptance, adherence, and effectiveness.

Objective

The aim of this study was 2-fold: first, to design and develop a usable Kinect-based exergame implementing Pilates exercises appropriately adapted to MS requirements; second, to evaluate the usability in people with MS for future research and clinical use. An Italian network of experts in the field of MS rehabilitation was involved in the different phases of the study. The first steps were dedicated to literature revision and exercise identification, followed by prototyping based on co-design with MS health care professionals and people with MS. Usability testing was conducted on the final version of the tool.

Methods

Overview

This study consists of 2 parts: the design and development of an exergame implementing Pilates exercises and its customization for the needs of people with MS (part 1) and evaluation of its usability in terms of ease of use, playability, enjoyment, satisfaction, and acceptance (part 2).

The exergame was developed for asynchronous telerehabilitation purposes. The patient should be clinically supervised by a physical therapist for the evaluation of the progress of training and performances (Table 1). Moreover, for patients with neurological problems, no limitations in terms of session frequency and duration are considered; the more use, the higher the effect size of the exergame [24].

Table 1. Summary of the characteristics of Multiple Sclerosis Fitness Intervention Training.

Characteristic	Description
Basic characteristics	
Targeted population	• People with MS[a] (adaptation needed for other clinical populations)
Exergame idea	• The exergame is an internet game-based training system using Microsoft Kinect motion sensor technology • It comprises games implementing Pilates exercises for breathing, posture, and balance
Target player	• Individual
Behavior change	• An exergame to enhance the motivation and engagement of people with MS in performing regular exercise
Clinical supervision	• Physical therapist
Data shared with the user and clinician	• Data are saved and stored in the hard disk and, if the tool is connected to the internet, uploaded to cloud • Performances in terms of the level of correctness, gained internet-based coins, frequency and duration of exercise sessions, exercises performed or skipped, unlocked cities, and completed missions are given as feedback on the display screen during the execution of the game or through dedicated menus
Type of game	• Pilates exercises for breathing, posture, and balance
Software version	• Release 2.0
Game components	
Exergame goal	

Physical components	• Balance improvement
	  • Improve flexibility, strength, core stability, muscle control, and breathing
	  • Improve posture
	  • Increase body awareness
	  • Reduce ground impact and joint stress

Cognitive components	• Cognitive improvement (however, no specific exercises stimulated cognition)
	  • Improve verbal and visuospatial memory, verbal fluency, and information processing speed
	  • Decrease cognitive fatigue
	  • Improve cognitive-motor, dual-task performances

Rules	• Breathing: breathe in and breathe out in correspondence of the teacher's instruction • Posture: sitting or standing depending on the exercise requirements (a chair should be ready to use for the sitting exercises) • Prompts: follow trajectories or arrows displayed in correspondence of the user's avatar during the exercise execution
Game mechanics	• The user interacts with the exergame by repeating the gesture of the Pilates trainer's avatar • The exergame also provides audio and visual feedback to the users while they are playing the games
Web environment	• Travel to visit some of the most important cities around the world
Setting	• Outpatient and at-home room environment with at least 3-m distance between the sensor and user

Characteristic	Description
Hardware configuration	• Minicomputer, monitor with a HDMI[b] connector (minimum suggested size: 27 tTFT[c]), Microsoft Kinect Sensor version 2, and power lead controller
Sensors used	• Microsoft Kinect Sensor version 2 (or new compatible commercial sensors such as Microsoft AzureKinect or MentorAge)
Estimated play time	• 30 minutes per day

[a]MS: multiple sclerosis.

[b]HDMI: high-definition multimedia interface.

[c]TFT: thin film transistor.

Ethical Considerations

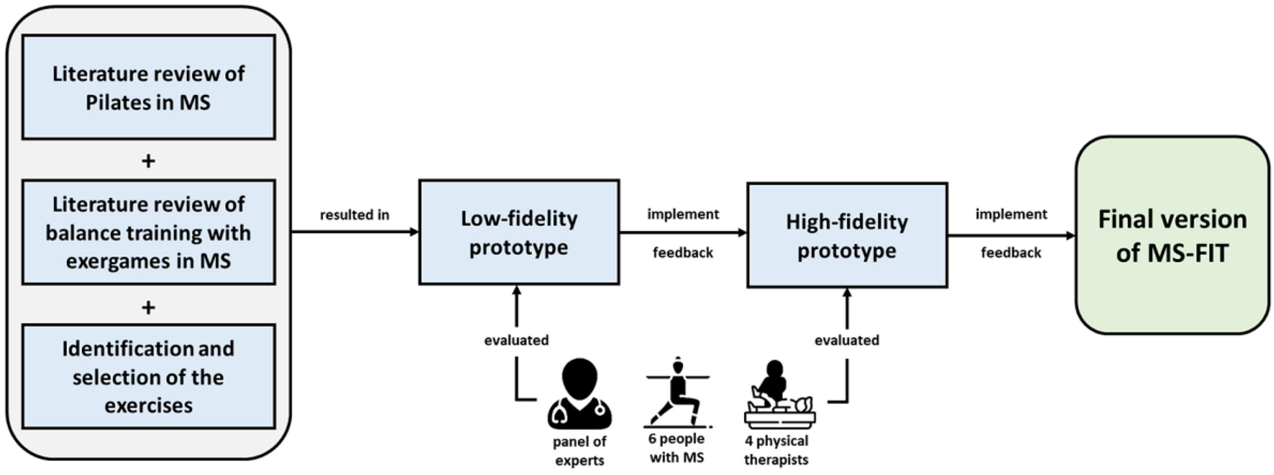
The study was approved by the regional ethics committee of the principal investigator (Azienda Ospedaliera San Martino Genoa; n° 134/2018). All participants gave written informed consent before entry into the study in accordance with the revised Declaration of Helsinki [39].

Part 1: Design and Development of a Pilates Exergame

Overview

Part 1 implements the user-centered design (UCD) approach [40-43], a user interface iterative design process that allows designers to gain the target user's perspective. Outcomes of the UCD process are products with a high degree of usability. The UCD approach is composed of 4 phases: design, prototype, users' feedback, and analysis [34]. All the study phases were performed between November 2018 and November 2019. The tool, customized for people with MS, was named MS Fitness Intervention Training (MS-FIT). Figure 1 presents the development process of MS-FIT.

Figure 1. The app development process involving a literature revision on Pilates and balance training with exergames in multiple sclerosis (MS) and the identification and selection of the exercises to be implemented in MS Fitness Intervention Training (MS-FIT). A low-fidelity prototype and a high-fidelity prototype have been developed after evaluation by people with MS, physical therapists, and a panel of experts. Feedback was implemented to obtain the final version of MS-FIT. The icons in the figure have been modified from free licensed images from Flaticon [44].



Phase 1: Analysis of Existing Findings and Tool Design

During the first phase, a development team of 4 members, composed of 1 physical therapist (25 years of experience in neurological disease, including MS, and certified Pilates instructor), 2 game programmers (5 years of experience in the Unity 3D game engine), and 1 game designer (10 years of experience in game design, game theory, innovative virtual reality, and computer vision techniques), provided the design of MS-FIT. It implements some decisive elements that could enhance usability and user experience such as accessibility, challenge, reward and feedback, skill development, and difficulty adjustment [45,46].

Potential core game ideas were generated by integrating the team knowledge and results from a literature review about Pilates in MS and balance interventions in MS with exergames [29,30,35-38,40-43,45-56]. The Pilates exercises were identified for feasible implementation and safe execution in a digital tool [46]. The exercises aimed to train *breathing* (exercises for abdominal, costal, and sternal breathing perception; sitting and kneeling Mermaid exercises; and sitting and standing arm circles exercises able to increase the respiratory capacity; improve mobilization of the rib cage; and align and stabilize the trunk, backbone, head, pelvis, and shoulder), *posture* (eg, arch-and-curl and spine stretch exercises for the correct alignment of the trunk, backbone, head, pelvis, and shoulder in neutral position and during flexion extension; spine twist exercises to correctly prepare the trunk and upper limbs to gait scheme; exercises for self-correction of posture; and elephant exercise to stretch the backbone and hamstring muscles), and *balance* (eg, side-to-side, hip circle, side leg kick, 1-leg circle, and single leg extension exercises for correct weight transfer and monopodalic support). To ensure that the exergame was appropriate for each potential user, exercises at different levels of accessibility were considered (eg, some exercises are executed while seated). The game-based training program underwent critical appraisal by the physical therapist.

Multimedia Appendix 1 includes the description of Pilates exercises considered to be clinically beneficial to improve physical (ie, balance, mobility, and fatigue) and cognitive performances and QoL and easily implementable in MS-FIT [49].

Besides the identification and selection of the exercises, the design model phase took into account other essential factors such as rules and gameplay, options, levels of challenge, game plot and story, and transfer into real life [46,57].

Phase 2: Prototyping

During the second phase, the Pilates exercises were implemented in a low-fidelity prototype. The characteristics of MS-FIT are presented in Table 1.

The developers used the Unity 3D game engine software with Kinect Sensor V2 for Windows, a markerless tool usually adopted in different research scenarios as a low-cost device alternative to time-of-flight sensors (eg, SR-4000 CW10 by Mesa technologies) and motion tracking systems (eg, Vicon and Optotrac). It was preferred to Kinect Sensor V1 because it provides great precision and more stable results [58]. Kinect Sensor V2 is a depth RGB (Red, Green, Blue) image sensor that provides information about the depth, color, and skeleton of a user who is standing in front of the sensor. Therefore, it can track and monitor full-body movements in 3D coordinates (ie, the x-axis, y-axis, and z-axis). It emits a grid of infrared light, and the distance of objects within the camera's recording range (0.5-4.5 m) is calculated using time-of-flight analysis of reflected light beams, which yields a depth model of the surrounding structures. On the basis of machine learning techniques, the software development kit of Kinect Sensor V2 allows the detection of human shapes and provides an artificial skeleton based on 25 anatomical landmarks ("Kinect joints") projected into these shapes based on depth data [59].

Kinect Sensor V2 acquired data at a rate of 30 frames per second, and all the tracked body joints were first filtered by using a third-order, low-pass Butterworth filter with a cutoff frequency of 5 Hz. The filter order and bandwidth were optimized to achieve the best results. The angle measures, velocity, and acceleration were computed for each joint type (eg, knee, shoulder, and neck) for each body frame. These measures were used to define the *gesture correctness*, calculated as the percentage of error (<5%) between the expected gestures shown by the avatar of a Pilates teacher and those executed by the user. The teacher's avatar gesture database was recorded, tagged, and compiled using a visual gesture builder app. On the basis of the gesture correctness, we also defined the reward and feedback system.

The hardware configuration of MS-FIT consists of other 3 devices: a minicomputer containing the exergame (eg, Intel Next Unit Computer), a monitor with a high-definition multimedia interface connector, and a power lead controller to access the exergame and move through the menus. Moreover, a chair without an armrest is needed for some exercises.

The Kinect sensor (in front) and the monitor (at the back) have to be set on a cabinet (or table) at a height of approximately 0.8 m. The user has to stay approximately 2 to 3 m from the Kinect sensor (Multimedia Appendix 2). At the first use of MS-FIT, the user has to calibrate the system, standing with the arms along the body for approximately 5 seconds in front of the sensor. The calibration will be valid for the next sessions also.

Phases 3 and 4: Co-Design With MS Health Professional Experts and People With MS

An Italian panel of experts in the field of MS rehabilitation composed of 12 neurologists, 3 physiatrists, 1 statistician, and 1 bioengineer (refer to Multimedia Appendix 3 for a list of participating centers) was invited to participate in the tool co-design [60]. Overall, 2 evaluation cycles were conducted during 2 separate meetings to refine the low-fidelity and high-fidelity prototypes. The evaluation was conducted by using a think-aloud method [61].

During the first cycle, the meeting started with a quick presentation of the aims of phases 1 and 2, followed by a demonstration of the low-fidelity prototype. Key questions regarding the advantages, disadvantages, and potential modifications were asked after each proposed feature. They suggested some preliminary customizations necessary for use with people with MS. Such modifications were mainly related to how the exercises should be implemented to take into account the different levels of physical disabilities of people with MS (eg, adaptation to safe positions).

Similarly, a first cycle of assessment was also conducted on the low-fidelity prototype with 60% (6/10) of people with MS and 40% (4/10) of physical therapists with experience in MS. They were required to specifically focus on user interface interaction, sound effects, and color contrast. Impaired movements and sensory loss (ie, somatosensory, auditory, and visual) such as those experienced by people with MS require specific user interface adaptations. People with MS proposed to use travel around the world as the game's context instead of a numbered track or an urban map; it was considered to be more motivating for themselves given that, often, MS limits the possibility to travel for both job and tourism.

Feedback from the first cycle was analyzed and used to modify the prototype before the second cycle. Experts, people with MS, and physical therapists agreed on the necessity of an introductory screen that reports safety information; moreover, they agreed on the necessity to wear comfortable clothes (eg, a tracksuit) while using the tool. No other relevant additional modifications were necessary.

Part 2: Usability Evaluation With Targeted Users

Part 2 was deputed to evaluate the usability of MS-FIT (release 1.0) with people with MS; an ad hoc questionnaire was used to analyze the ease of use, playability, enjoyment, satisfaction, and acceptance.

Participants

People with MS were enrolled at the Rehabilitation Service of the Italian Multiple Sclerosis Society in Genoa, IRCCS Institute of the Neurological Sciences of Bologna in Bologna, and Neurological Institute Carlo Besta IRCCS Foundation in Milan. The inclusion criteria were (1) age ≥18 years, (2) all MS courses (relapsing remitting, secondary progressive, and primary progressive), (3) disability level 2 to 4 as determined by the Expanded Disability Status Scale [62], (4) normal cognitive function (determined by a Mini-Mental State Examination score >24) [63], (5) no mood disorders as determined by a Hospital Anxiety and Depression Scale score <10 in the 2 subsets for anxiety and depression [64], (6) ability to maintain balance as determined by a Berg Balance Scale score >46 [65], and (7) at least 1 month without having been treated with rehabilitation. The exclusion criteria were (1) visual deficits that could compromise the use of MS-FIT and (2) relapses in the past 3 months.

Protocol

Each participant was involved in 3 outpatient usability test sessions. Before the first session, they received a comprehensive description of the MS-FIT concept and rules; furthermore, they learned to autonomously assemble and calibrate the MS-FIT tool. After the calibration, the participant could play the exergame.

Recent MS recommendations [66] encourage people with MS to practice ≥150 minutes per week of exercise or ≥150 minutes per week of lifestyle physical activity. For this reason, MS-FIT should be routinely used at home for 30 minutes per day for at least 5 days a week. Therefore, a minimum of 30 minutes per session was considered as proof of concept for the usability study.

Outcomes

Before the first session, participants were administered a questionnaire investigating their inclination to play traditional games (eg, game of checkers and cards; options: yes or no) and video games and exergames (options: nothing, consoles, tablets/smartphones, and PC), how long they play video games and exergames (options: 0, <4, 4-10, and >10 hours per month), and whether they agree (options: strongly agree, agree, do not know, disagree, and strongly disagree) that a digital assistant is an appealing way to present exercises.

After the last session, participants were asked to rate their experience through an ad hoc, 8-item questionnaire evaluating usability in terms of ease of use, playability, enjoyment, satisfaction, and acceptance, similarly to previous studies [67,68]. All items were rated on a 5-point scale ranging from 1 (strongly disagree) to 5 (strongly agree). Moreover, the usability was determined with a structured interview about the impressions of participants toward MS-FIT features in terms of rules, mechanics, interfaces, and scoring (Table 2).

In addition, the therapists involved in the user test were administered a structured interview about the interaction the participants had with MS-FIT. Specifically, we inquired them about whether the patients were autonomous at the end of the third session (options: yes/no) in using both hardware and software and how long the patients took to set up the system and start to play (options: <5, 5-10, 10-15, 15-20, and >20 minutes). Moreover, a free-text question was administered about their impressions and suggestions regarding the tool in terms of rules, mechanics, interfaces, and scoring.

Feedback from both interviews has been used by the research team to update MS-FIT to a new release for use in MS (MS-FIT 2.0 release).

Table 2. Questions of the ad hoc, 8-item questionnaire administered to the participants and the related scores.

Domain and question	Participants' score									Score, mean (SD)
	P[a]1	P2	P3	P4	P5	P6	P7	P8	P9	
Ease of use										
Are the instructions on the MS-FIT[b] hardware configuration clear to follow?	4	4	3	4	4	4	4	4	4	3.89 (0.33)
Is the hardware configuration easy in practice?	4	4	4	4	4	4	4	4	2	3.78 (0.67)
Are the instructions on the MS-FIT use clear and easy to follow?	4	4	4	4	5	4	4	4	4	4.11 (0.33)
Is the user interface pleasant?	4	4	4	4	4	3	4	4	3	3.78 (0.44)
Playability										
Is MS-FIT easy to be played?	5	4	4	4	4	4	4	4	2	3.89 (0.78)
Enjoyment										
Does a virtual trainer increase the enjoyment towards exercise?	4	4	4	4	5	3	4	4	5	4.11 (0.60)
Satisfaction										
Are you satisfied of the experience with MS-FIT?	3	4	3	4	5	4	4	4	4	3.89 (0.60)
Acceptance										
Are you motivated to use MS-FIT autonomously at home?	3	3	3	5	5	5	5	5	5	4.33 (1)

[a]P: participant.

[b]MS-FIT: Multiple Sclerosis Fitness Intervention Training.

Data Analysis

Descriptive statistics were used to describe both participants' characteristics and their scores on the ad hoc questionnaire. All data were analyzed using STATISTICA 7.1 (StatSoft).

Follow-Up

In total, 14 therapists with specific backgrounds in MS (one for each center; Supplementary Material 3) participated in a dedicated meeting in Milan to evaluate the MS-FIT 2.0 release and to suggest eventual further refinements.

Results

Part 1: Design and Development of a Pilates Exergame

MS-FIT is a tool for individual, internet-based, game-based training using Microsoft Kinect Sensor V2. The high number of implemented exercises (Multimedia Appendix 1) and the different levels of difficulty prevent boredom.

The MS-FIT context is *travel* around the world to visit some of the most important cities (Figure 2 and Multimedia Appendix 4) and to learn the aspects of their culture through pictures (eg, landscape) and stories (eg, curiosity; Textbox 1). At each stay of the travel, a teacher of Pilates, represented by an avatar, shows and explains to the user the exercise they will have to perform; a related caption is displayed. The teacher's avatar (a human model wearing web-based garments) is represented on the left of the screen, whereas the user's avatar (a human model in a density gradient visualization) is represented on the right and allows real-time feedback to the participant (Figure 3).

Accessibility was guaranteed through the implementation of exercises tailored for people with MS and owing to the use of auditory instructions provided by the teacher's avatar before starting the exercise while showing the related captions.

The challenge for the user is the execution of the exercises as correctly and accurately as possible at the same time as the teacher; green arrows (or circles for circular gestures), applied to the user's body joint and segment mainly involved in the exercise, are displayed to suggest the correct direction and to guide the execution (Figure 3). For each correct gesture, the user is rewarded with web-based coins visible while gaming; the reward represents the feedback about performances given to the participant while playing MS-FIT. The accumulated web-based coins can be used to unlock the next stay (ie, next city) and progress along the travel; this progress represents another feedback to the user. Besides this modality of game progress, MS-FIT also provides several missions; for example, twice-daily trainings for 5 consecutive days allow completing the mission, *Methodic* (Multimedia Appendix 5).

As the game progresses, the user develops more skills that motivate them to continue the training; according to the travel progress, the level of difficulty in the next city increases in terms of the number of consecutive repetitions of the same exercise or in terms of exercise complexity; however, the user can also repeat the exercises of previously unlocked cities without training at increasing levels of difficulty.

All these aspects of MS-FIT are expected to be crucial for the engagement of the users and the success of the product.

MS-FIT collects use data and exercise metrics about the frequency and duration of exercise sessions, types of exercises that are performed or skipped by the user, performance in each single exercise, and other statistics (eg, the ratio of unlocked cities to total cities and the ratio of completed missions to total missions). However, these in-game metrics are not shown to the user and were not investigated in this usability study. All data are anonymized and sent to a central server for storage.

Figure 2. (A) The main interface of Multiple Sclerosis Fitness Intervention Training. On the left, the different menus allow accessing the training, extra contents, user's profile, and unlocked missions and closing the program; a report of performances and metrics is also present. On the right, a representative picture of the current city and the preview of the last 4 unlocked cities are shown. (B) shows an example of the stays of the travel in Europe. In this case, Rome, Florence, Bologna, and Venice were already unlocked; the user has returned from Venice to Bologna to continue to Greece or Milan.

Textbox 1. Stories about a city—an example of stories related to Venice. In Multiple Sclerosis Fitness Intervention Training, each story is associated with the corresponding picture.

General

Venice is the capital of the Veneto region. It is built on a group of 118 islands separated by canals and linked by many bridges. During the Middle Ages and Renaissance the city played a central financial and maritime role in Europe. Today Venice is one of the most popular tourist destinations in Europe, so that most of its economy is based on tourism. One of the greatest challenges for Venice in the next future will be to face erosion and rising seas that threaten the delicate balance of this unique city in the world.

History

The popular class of Venice was divided into two factions: Castellani and Nicolotti. The former lived in the eastern part, i.e. the industrial area, of the city, while the latter prevalently resided on western area and were mainly engaged in fishing. Venice turned a blind eye to the skirmishes between the two factions, so much to permit them to clash during the so-called "Wars of the Fists." These battles took place on the bridges of Venice (one of these is still named "Ponte dei Pugni," i.e. "Bridge of Punches") and consisted of people fighting each other with bare hands. The fights could be one-on-one, multiple or as battle to take the bridge. During the clashes many contenders fell into the water, often injured, and more rarely someone dead. In 1705 Venice forbade these battles forever, replacing them with the custom of the "Forces of Hercules."

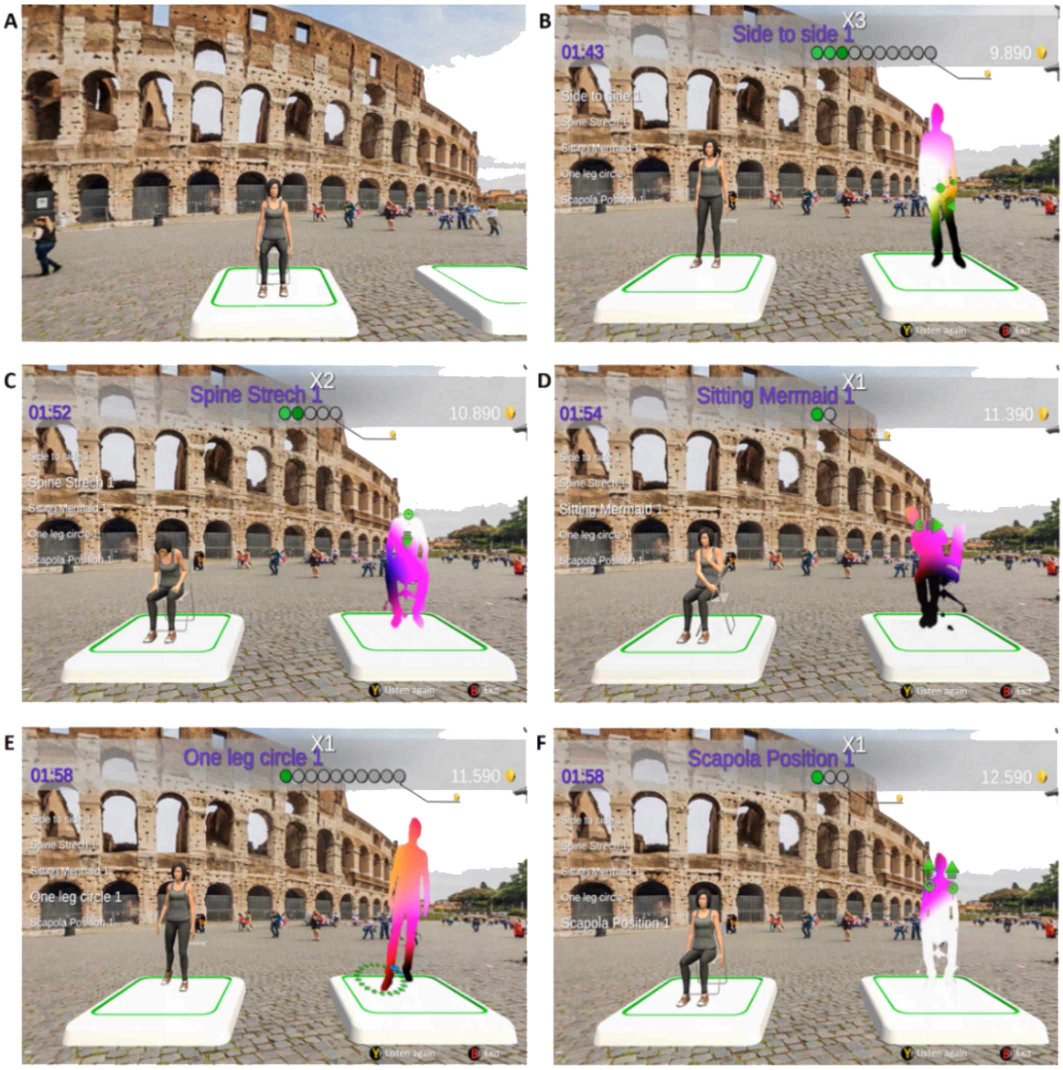
Monuments

The bell tower of of St Mark's Basilica initially had five bells used for different purposes. The "Maleficio" bell announced an imminent death sentence; the "Marangona" bell marked the beginning and the end of the Arsenale's workshift; the "Mezzana" bell rang at noon; the "Pregadi" bell announced the start of a meeting at the Doge's Palace; the "Trottera" bell, which takes its name from the trot of the horses, summoned the nobles to the Doge's Palace. Of these only the "Marangona" was saved from the collapse of the bell tower of St Mark's Basilica.

Curiosity

In the gardens of the Biennale of Venice there is a statue of Garibaldi on which a funny legend was born. The protagonist of this story is Giuseppe Zolli, a Venetian Garibaldian; it is said he swore to Garibaldi his protection for eternity. In 1921 some witnesses claimed to have seen the ghost of Zolli next to the statue of Garibaldi, intent on persecuting anyone who approached it. The inhabitants erected a statue of Zolli behind that of his protege, to allow him to always watch over him. The ghost has not been seen since.

Figure 3. The execution of some exercises implemented in the exergame. During the preview of the exercise (A), the teacher stays in the center of the view; she shows and explains the next exercise that the user will have to perform. Then, she moves to the left, and the user's avatar is displayed on the right. (B) to (F) represent instants of the execution of Side to side 1, Spide Stretch 1, Sitting Mermaid 1, One leg circle 1, and Scapola Position 1.



Part 2: Usability Evaluation With Targeted Users

Participants

A total of 9 people with MS (n=4, 44% women) participated in the usability phase. Their mean age was 42.89 (SD 11.97; range 22-61) years. Of the 9 participants, 8 (89%) were relapsing remitting, and 1 (11%) was secondary progressive; the mean Expanded Disability Status Scale score was 3.17 (SD 0.75; range 2-4), and the mean disease duration was 10.19 (SD 9.18) years.

Of the 9 participants, 6 (67%) did not have experience with video games, 1 (11%) played for <4 hours per month, and 2 (22%) played for 4 to 10 hours per month. Those who played video games used smartphones and tablets. Only 22% (2/9) of the participants reported to be traditional game players. In general, they agreed to consider a digital assistant (an avatar in MS-FIT) as a useful way to make exercise more appealing.

User Experience With MS-FIT

All people with MS (9/9, 100%) completed the 3 outpatient sessions of the user test and answered the ad hoc questionnaire. The average score on each item ranged from 3.78 and 4.11, which indicated a high usability level. The 8-item, ad hoc questionnaire scores are illustrated in Table 2.

As reported by the 5 therapists involved in the user test, of the 9 participants, all (n=9, 100%) were autonomous in using both hardware and software at the end of the third session, 6 (67%) needed <10 minutes to set up the system, and 3 (33%) needed 10 to 15 minutes.

At the end of the third session, on average, they visited 2 cities (range 1-3; Rome and Florence) and collected 1044 coins (range 945-1324).

Feedback and suggestions provided by the 9 people with MS and the 5 therapists are presented in Textbox 2 and were implemented in the MS-FIT 2.0 release.

A few final refinements were suggested by the 14 therapists participating in the follow-up meeting and have been implemented in the MS-FIT 2.0 release.

Thus, MS-FIT 2.0 was ready to be tested in a feasibility or a randomized controlled trial (RCT) study.

Textbox 2. Feedback and suggestions provided by people with multiple sclerosis (MS) and therapists.

Feedback and suggestions from people with MS

- Increment of the variety of exercises (especially for standing balance)
- Possibility of standby during the execution of an exercise (not only pause at the end of an exercise)
- Tailoring of treatment plan (eg, based on the disability level)
- Increment of the font size of writings (difficulty in reading for people with MS)
- Necessity of more colloquial terms for the instructions (very technical language is difficult to understand)
- Improvement of the reward system (need for visual feedback besides verbal feedback)

Feedback and suggestions from therapists

- Increment of the variety of exercises
- Possibility of detecting an aid (especially in the monopodalic exercises)
- Necessity of more colloquial terms for the instructions (very technical language is difficult to understand)
- Improvement of the reward system (although motivational feedback was implemented, more attention was required for negative performances)

Discussion

Principal Findings

In this study, we aimed to design, develop, and user test MS-FIT, an internet-based, game-based tool deputed to deliver Pilates exercises for people with MS. Study outcomes support the therapeutic use of Pilates in MS management because it is a safe, active treatment method (few adverse effects) with high adherence (low dropout rate) and can improve important parameters in the target population, such as balance, gait, physical functional capacities, and even cognitive functions [69].

MS-FIT was formulated by integrating the principal knowledge and existing evidence from MS literature and by subjecting the exergame to critical appraisal from patients and experts. We adopted a research-based and iterative development process that considered the knowledge gained from different disciplines (human movement science, rehabilitation, physical activity, game design, and research) and users' perspectives (people with MS and therapists) to holistically generate a potentially attractive and effective user-centered exergame for people with MS.

Although the participants had few experiences with exergames/video games and consoles, they became autonomous in using MS-FIT after only 3 sessions. All of them (9/9, 100%) completed the three 30-minute sessions and reported finding the tool easy to use, playable, enjoyable, and satisfactory. This result was corroborated by the quantity of coins gained and the number of cities unlocked, which could be considered as a surrogate index of the ease to use, playability, and acceptance. Feedback and suggestions provided by people with MS and therapists allowed for increasing the number of implemented exercises and, overall, improving the quality of the MS-FIT exergame.

Comparison With Previous Studies

In MS-FIT, we used Microsoft Kinect because it has been reported to be well accepted by users and for its effectiveness in several rehabilitative interventions for people with MS. For example, RemoviEM [36] is an intuitive and motivating way to train weight transfer and upper limb coordination of people with MS and to improve balance and mobility. Similarly, Molhemi et al [37] demonstrated the efficacy of a Kinect-based rehabilitative tool to train standing, walking, and weight shifting in MS. In addition, more consolidated experiences with a portable, low-cost tool such as the Nintendo Wii Balance Board could pave the way for an easy future adoption of Kinect-based exergames into clinical practice [24]. In this context, Brichetto et al [70] investigated the effectiveness of balance training based on the Nintendo Wii Balance Board versus a traditional rehabilitative training. Despite the excellent compliance with both interventions, a high clinically significant improvement in balance was shown in the group using the exergame. In addition, Prosperini et al [71] showed that training with the Nintendo Wii Balance Board induced microstructure modifications of the superior cerebellar peduncles, suggesting that high-intensity and task-oriented exercises such as those implemented in the Nintendo Wii Fit Plus package could favor brain reorganization in people with MS. Overall, internet-based, game-based training is an effective and efficient approach for empowering user engagement, which contributes to positive outcomes of an intervention [72,73].

To limit high dropout rates owing to potential low engagement with modern digital technology, the UCD approach, which incorporates game design principles (ie, goals, rules, feedback, points, time, reward structures, levels, and esthetics), was used in the process of designing and developing MS-FIT. Many studies demonstrated the benefits of using the UCD concept for developing exergames. For example, Lange et al [18] used the UCD approach to develop an internet-based, game-based program aimed at training the dynamic balance of individuals who had experienced a stroke. Hemingway et al [43] used the UCD process to develop a mobile game to influence the behavior of HIV service uptake among a key population. Howes et al [74] also used UCD to develop a bespoke exergame to deliver strength and balance exercise programs to older adults. Similarly, Kamnardsiri et al [34] developed and tested an internet-based, physical-cognitive, game-based training system using Kinect for older individuals. Therefore, the UCD approach is a core process that should be embedded in health game development to ensure usability and acceptability of and full benefit from exergame technology.

The findings from this study seem to be confirming these results. Consistent with previous studies, our game system provides feedback, including scores and performance outcomes, which enhances the motivation of the users [75,76]. However, it was not possible to evaluate the clinical benefit of MS-FIT because the number of user test sessions was very low; future planned studies will assess this aspect.

To the best of our knowledge, MS-FIT is the first exergame designed and developed to deliver Pilates exercises through an internet-based, game-based technology. Although MS-FIT was customized for people with MS, few adaptations would be necessary for use in the context of other clinical conditions [77-80].

Plans for Future Studies

The design, development, and usability testing of MS-FIT is the first step of a large research plan including an ongoing feasibility study followed by an RCT. The feasibility study has been planned to assess the satisfaction and acceptance toward the tool, adherence to the intervention, and dropout rate on a large sample size and for a long period of more intense use (ie, 5 sessions a week for 6 weeks). The use of validated questionnaires investigating usability [81-83] and the identification of potential bugs will be useful for further tool refinement. Moreover, the administration of clinical tests evaluating balance (eg, timed up-and-go test) will allow for estimating the effect of the intervention and its variance, which are necessary to calculate the appropriate sample size for the RCT. Finally, the feasibility study will allow the identification of groups of exercises with a level of difficulty that is suitable for the specific needs and capabilities of people with MS in different clinical stages.

An RCT (ClinicalTrials.gov; ID NCT04011579) will assess the effect of MS-FIT on physical and cognitive domains, mood, and QoL of people with MS. If RCT results are positive, MS-FIT could be proposed in combination with rehabilitation to potentiate the rehabilitative intervention effect or guarantee the continuity of care of people with MS.

Owing to the discontinuation of the Kinect Sensor V2, for the continued development of MS-FIT and successful translation into clinical practice, a new compatible commercial sensor must be identified and the app should be adapted. The Microsoft AzureKinect demonstrated sufficiently high interrater and intrarater reliability when compared with the Kinect Sensor V2. Moreover, a full-body skeletal tracking library in Python has recently become available. These aspects suggest that the Microsoft AzureKinect may be an adequate replacement within the MS-FIT system [84]. Another alternative solution to the Kinect Sensor V2 is MentorAge, a depth RGB (Red, Green, Blue) image sensor tracking system that operates on the Android system and uses infrared 3D capturing technology. It can detect a maximum of 4 people in a single room within a range of 0.6 to 5 m and has proven its capabilities and potentialities in real-life scenarios [80,85,86]. No additional equipment is thought to be used compared with the current version of MS-FIT.

Limitations

Some limitations of the study need to be acknowledged. First, the evaluation of the target user's experience involved a small number of participants. Furthermore, the usability results were obtained from a few training sessions. Thus, the findings should be considered as preliminary and interpreted with caution. Second, the minimum requested distance between the Kinect sensor and user could limit at-home use. New versions of the Kinect sensors could allow overcoming this limitation. Finally, this study investigated the usability by using an ad hoc questionnaire; however, in a future feasibility study, the use of validated questionnaires should be encouraged.

Conclusions

MS-FIT is an exergame using the Microsoft Kinect sensor for outpatient and at-home MS balance interventions. It digitally implements Pilates exercises for breathing, posture, and balance. MS-FIT is usable and well accepted by the target users, with positive feedback. Thus, the exergame is a promising tool for enhancing the motivation among people with MS to engage in exercise with the aim of improving their physical status.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

AT was involved in conceptualization, data curation, formal analysis, investigation, supervision, writing the original draft, and reviewing and editing the paper. MP was involved in conceptualization, data curation, formal analysis, methodology, and reviewing and editing the paper. PC was involved in conceptualization, data curation, and reviewing and editing the paper. LL, MI, DC, EC, PG, DP, MR, GT, LP, FP, and PB were involved in conceptualization and reviewing and editing the paper. LS was involved in conceptualization, data curation, and reviewing and editing the paper FP was involved in conceptualization and reviewing and editing the paper. PB was involved in conceptualization and reviewing and editing the paper. EP was involved in reviewing and editing the paper. MAB was involved in funding acquisition and reviewing and editing the paper. GB was involved in conceptualization, data curation, funding acquisition, project administration, and reviewing and editing the paper.

Conflicts of Interest

AT, MP, PC, EC, MR, LS, GT, LP, FP, PB, EP, MAB, and GB have no conflicts of interest to disclose. LL has received honoraria for consultancy over the past 3 years from Almirall, Merck, Novartis, and Roche. MI received compensation for participation in advisory boards from Almirall, Biogen, BMS, Merck, Novartis, Janssen, Roche, and Sanofi. MI is coeditor for MS Journal. DC is an advisory board member or has given advice to Almiral, Bayer Schering, Biogen, GW Pharmaceuticals, Merck Serono, Novartis, Roche, Sanofi-Genzyme, and Teva; has received honoraria for speaking or consultation fees from Almiral, Bayer Schering, Biogen, GW Pharmaceuticals, Merck Serono, Novartis, Roche, Sanofi-Genzyme, and Teva; and is the principal investigator in clinical trials for Bayer Schering, Biogen, Merck Serono, Mitsubishi, Novartis, Roche, Sanofi-Genzyme, and Teva. His preclinical and clinical research was supported by grants from Bayer Schering, Biogen Idec, Celgene, Merck Serono, Novartis, Roche, Sanofi-Genzyme, and Teva. DP has received honoraria for consultancy and speaking from Biogen, Merck, Novartis, Sanofi, and Roche.

Multimedia Appendix 1
Pilates exercises implemented in Multiple Sclerosis Fitness Intervention Training.
[DOCX File , 49 KB - games_v11i1e41371_app1.docx]

Multimedia Appendix 2
Additional illustration of the device and implementation.
[DOCX File , 3378 KB - games_v11i1e41371_app2.docx]

Multimedia Appendix 3
List of participating centres.
[DOCX File , 21 KB - games_v11i1e41371_app3.docx]

Multimedia Appendix 4
List of cities.
[DOCX File , 21 KB - games_v11i1e41371_app4.docx]

Multimedia Appendix 5
List of the missions.
[DOCX File , 20 KB - games_v11i1e41371_app5.docx]

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Abbreviations

MS: multiple sclerosis
MS-FIT: Multiple Sclerosis Fitness Intervention Training
QoL: quality of life
RCT: randomized controlled trial
UCD: user-centered design

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Original Paper

Usability of the GAIMplank Video Game Controller for People With Mobility Impairments: Observational Study

Laurie A Malone[1], MPH, PhD; Christen J Mendonca[1], PhD; Sangeetha Mohanraj[1], MS; Samuel R Misko[2], MSEE; Joseph Moore[2], BSEE; James Michael Brascome[2], MS; Mohanraj Thirumalai[1], PhD

[1]School of Health Professions, The University of Alabama at Birmingham, Birmingham, AL, United States

[2]Engineering and Innovative Technology Development, The University of Alabama at Birmingham, Birmingham, AL, United States

Corresponding Author:
Laurie A Malone, MPH, PhD
School of Health Professions
The University of Alabama at Birmingham
3810 Ridgeway Dr.
Birmingham, AL, 35209
United States
Phone: 1 205 934 0142
Email: lamalone@uab.edu

Abstract

Background: Replacing sedentary behaviors during leisure time with active video gaming has been shown to be an enjoyable option for increasing physical activity. However, most off-the-shelf active video gaming controllers are not accessible or usable for individuals with mobility impairments. To address this requirement, a universal video game controller (called the GAIMplank) was designed and developed.

Objective: This study aimed to assess the usability of the GAIMplank video game controller for playing PC video games among individuals with mobility impairments. Measures of enjoyment, perceived exertion, and qualitative data on the user experience were also examined.

Methods: Adults (aged 18-75 years) with a mobility impairment were recruited to participate in a single testing session in the laboratory. Before testing began, basic demographic information, along with minutes of weekday and weekend physical activity, minutes of weekday and weekend video game play, and video game play experience were collected. The GAIMplank was mapped to operate as a typical joystick controller. Depending on their comfort and functional ability, participants chose to play seated in a chair, standing, or in their own manual wheelchair. Leaning movements of the trunk created corresponding action in the game (ie, lean right to move right). The participants played a total of 5 preselected video games for approximately 5 minutes each. Data were collected to assess the usability of the GAIMplank, along with self-efficacy regarding execution of game play actions, rating of perceived exertion and enjoyment for each game, and overall qualitative feedback.

Results: A total of 21 adults (n=15, 71% men; n=6, 29% women) completed the usability testing, with a mean age of 48.8 (SD 13.8; range 21-73) years. Overall, 38% (8/21) of adults played while standing, 33% (7/21) of adults played while seated in a chair, and 29% (6/21) played in their own manual wheelchair. Scores from the System Usability Scale indicated above average (74.8, SD 14.5) usability, with scores best for those who played seated in a chair, followed by those standing, and then individuals who played seated in their own wheelchairs. Inconsistencies in the responsiveness of the controller and general feedback for minor improvements were documented. Rating of perceived exertion scores ranged from light to moderate intensity, with the highest scores for those who played seated in a chair. Participants rated their experience with playing each game from above average to very enjoyable.

Conclusions: The GAIMplank video game controller was found to be usable and accessible, providing an enjoyable option for light-to-moderate intensity exercise among adults with mobility impairments. Minor issues with inconsistencies in controller responsiveness were also recorded. Following further development and refinement, the next phase will include a pilot exercise intervention using the GAIMplank system.

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KEYWORDS

exergaming; physical disability; equipment design; video gaming; physical activity; exercise; wheelchair

Introduction

Background

Physical activity is an important component of a healthy lifestyle. A myriad of health benefits, both physical and psychological, can be achieved with daily physical activity [1]. Physical activity options, however, are limited for people with mobility impairments. Issues with accessibility and transportation are experienced by many individuals wanting to fulfill their daily physical activity needs. Fitness center parking, inaccessible entrances, limited staff knowledge on inclusive programming, and cost of membership and transportation are some of the limiting factors [2]. Equipment such as a stationary arm ergometer can provide a means to exercise at home but may be seen as boring and difficult to adhere to by many [3]. In an effort to combat the tedium of routine exercise, active video gaming (AVG) has become popular.

Replacing sedentary behaviors during leisure time with AVG has been shown to be an enjoyable option for increasing the amount of physical activity acquired each week [4-12]. The promise of AVGs is particularly appealing for people with disabilities, given the high rate of inaccessible features in the built environment and the difficulty in finding fun and engaging activities [5-8]. Because AVG systems are relatively affordable, they also hold promise as a scalable product for promoting improved health outcomes and higher levels of physical activity and fitness among people with disabilities [13]. Several AVG systems have been in the market for the last 2 decades; however, most are not adapted to suit the needs of individuals with mobility impairments. Using a mixed methods study, the usability of a somatosensory square dance system for older adults was examined [14]. The system was developed to support a popular fitness activity and to eliminate some of the common barriers (risk of injury, noise, and space) experienced by older adults. The system was well received by the participants, providing them with a fun fitness activity that could be safely performed indoors in a private space. The participants included a group of older adults (aged 55-68 years); however, specific adaptation for individuals with mobility impairments was not the focus and therefore was not considered. Another study examined the usability of an AVG platform for older adults with various physical and sensory impairments residing in long-term care homes, with 85% having a mobility impairment [15]. After several rounds of usability testing with residents, staff, and family, the feedback indicated that the system was an enjoyable way to engage in physical activity. Although efforts are being made, there continues to be a pressing need to make AVG controllers accessible to people who are unable to stand for long periods, cannot stand on a small platform because of poor balance or extreme obesity, or those who use a wheelchair for all daily activities.

Our engineering design and development team, with the Rehabilitation Engineering Research Center on Interactive Exercise Technologies and Exercise Physiology for People with Disabilities, previously built a proof-of-concept (PoC) wheelchair-accessible adapted gaming controller for the Wii system [16] and our research team tested its usability rating compared with the commercial off-the-shelf (OTS) balance board controller provided with the product [17]. Participants with mobility impairments found the wheelchair-accessible version to be more usable compared with the Wii OTS board ($P<.01$). The mean usability scores were 71.7 (SD 18.03) for the adapted controller and 32.1 (SD 36.72) for the Wii OTS board (higher scores reflect greater usability). In addition, a significant negative correlation (r=0.692; $P<.001$) was found between lower extremity function and system usability scores, indicating that for participants with poorer lower extremity function, the adapted board was perceived as more usable. Furthermore, participants reported activity using the adapted board to be enjoyable, achieving light-to-moderate intensity exercise [18].

As a next step, the aim was to transition from a PoC gaming controller to the performance of highly targeted proof-of-product (PoP) activities for the design of a new wheelchair-accessible AVG controller using the expertise and input of engineers, product designers, potential users, and other stakeholders from the community. The goal was to convert from a Wii-only interface to a universal controller for use with all games available to play on a PC.

Study Objectives

Following the design and development process, this study aimed to assess the usability of a wheelchair-accessible GAIMplank video game controller for individuals with mobility impairments. Measures of enjoyment, perceived exertion, and qualitative data on user experience were also collected.

Methods

PoP Development Process

To begin our PoP development effort, approximately 30 semistructured interviews were conducted with end users in various market segments to discover use cases that would be used to drive design features, functions, and capabilities. The physical therapy clinic market segment was found to be lacking in financial resources for investment into technology for nonreimbursable activities such as AVG. The market segment for inpatient rehabilitation and retirement facilities and communities was found to have the financial resources for recreational activities but lacked robust end user interest. The universal video game accessory market was found to be much more robust in terms of interest for nontraditional game controllers to facilitate intuitive player movement in virtual reality environments as well as to encourage AVG. Effective entry into this market requires the game controller to (1) be easily transportable and stowable, (2) have a purchase price comparable with other high-end game controllers (<US $300), and (3) be universally compatible with all major gaming platforms.

The design process began based on the PoC prototype developed previously (Figure 1), which used a custom-built aluminum frame, user interface, and load cell sensors combined with repurposed internal electronics from a deconstructed Wii Fit Board to allow for wireless connection to Wii game consoles. On the basis of the market study results, the preliminary PoP design effort targeted 3 areas for improvement, including reducing the weight of the balance board to <6.8 kg, integrating custom electronics for universal compatibility with all major gaming platforms, and optimizing design for low-cost manufacturing.

A redesign of the PoC balance board platform began with the determination of the critical dimensions for use by standing and seated users while also minimizing the footprint and structural support of the weightbearing structure. Early conceptual designs featured novel solutions to these design challenges through the integration of handrails, footrests, and ramps into the platform design (Figure 2). After evaluating a series of finite element models and simplified prototypes, a resin-infused sandwich composite was the material selected for use to reduce the weight of the balance board while maintaining the stiffness necessary to redistribute the user's weight to a minimum number of load cells.

The redesign of the PoC balance board electronics began with the selection of the embedded processor, load cell measurement integrated circuits, and wired and wireless communication modalities. The user interface components such as the sensitivity adjustments (overall, front and back, right and left) were upgraded from the PoC's buttons and knobs to an Android app that can easily provide access to any number of different controller settings and functions to optimize the user's game play experience. A Raspberry Pi Zero was implemented as the primary processor facilitating Bluetooth connection to an Android tablet as well as allowing remote access to data and programming via Wi-Fi. The USB Human Interface Device periphery connection to PCs and gaming console adapters was facilitated using an ARM Cortex-M4 microcontroller configured as a generic joystick device. Load cell measurements were performed using dedicated low-noise 24-bit analog-to-digital microchips.

The final design of the GAIMplank balance board platform (Figure 3) features rims on 3 sides of the board that serve as a physical barrier at the edge of the board. A downward tapered edge along the back of the board, and a slimline ramp, allowed for easy roll-on access (eg, if the user is in a wheelchair). The GAIMplank platform also features yellow high-visibility graphics that provide the user with a sense of their alignment on top of the board. The weight capacity of the GAIMplank platform is ≤270 kg, which is sufficient to support a wide range of users.

The final design of the GAIMplank Android App features real-time bidirectional information flow and access to a large range of customizable settings for real-time adjustments (Figure 4) to the measured load cells' bias, dead zones, and sensitivity, as well as to allow for on-demand calibration of the GAIMplank's output based on a player's measured weight and range of movement and game play mode (joystick vs directional pad).

The final design of GAIMplank electronics includes a custom printed circuit board (PCB) stack and an LED matrix display (Figure 5). The need for this display was discovered during the early developmental testing of prototypes with 3 volunteers recruited from local video gaming clubs, whereby they required instant feedback to build confidence that the board was indeed responding accurately and quickly to their movements during game play. This display is also used to guide the user through the required movements during calibration (step off, step on, move forward and backward, and move left and right). The PCB stack includes a Raspberry Pi as the central processor for the device, controlling wireless and wired communication, the LED matrix, and the measurement of the position of the user's center of balance at a rate of approximately 50 Hz. The stack also provides robust fixturing for the 22-pin D-Sub connector, which is used to connect to the load cells embedded in the platform via a flat flexible cable, as well as for the mini USB port for a wired connection to the gaming PC for the game console adapter.

To ensure safety during game play, height-adjustable handrails were located on 3 sides of the GAIMplank. In addition, a Microsoft adaptive controller was integrated into the system to facilitate the use of external buttons and triggers used during game play.

Figure 1. Proof-of-concept balance board prototype.

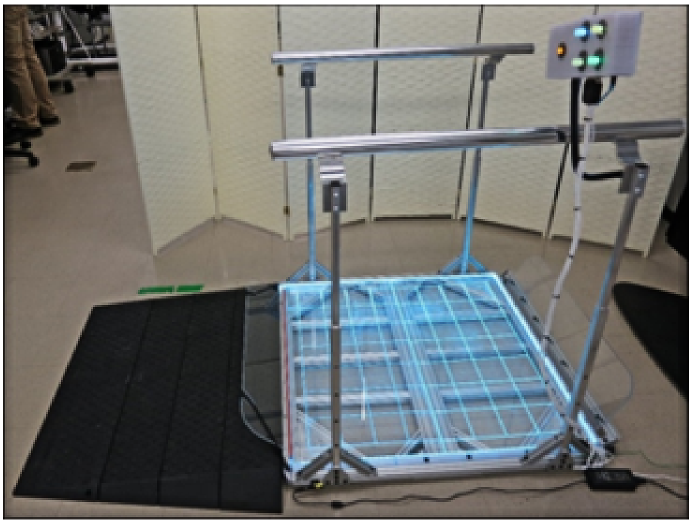


Figure 2. Early proof-of-product conceptual design for inpatient rehabilitation market.

Figure 3. Final proof-of-product design and prototype for the GAIMplank video game controller. Photos on the left show the top view (upper left) and bottom view (lower left) of the board before the final coating and graphics were applied (right).

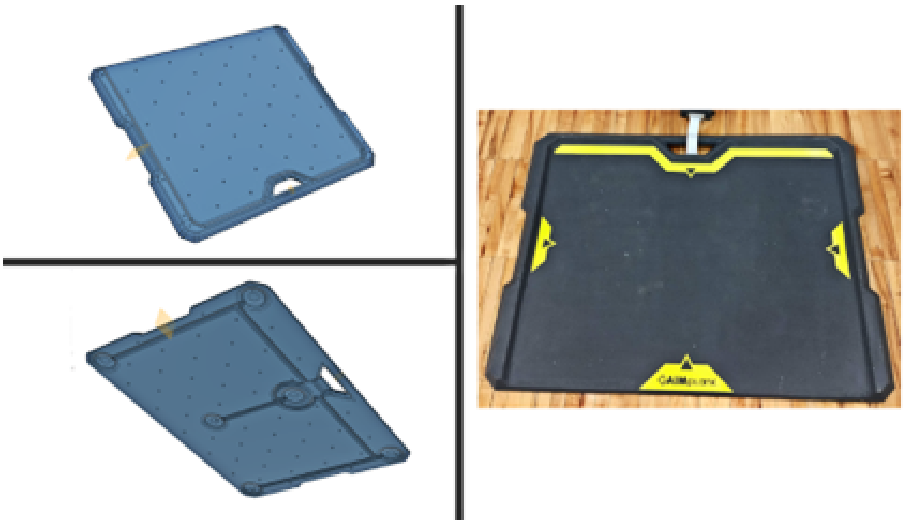


Figure 4. Picture of the GAIMplank app with slider bars used to calibrate the device; select mode of play; and adjust sensitivity, bias, and dead zone area.

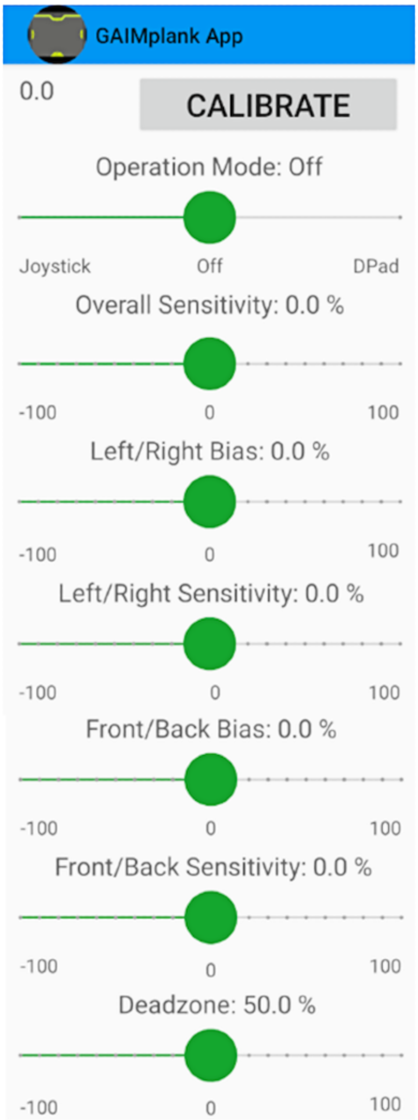
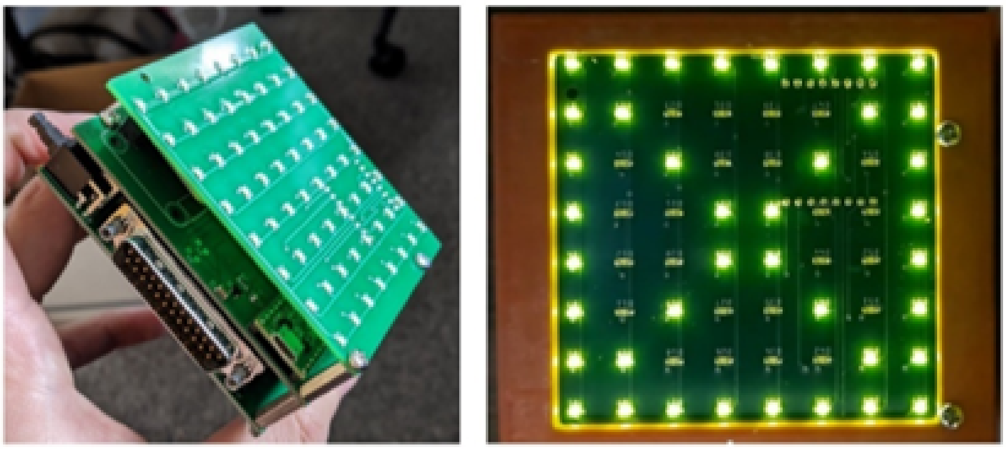


Figure 5. Proof-of-product design of the GAIMplank electronics stack.



Usability Testing

Design and Setting

Data collection for usability testing was performed at the RERC RecTech Exercise Science and Technology Laboratory (University of Alabama at Birmingham). For the purposes of this study, participants came to the laboratory for a single visit, which lasted for approximately 60-90 minutes.

Ethics Approval

All study procedures were approved by the institutional review board at the University of Alabama at Birmingham (IRB-300003265).

Participant Recruitment

Participants were recruited via flyers and word of mouth at a local community health and fitness center for individuals with physical disabilities and chronic health conditions. To assess the usability of the GAIMplank for different play styles (sitting in a chair, personal wheelchair, and standing), recruitment was stratified. Sample size estimates were based on identifying common usability barriers and issues specific to the 3 game play styles. According to Cazañas et al [19], a sample of 17 individuals would reasonably identify 80% of common problems in the system, with groups of 4 to 9 sufficient to identify problems specific to the mode of play. Additional participants were recruited to account for modest attrition.

Inclusion criteria for potential participants were (1) age 18-75 years; (2) a self-reported lower extremity mobility disability (eg, spina bifida, cerebral palsy, muscular dystrophy, >1 year after spinal cord injury, multiple sclerosis, stroke, or limb loss) with partial or full use of the upper extremities; (3) mobility impairment (ie, gait deviation and balance issue) or use of an assistive device (manual wheelchair, walker, crutches, and canes) for balance or mobility purposes; (4) ability to use arms for exercise; and (5) body weight <180 kg. Exclusion criteria included (1) significant impairment in visual acuity that prevents seeing a 52” television screen to follow exercise, (2) cardiovascular disease event within the past 6 months, (3) severe pulmonary disease or renal failure, (4) current pregnancy, (5) ongoing exacerbation of a health condition, and (6) other conditions that would interfere with intervention or testing procedures. Following the distribution of a flyer, the project recruitment coordinator answered calls from or met interested individuals. If contacted, the recruitment coordinator reviewed the inclusion and exclusion criteria using a screening form to determine whether they were eligible to participate.

Testing Session

Upon arrival at the laboratory, all study procedures were reviewed with the participant. After being given an opportunity to ask questions, the participants provided informed consent. Before the testing began, basic demographic information, along with information regarding minutes of weekday and weekend physical activity, minutes of weekday and weekend video game play, and video game play experience were collected. All procedures for data collection and video game operation were reviewed with the participants before game play. The participants were then settled at the GAIMplank station. Before playing the first game, a calibration procedure was conducted by following a pattern of movements as indicated on the LED matrix.

The GAIMplank was mapped to operate as a typical joystick controller. Leaning movements of the trunk created corresponding actions in the game (ie, lean forward to move character forward and up, lean right to move character right; Figure 6). The participants played a total of 5 preselected video games. The game Feather, a slow-paced flying game, was played first by all participants to introduce them to the movements required for operating the GAIMplank. The order in which the remaining 4 games were played was randomized. To minimize offensive content, the games had an Entertainment Software Rating Board score of E (Everyone), E+10, or Teen. The description of each game played and movements required is provided in Table 1. Each game was played for approximately 5 minutes.

Figure 6. Participants standing (right), seated in a chair (upper left), or wheelchair (bottom left) engaging in active video gaming using the GAIMplank controller. Game play movement was controlled by shifting the body weight or leaning forward, back, right, left as needed. External buttons to activate actions such as jump or shoot could be configured in various formations on a flexible arm within the player's reach. A trigger button used for acceleration or shooting could be held in the hand or placed on the external button pad.

Table 1. Description of games played and movements required.

Game	Genre	Game description	Trunk leaning movements required	External buttons used
Feather	Flight; exploration	Relaxing flight to explore a scenic nature landscape	Left, right, forward (down), backward (up), diagonal	None
Let's Go Nuts	2D platformer; action	Jump, avoid danger, and collect nuts as you progress through the levels	Left, right	1 large button for jump
Horizon Chase Turbo	Racing; sports; arcade	Arcade racing games with various cars and tracks to select from	Left, right	Variable trigger for car acceleration
PAC-MAN Championship Edition DX+	Arcade; action	Move through the maze in this classic ghost chomping arcade game	Left, right, forward (up), backward (down)	1 large button to scare away the ghosts
Stardust Galaxy Warriors	Shooter; action	Soaring through space using various weapons to combat asteroids and enemy ships	Left, right, forward (up), backward (down), diagonal	Up to 4 buttons for weapon use

Measures

Quantitative Measures

The participants' responses to a series of survey measures were collected during the session. Descriptive information was collected regarding enjoyment and current level of physical activity and video gaming. Before beginning game play, participants were shown a short video demonstrating a player using the system under 3 different conditions: sitting in a 4-legged chair, sitting in a wheelchair, and standing.

Given that higher self-efficacy is correlated with higher exercise participation [20], positive physical activity behaviors [21], AVG enjoyment [22], exercise adherence [23], exercise duration [24], and AVG approval [25], participants were asked to rate their level of task self-efficacy after watching the video. This scale (Multimedia Appendix 1) was developed based on the recommendations of Bandura et al [26] and consisted of 6 items that best represent the dimensions of the task. These dimensions equally represent the steps to the Videogame Interaction Model proposed by Yuan et al [27], which include receiving stimuli, determining response, and providing input. Each item on the scale was scored on an 11-point Likert scale from no certainty (0) to absolute certainty (10) in performing the 6 dimensions related to game play (maintaining focus, seeing and hearing game information, reacting fast, determining movement strategies, coordinating movements, and moving well). The gradations of scoring for the scale were consistent with expert recommendations for measuring self-efficacy [26]. Participants rated their self-efficacy again at the end after playing all 5 games. An average score for the 6 items was calculated, with a higher score indicating greater self-efficacy in their ability to execute game play actions.

After playing each game, participants were asked to rate their level of perceived exertion (rating of perceived exertion [RPE]) and enjoyment. For RPE, the 0 (extremely easy) to 10 (extremely hard) point adult OMNI scale was used [28]. For enjoyment, participants were presented with a visual analog scale, with anchors from "Not at All Enjoyable" on the left to "Extremely Enjoyable" on the right, and were asked to mark a spot on the line to represent their enjoyment.

After finishing all game play, participants were asked to complete 2 usability surveys. The participants' perceived usability of the adapted video gaming controller was assessed using the System Usability Scale (SUS) and Health-IT Usability Evaluation Scale (HITUES). These 2 scales were selected to obtain general system usability data (SUS) in addition to usability data specific to AVG play using the GAIMplank (HITUES).

For the SUS, respondents answered 10 questions using a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). The SUS is widely used as a reliable and valid measure of a system's usability [29-31]. Reliable results can be obtained with small samples [32], and the tool is applicable to a wide range of systems [29,33]. Using the recommended scoring guidelines, the SUS produces a score ranging from 0 to 100 [31,34]. An average SUS score of 68 corresponds to a percentile ranking of 50%, so a score >68 would be considered above average, and a score <68 is considered below average [30,33]. Adjective ratings, to help with interpretation, have been found to correlate well with the SUS scores [35].

The HITUES consisted of 20 items rated on a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). The HITUES has 4 sections with questions to address impact, perceived usefulness, perceived ease of use, and user control. Furthermore, the HITUES allows questions to be tailored to the system under study. For the purposes of this study, each question was phrased to assess the use of the "adapted gaming board" for "active video gaming" (Multimedia Appendix 2). Studies have demonstrated the reliability and validity of the HITUES [36-38]. One recent study suggested a cutoff score of 4.32 to indicate acceptable usability, but further validation studies are required to confirm this [39].

Qualitative Measures

Completion of the usability surveys was then followed by collection of feedback data via surveys and semistructured interviews. The questions for both were written with input from members of our engineering team to obtain feedback regarding current usability and to identify issues that needed to be addressed in future iterations and to help in the next phase of the GAIMplank development. Initially, the participants provided written responses to a series of multiple choice, yes or no, and short answer questions to obtain feedback regarding the system (Multimedia Appendix 3). Participants completed these questions on their own. After the first 8 participants, the research staff began conducting semistructured interviews with participants to facilitate more in-depth responses. Using an interview guide (Multimedia Appendix 4), the feedback questions were asked by a member of the research team in a semistructured interview format, with simple prompts (eg, please tell me more) given when appropriate. The interviews were audio recorded and later transcribed.

Results

Overview

A total of 21 adults (n=15, 71% men and n=6, 29% women) completed the usability testing. The participant characteristics are provided in Table 2. The mean age of the participants was 48.8 (SD 13.8; range 21-73) years, with 57% (12/21) White, 38% (8/21) Black, and 5% (1/21) Asian. All participants had a mobility impairment resulting from a physical disability, including stroke (9/21, 43%), spinal cord injury (3/21, 14%), amputation (3/21, 14%), cerebral palsy (2/21, 9%), spina bifida (2/21, 9%), or other (2/21, 9%). The primary modes of mobility included walking without an assistive device (7/21, 33%), cane (6/21, 29%), prosthetic leg (1/21, 5%), rollator walker (1/21, 5%), and manual wheelchair (6/21, 29%). The participants played in 1 of the following 3 ways: standing (8/21, 38%), seated in a 4-legged chair (7/21, 33%), or seated in their own manual wheelchair (6/21, 29%).

Participants reported enjoyment of leisure time physical activity, were physically active, and varied in their level of video game play (Table 3). All but 2 participants were aware of AVG. The 2 most preferred devices for playing video games included video game consoles and cell phones.

The usability data for each individual participant are reported in Table 2, with the summary group scores in Table 4. Subscale scores (usability and learning) for the SUS usability tool are also reported. The overall SUS score for all participants was 74.8 (SD 14.5), suggesting above average usability for the GAIMplank. On the basis of the adjective ratings for the SUS scale as provided by Bangor et al [35], the participant scores suggested *good* usability. When broken down by play style group, the average SUS scores indicated that the usability was best for those who played while seated in a chair, followed by those who played standing, and lowest for individuals who played while seated in their own wheelchairs. A similar pattern of scores was seen with the HITUES scale, with an average score of 4.3 (SD 0.3) for all participants. The HITUES scores can range from 1 to 5, with a higher score indicating greater usability.

RPE and enjoyment scores are reported for each game by play style group in Table 5. RPE scores ranged from light to moderate intensity, with the highest scores for those who played while seated in a chair. Participants rated their experience with playing each game from above average to very enjoyable.

The task self-efficacy questions were used to gauge the participants' self-efficacy in performing certain video game play tasks using the GAIMplank system. Above average scores were reported by all 3 groups for each task (Table 6). It appears that one exposure to video game play with the GAIMplank did not diminish their task self-efficacy, and the participants felt confident in their ability to complete game video play tasks using the GAIMplank system.

Table 2. Participant characteristics and usability scores presented by play style grouping (wheelchair, seated, and standing).

ID	Age (years)	Sex	Condition	Primary, secondary assistive device	GAIMplank play style	Enjoy video game play (1-5)	Video game play (minutes per week)	SUS[a] total score	HITUES[b] score
4	38	Male	Spinal cord injury	Wheelchair	Wheelchair	5	320	52.5	4.35
12	52	Male	Spinal cord injury	Wheelchair	Wheelchair	4	480	70	4.3
13	52	Male	Double above-knee and double below-elbow amputation	Wheelchair	Wheelchair	4	210	87.5	4.18
14	39	Male	Spina bifida	Wheelchair	Wheelchair	5	120	40	4.15
20	48	Female	Spina bifida	Wheelchair	Wheelchair	3	0	87.5	4.1
21	58	Male	Spinal cord injury	Wheelchair	Wheelchair	5	2520	62.5	3.6
2	65	Male	Stroke	Cane	Seated	1	0	82.5	4.75
3	73	Male	Stroke	Cane	Seated	4	30	90	4.5
6	70	Male	Stroke	Cane, walker, wheelchair	Seated	5	30	87.5	4.6
7	63	Male	Stroke	Cane, wheelchair	Seated	4	0	x	x
8	41	Female	Stroke	Cane, wheelchair	Seated	2	0	67.5	4.3
10	48	Male	Stroke	None, cane	Seated	5	0	90	4.58
15	63	Male	Spinal cord injury	Rollator	Seated	4	70	80	4.58
1	50	Male	Stroke	Cane, wheelchair	Stand	5	60	62.5	4.8
5	42	Male	Single above-knee amputation	Prosthetic leg	Stand	5	1380	72.5	4.15
9	59	Female	Stroke	Walk	Stand	4	900	75	4.05
11	42	Female	Stroke	None, cane	Stand	5	630	97.5	4.45
16	29	Male	Cerebral palsy	None	Stand	4	320	65	4.15
17	32	Female	Single below-knee amputation	Prosthetic leg, wheelchair	Stand	5	1275	77.5	4.6
18	21	Female	Hydrocephalus, balance issues	None	Stand	4	10	85	4.43
19	40	Male	Cerebral palsy	None	Stand	3	0	62.5	4.15

[a]SUS: System Usability Scale.

[b]HITUES: Health-IT Usability Evaluation Scale.

Table 3. Participants' enjoyment of physical activity, weekly minutes of physical activity, enjoyment of playing video games, and weekly minutes of video game play.

	All (n=21), mean (SD)	Wheelchair (n=6), mean (SD)	Seated in chair (n=7), mean (SD)	Standing (n=8), mean (SD)
I enjoy engaging in physical activity during my leisure time (1=strongly disagree, 5=strongly agree)	4.6 (0.6)	4.5 (0.5)	4.7 (0.5)	4.5 (0.8)
Weekday leisure-time physical activity that increases heart rate (minutes)	259 (177)	263 (230)	248 (171)	263 (163)
Weekend leisure-time physical activity that increases heart rate (minutes)	116 (103)	100 (131)	108 (70)	134 (111)
I enjoy playing video games (1=strongly disagree, 5=strongly agree)	4.1 (1.1)	4.3 (0.8)	3.6 (1.5)	4.4 (0.7)
Weekday video gaming (minutes)	264 (462)	462 (756)	14 (27)	359 (389)
Weekend video gaming (minutes)	138 (219)	204 (296)	4 (11)	213 (230)

Table 4. Self-reported GAIMplank usability scores.

Game play style	SUS[a] overall, mean (SD)	SUS: usability subscale, mean (SD)	SUS: learning subscale, mean (SD)	HITUES[b], mean (SD)
All players	74.8 (14.5)	75.2 (15.5)	73.1 (24.8)	4.3 (0.3)
Wheelchair (n=6)	66.7 (19.0)	66.7 (19.2)	66.7 (30.3)	4.1 (0.3)
Seated in chair (n=7)	82.9 (8.6)	85.4 (10.8)	72.9 (16.6)	4.6 (0.1)
Standing (n=8)	74.7 (12.1)	73.8 (12.3)	78.1 (27.3)	4.3 (0.3)

[a]SUS: System Usability Scale.

[b]HITUES: Health-IT Usability Evaluation Scale.

Table 5. Rating of perceived exertion and enjoyment rating for each game by player group.

Game	Rating of perceived exertion (0-10), mean (SD)	Enjoyment (0-100), mean (SD)
All players, across games	4.2 (1.7)	72.3 (16.5)
Wheelchair	4.5 (1.1)	68.9 (12.4)
Seated in chair	5.1 (2.2)	79.5 (21.1)
Standing	3.4 (1.5)	69.4 (15.7)
Feather	3.4 (1.9)	62.7 (32.7)
Wheelchair	3.7 (1.4)	68.5 (23.9)
Seated in chair	4.0 (2.2)	69.0 (38.9)
Standing	2.6 (1.9)	52.9 (34.3)
Let's Go Nuts	3.6 (2.0)	76.3 (17.8)
Wheelchair	4.0 (1.1)	67.3 (15.8)
Seated in chair	4.3 (2.9)	78.2 (17.7)
Standing	2.7 (1.5)	82.3 (18.9)
Horizon Chase Turbo	4.0 (2.0)	70.1 (28.5)
Wheelchair	4.0 (1.5)	65.8 (18.0)
Seated in chair	5.0 (2.2)	71.3 (45.0)
Standing	3.0 (1.9)	72.3 (18.0)
PAC-MAN	4.9 (2.2)	66.3 (24.6)
Wheelchair	5.3 (2.3)	68.8 (18.2)
Seated in chair	5.5 (2.7)	66.7 (36.8)
Standing	4.1 (1.8)	64.1 (20.6)
Stardust galaxy warriors	5.2 (1.9)	80.9 (15.2)
Wheelchair	5.5 (1.4)	74.0 (4.2)
Seated in chair	6.0 (2.5)	91.7 (11.7)
Standing	4.3 (1.4)	77.9 (19.0)

Table 6. Self-reported task self-efficacy before and after the game play session.

Task self-efficacy question	All (n=21), mean (SD)		Wheelchair (n=6), mean (SD)		Seated in chair (n=7), mean (SD)		Standing (n=8), mean (SD)	
	Before	After	Before	After	Before	After	Before	After
Maintaining focus throughout a 15-minute session	8.8 (1.7)	9.6 (0.9)	9.5 (1.2)	10.0 (0.0)	7.1 (1.9)	8.7 (1.2)	9.8 (0.7)	10.0 (0.0)
Seeing and hearing all the game information	9.4 (1.3)	9.6 (0.9)	9.5 (1.2)	9.7 (0.8)	9.0 (1.9)	9.3 (0.8)	9.8 (0.7)	9.6 (1.1)
Reacting fast enough to choose a next action	7.0 (2.0)	7.7 (1.8)	6.5 (2.3)	7.3 (1.4)	6.1 (1.6)	6.7 (1.9)	8.1 (1.6)	8.6 (1.6)
Determining strategies to move during play	7.0 (2.6)	7.7 (1.8)	5.8 (3.3)	7.0 (1.7)	6.0 (2.2)	6.7 (1.9)	8.6 (1.7)	8.9 (1.4)
Coordinating body movements to carry out a strategy	6.9 (2.5)	7.7 (1.8)	6.2 (3.5)	7.7 (1.0)	6.0 (1.7)	7.7 (1.2)	8.1 (1.8)	7.8 (2.7)
Moving well enough to maintain successful play	7.0 (2.4)	8.1 (2.0)	5.7 (2.4)	7.7 (2.1)	6.6 (2.4)	8.3 (1.2)	8.3 (2.0)	8.3 (2.5)
Overall	7.7 (1.7)	8.4 (1.1)	7.2 (1.8)	8.2 (0.8)	6.9 (1.9)	7.9 (0.8)	8.8 (1.1)	8.9 (1.4)

Participant Feedback

Overview

Feedback data were collected in a written response to multiple choice, yes or no, and open-ended survey questions (6/7, 86% seated and 1/7, 14% standing) or orally via a semistructured interview (5/11, 45% wheelchair; 1/11, 9% seated; and 5/11, 45% standing) conducted by the researchers. Data were missing for 1 survey participant and 2 interview participants.

From the survey feedback, when asked about the ease of mounting and dismounting the gaming board as "relatively simple," "needs improvement," or "difficult," all participants rated both actions as "relatively simple." When asked whether the gaming board was sturdy, 6 of the 7 participants reported "yes." All participants indicated that "yes" they were able to determine where best to position themselves on the gaming board and 86% (6/7) reported that "yes" visual cues should be included to locate the central position (on the gaming board). In addition, 86% (6/7) of participants indicated that "yes," moving their trunk (leaning) provided a responsive input for game control. Additional input functions that the participants would like to see incorporated into the gaming board included visual markers for foot placement, more games, and moving the side handrails closer. When asked to describe their overall experience on the gaming board, comments included "Positive, thank you!" "Very good," "Something new to keep alert and enjoy," "Entertaining," "A lot of fun," "It was cool to watch my character turn as I leaned left or right," and "It was great. It was challenging because I am not a gamer, but it was a good challenge."

Audio recordings of the interviews were transcribed verbatim. The transcripts were then reviewed independently by 2 members of the research team. From the independent reviews, themes were drawn, followed by discussion and review, with a final consensus reached on 5 main themes. These themes included accessibility of the GAIMplank for persons with mobility impairments, usability of the GAIMplank for persons with mobility impairments, overall experience using the GAIMplank, physical activity associated with game play, and suggestions for future iterations.

Accessibility of the GAIMplank

This category examined the perceptions of the participants regarding the accessibility of the GAIMplank controller for video game play. Three specific features were discussed, including mounting and dismounting of the GAIMplank, handrails, and accessories. Most participant comments indicated adequate accessibility for video game play. None of the participants reported difficulty in mounting or dismounting the GAIMplank. The handrails provided support when needed, an overall sense of safety, and facilitated greater movement during game play by reducing the fear of falling.

Overall, the use of an assistive device during the session (ie, manual wheelchair or prosthetic limb) did not inhibit gaming activities. For participants who played seated in their manual wheelchair, blocks were placed behind their back wheels to keep them stationary for a better response to their movements. However, both participants who wore a prosthetic leg (one above the knee and one below the knee amputee) reported that they had to adjust their stance on the GAIMplank to obtain a better response.

The positioning of the external buttons and variable trigger used for game play actions such as jumping, shooting, and car acceleration was acceptable for all participants. Participants reported that the ability to adjust the height of the buttons and position them relative to their arm reach and preferred side (right, left) facilitated game play. The participants felt that the size of the buttons was suitable and that they were easy to access. One participant, who had difficulty keeping his hand on the buttons because of partial paralysis, reported that the surface friction of the buttons could be improved.

Usability of the GAIMplank

This category describes the participants' perceptions regarding the use of the GAIMplank controller for playing video games. Specific aspects that were discussed included learning how to move for game control and responsiveness of the GAIMplank. Participants across the 3 groups acknowledged that it took some time to learn how to control and shift their weight to maneuver their character in the game. Sometimes it took time for them to feel secure to move.

Some participants reported inconsistency issues with the GAIMplank not calibrating correctly and not being responsive to their weight shifts. In some instances, recalibrating the system helped. Despite technical issues with the board during some sessions, the participants felt positive and eager to continue playing. Regardless of responsiveness issues with the GAIMplank, several participants indicated that this was the first time they were able to play such games because of accessibility issues with other AVG systems.

Overall Experience Using the GAIMplank for Video Game Play

Participants described their overall experience using the GAIMplank for video game play. Participants mainly shared positive feedback regarding their experiences with the device. As noted above, the most frequently reported barrier affecting the overall experience was the inconsistency in responsiveness of the GAIMplank system. Specific aspects highlighted by the participants regarding the GAIMplank were that the device is innovative, playing video games using the GAIMplank increases the physical activity demands of videogaming, and using the device is enjoyable. The participants expressed an interest in participating in future AVG research projects and having a device like the GAIMplank in their home setting.

"Active" Video Gaming

Several participants noted that playing video games using the GAIMplank system provided a level of physical activity. Participants described how they enjoyed the experience of moving their body to play the games instead of sitting on the couch and simply using a handheld controller or their phone. Although some frustration was experienced when the controller did not respond as expected to their movements, the participants acknowledged the value of this accessible controller in allowing them to engage in AVG play, which most of the participants were unable to do with current OTS products. Description of their game play experience included statements such as the following:

> *I like the board because I get to move with my body versus just sitting down. Gets me up instead of just using phone. This gaming board encourages body movement.* [AVGu011, walks without an assistive device, played standing]

> *It was fun. It was different. With me I'm reserved to buy some of the more active games, not knowing if I can do them. To come to a controlled environment and be able to do the movements, able to sense the movements with a prosthetic.* [AVGu017, walks with a prosthetic leg, played standing]

> *Use the whole body. It would be great to know how many calories burned.* [AVGu013, uses a manual wheelchair for mobility, played in a wheelchair]

> *But at the same time its accomplishing different goals, its being more core strength and stuff than with a (hand) controller and so...(shoulder shrug).* [AVGu014, uses a manual wheelchair for mobility, played in a wheelchair]

Future Iterations

The participants were asked to provide suggestions for improving the GAIMplank and any additional features they would like to see incorporated. The input from standing players included visual markers for foot placement, inward adjustment of handrails, handrail hook–like grip to accommodate persons without dexterity, and elevated placement of the LED matrix for better visibility. For individuals who were seated in their wheelchair, a suggestion was made to eliminate the use of the blocks behind the back wheels by adding some sort of ridge or divot to keep them from rolling.

Researcher Observations

During data collection for several participants (approximately 50%), technical difficulties with the GAIMplank controller occurred. The most frequent were calibration issues. During these sessions, the calibration procedure did not work as intended resulting in an inability of the device to find center, and causing difficulty for players to produce the necessary actions for game play. Recalibration and adjustments to the sensitivity and bias were attempted, but the problem was not corrected. Adjustments to the participant's positioning on the board were also attempted, but these were not successful. Sometimes it was just one particular game during a session that would not respond to the participant's movement. A pattern to these difficulties was not detected, and usually during the next testing session the controller worked appropriately. Specific issues based on play style (wheelchair, seated in a 4-legged chair, or standing) were not evident, except for participants who played standing and were not able to distribute their weight evenly. It appeared that the calibration procedure may not have accounted for this shift in body weight. Owing to time constraints, sufficient time was not always available to spend on troubleshooting during participant visits. Although enjoyment and RPE scores were likely affected by technical issues, participants still reported having fun and felt confident in their ability to use the system. Participants also recognized the system as providing an opportunity, typically not available to them, to engage in AVG.

Discussion

Principal Findings

Physical activity options are limited for people with mobility impairments. AVG, also known as exergaming, has the potential to provide a fun and engaging way to increase daily physical activity or reduce sedentary time. This project aimed to develop an AVG controller that was accessible and usable by individuals with mobility impairments. A sample of 21 adults with various mobility impairments was able to successfully access and play a series of standard PC video games using trunk and body movements to produce game play action. Participant usability scores (SUS and HITUES) and qualitative feedback indicated above average usability for the GAIMplank system. A previous study adapted the Wii Fit balance board controller and demonstrated successful use among people with mobility impairments with an average SUS score of 71.7 (SD 18.03) [17]. Physiological testing during game play on the adapted board indicated light-to-moderate intensity exercise for some participants [18]. This previously adapted gaming board controller was limited to use with only Wii Fit games, whereas the new GAIMplank system includes several new options for playing AVGs among people with mobility impairments and allows use with all PC games. The GAIMplank system provides a means for making games that are typically sedentary, using only the hands and fingers, more active by incorporating larger body movements. Furthermore, participants reported game play enjoyment and for some their first opportunity to engage in AVG owing to accessibility issues with OTS systems.

Looking at the average SUS scores for each participant, the lowest score was 40, well below what is considered acceptable usability. Similarly, the participant's HITUES score (4.18) suggested below acceptable usability. The participant was a regular video game player (120 minutes per week), played seated in his wheelchair, reported moderate level enjoyment across games, game play was rated as a light-intensity exercise, and a large drop in self-efficacy was reported at the end of the session for the questions that pertained to reacting fast enough to choose the next action and moving well enough to maintain successful play. His postplay feedback highlighted issues with responsiveness, which he found frustrating. The next lowest SUS score (52.5) was also reported by a wheelchair user, which can be attributed to the GAIMplank malfunctioning, making the calibration off and the games moving slow. Regardless, this participant who was physically active (960 minutes per week) and a frequent video game player (320 minutes per week) reported above average enjoyment scores, game play as light-intensity exercise, with an improvement in overall self-efficacy after using the GAIMplank system. Of the 4 other participants who reported less than optimal usability (62.5-65), 3 (75%) were standing players who were all physically active, with varying levels of weekly video game play. Two players also had low HITUES scores (4.15) and reported moderate enjoyment, light-intensity exercise, and above average self-efficacy. In both cases, technical issues were encountered with the GAIMplank system during the testing session, resulting in poor responsiveness and making the games very difficult to play. The other standing player typically used a rollator to assist with mobility but was able to play without it. His average enjoyment score was high (86) with light-intensity RPE ratings and maximum self-efficacy scores. Although his SUS score was low (62.5), his HITUES score (4.8) was the highest among all participants. These scores may suggest that although the participant perceived general usability (SUS) issues with the system, he recognized the usability of the GAIMplank as an adapted controller to provide an option for active video game play for individuals with mobility impairments.

At the other end of the spectrum, 7 players reported "excellent" usability (SUS ≥85) for the GAIMplank system. Of those, 2 played in their wheelchair, 2 played standing, and 3 played while seated in the chair. For the standing and seated players, the HITUES scores reflected acceptable usability. All 3 seated players (poststroke) spent little to no time playing video games each week but were physically active, with 2 reporting >400 minutes per week of physical activity. The average enjoyment scores were high, the RPE scores varied, and all were reported to have certainty in their ability to conduct various video game play tasks using the GAIMplank system. Both standing participants were physically active (120 minutes per week); one spent a lot of time playing video games each week (630 minutes), whereas the other played very little, if any. Average enjoyment scores were higher for the person who typically spent a lot of time playing video games each week, whereas RPE was higher for the other participant. Both participants reported high self-efficacy in using the GAIMplank system for video game play. Both participants who played seated in their wheelchairs with high SUS scores were physically active (120 minutes per week); one spent a lot of time playing video games each week (210 minutes), whereas the other one played none. The HITUES scores were lower than those of other participants who reported high SUS scores. Both players enjoyed the games, with RPE scores indicating light-to-moderate intensity exercise. The self-efficacy scores were high for both players at the end of the session.

The results demonstrate the usability of a newly developed adapted gaming board for AVG play, but attention is needed to improve the stability of responsiveness and to address issues experienced by different subgroups of individuals with mobility impairments. Considerations for the engineering team during the next phase of development include different weight distribution patterns during game play by individuals wearing a prosthetic leg, varying movements associated with spasticity among certain players, foot placement outside the board (ie, on stool in front) for some seated players, and overall improvement to better accommodate wheelchair play. Overall, the ability of the adapted controller to provide a fun and accessible option for AVG play was clearly recognized by the players, suggesting the need for additional development and research in this area.

Study Limitations

The heterogeneous nature of the sample makes it difficult to determine whether different aspects of the GAIMplank better suited one group over another. The number of participants within each play style group was small and consisted of individuals with various mobility impairments. In addition, participants were recruited from a community-based health and fitness center, so all had experience with physical activity and were currently active with reported weekly physical activity minutes ranging from 60 to 960 (mean 375, SD 257) minutes. Therefore, the results cannot be generalized to more sedentary populations. Previous gaming experience was captured, but its influence on system usability or their game play experience could not be teased out. With regard to the specific games used for the sessions, game selection was limited and may not have appealed to some participants. In addition, sufficient time to learn how best to move for each game was not provided. Initially, qualitative feedback data were not collected from participants. As the need for more in-depth user input was recognized, semistructured interviews were conducted to collect richer feedback data. This change occurred after most of the seated players had completed testing; therefore, limited qualitative data were available from this group.

Future Considerations

Continued testing and refinement of the GAIMplank system are underway. The usability testing results were discussed with the engineering and design teams, and a new wave of refinements is planned with a focus on improving the stability of the platform. Specifically, elimination of the Raspberry Pi and addition of a custom-fabricated PCB board are being considered. Following further refinement of the system, the plan is to conduct a feasibility study to examine the use of the GAIMplank for an AVG exercise intervention. The outcomes of interest will include various physiological and psychosocial measures. Other factors to be considered include game play selection and preferences, previous gaming experience, participants' physical activity level, and single versus multiplayer options. In addition, consideration of factors that affect game play-by-play style (eg, seated and standing) needs to be examined. The potential of integrating other gaming controllers is also of interest.

Conclusions

The GAIMplank, an adapted gaming controller, allowed people with various mobility impairments to engage in AVG. Using the GAIMplank system, standard PC video games can be played while sitting, standing, and in a manual wheelchair. Participants reported above average usability for the GAIMplank and found game play to be enjoyable and provide light-to-moderate intensity exercise. Further design and development work to refine the device is recommended.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey to assess participant pregame and postgame play self-efficacy.

[DOCX File , 18 KB - games_v11i1e38484_app1.docx]

Multimedia Appendix 2

Health-IT Usability Evaluation Scale used to collect usability data specific to active video gaming using the GAIMplank.

[DOCX File , 23 KB - games_v11i1e38484_app2.docx]

Multimedia Appendix 3

Survey questions used to gather additional feedback from participants regarding the GAIMplank.

[DOCX File , 18 KB - games_v11i1e38484_app3.docx]

Multimedia Appendix 4

Questions used to guide semistructured interview with participants to collect feedback data at the end of game play using the GAIMplank system.

[DOCX File , 18 KB - games_v11i1e38484_app4.docx]

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Abbreviations

AVG: active video gaming
HITUES: Health-IT Usability Evaluation Scale
OTS: off-the-shelf
PCB: printed circuit board
PoC: proof-of-concept
PoP: proof-of-product
RPE: rating of perceived exertion
SUS: System Usability Scale

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Original Paper

Impact of Gamification on Consumers' Favorability in Cause-Related Marketing Programs: Between-Subjects Experiments

Yanhe Li[1*], PhD; Yanchen Li[2*], PhD; Xiu Zhou[3*], PhD; Kunshu Ma[4*], PhD

[1]School of Management, Zhejiang Shuren University, Hangzhou, China
[2]School of Business, Macau University of Science and Technology, Macau S.A.R, China
[3]School of Accounting and Finance, Beijing Institute of Technology, Zhuhai, China
[4]School of Management, Southwest Minzu University, Chengdu, China
[*]all authors contributed equally

Corresponding Author:
Yanchen Li, PhD
School of Business
Macau University of Science and Technology
Avenida Wai Long
Taipa
Macau S.A.R, 999078
China
Phone: 86 88972037
Email: ycli@must.edu.mo

Abstract

Background: Successful cause-related marketing (CRM) campaigns can help companies stand out from their competitors; however, CRM may not have pleasant outcomes, even if it receives substantial investment.

Objective: This research aimed to investigate how gamified CRM projects influence consumers' favorability.

Methods: We introduced 3 different CRM projects in 3 different studies. Every project had 2 versions according to the level of gamification, and participants were randomly assigned into these 2 groups. Additionally, we used a 2 (gamification: lower, higher) 2 (rules presentation: without visual cues, with visual cues) between-subjects design to test the moderation role of rules presentation in gamified CRM projects.

Results: In Study 1, we identified that the highly gamified CRM program induces more enjoyment ($F_{1,139}$=21.11, P<.001) and higher favorability ($F_{1,139}$=14.57, P<.001). Moreover, we found that enjoyment played a mediation role between gamification and favorability (P<.001) in Study 2. In addition, the results of Study 3 indicated rules presentation in a gamified CRM program can moderate the indirect effect of gamification on favorability via enjoyment (index of the moderated mediation: 95% CI –1.12 to –0.10; for rules presentation with visual cues: 95% CI 0.69 to 1.40; for rules presentation without visual cues: 95% CI 0.08 to 0.83).

Conclusions: Overall, this research contributes to the CRM literature and suggests gamification is an effective way of managing CRM campaigns.

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KEYWORDS

cause-related marketing; gamification; enjoyment; favorability; business; marketing; gamified

Introduction

Background

Corporate social responsibility practices are currently popular for firms to enable themselves to stand out from their competitors and achieve sustainable performance [1]. Generally, companies undertake cause-related marketing (CRM) as one solution to show their commitment to corporate social responsibility [2]. Successful CRM campaigns can help companies elicit positive attitudes [3] and emotional bonds between them and their customers [4]. However, CRM may not have pleasant outcomes, even if it receives substantial investment [5,6]. It is therefore critical to understand the related predictors so that practitioners can develop CRM activities that will have desirable outcomes.

Gamification is a new and effective way to generate CRM success. Recently, some companies have applied gamification to their CRM practices. For example, Alipay, one of the famous e-payment applications in China, launched a gamified CRM scheme called “Ant Forest” in 2016. Users grow virtual trees in Ant Forest by collecting game points. As users complete the game tasks, they earn points for taking buses, walking daily steps, or using online payment in a low-carbon lifestyle. After obtaining enough points, users can turn their virtual trees into real ones and thus contribute to environmental protection. The hedonic benefit provided by a gamified system motivates users to take action. However, to our best knowledge, few studies discuss gamified CRM and its impact on people's attitudes or behaviors [7]. In this article, we advanced previous research and performed empirical studies to answer related questions.

Enjoyment and Favorability

Consumers are not totally rational. As they make purchase decisions, they involve their fantasies, emotions, or other experiential perspectives rather than just processing the information [8].

Gamification is thus the popular choice for practitioners to satisfy consumers with utilitarian values, hedonic values, and social values [9]. On one hand, the concept of gamification originates from “game.” Gamification indicates the use of game design elements, game mechanisms, or games in nongame contexts [10]. It aims to provide consumers with positive emotional and involved experiences (ie, gameful experiences) [11]. On the other hand, some research (eg, Jung et al [12], Kim and Ahn [13], and Sailer et al [14]) has proved that game design elements (eg, points, badges, and leaderboards) can not only evoke users' intrinsic motivations and yield performance gains but also internalize extrinsic motivations (eg, external rewards).

Therefore, we believed that, compared with traditional CRM activities, consumers enjoy more hedonic values and feel as if they are more involved in gamified activities, leading to the following hypothesis: (H1) Gamification has a positive influence on enjoyment.

Consumers do not adopt CRM activities casually [6]. Consumers’ personal evaluation of or beliefs around the cause can influence the success of CRM [15]. Thus, in this study, we defined favorability as consumers' positive attitudes toward CRM activities [16,17], to measure the success of CRM programs.

Generally, CRM campaigns work when consumers benefit from feeling pleasure during participation [18]. We posited that consumers are more willing to accept gamified CRM activities, since they can offer more opportunities for consumers to interact with the cause and the perceived enjoyment from gamified CRM campaigns positively influence consumers’ favorability.

Extant research suggests that positive emotions can arouse individuals' positive attitudes [19]. Especially in the context of CRM, hedonic products that are associated with positive emotional processing are more likely to provoke emotional contagion; individuals thus have more favorable attitudes toward the CRM programs [20].

Although studies examining the relationship between enjoyment and favorability in the context of gamified CRM are lacking, various studies (eg, Yang et al [21], Catalán et al [22], and Hwang and Choi [23]) validated the positive influence of perceived enjoyment from gamification on positive attitudes, such as consumers’ brand attitudes [24], continuous use intention [25], and brand loyalty [26].

Therefore, we hypothesized that (H2) enjoyment has a positive influence on favorability and mediates the relationship between gamification and favorability.

Rules Presentation

Gamification embraces the nature of games. Importantly, rules are the core factors of games [27]. Containing various game mechanics [28], rules stipulate how to achieve the goal of a game and the outcome of each trial [29].

In this article, we defined rules presentation as the way of presenting the rules of a CRM project, with or without visual cues. We believe that the way rules are presented can influence people's enjoyment. Rules with visual cues tend to help people to process information fluently and thus induce enjoyment at a higher level. According to processing fluency theory, the ways of processing information vary from the degrees of effort and speed [30]. With a fluent process, it is faster and easier to make judgments; however, a process that is not fluent has the opposite effect.

Generally, individuals prefer a stimulus that is easier to perceive and tend to favor it [31-33]. Thus, fluency always results in positive outcomes [34]. Past research has shed light on that fact that fluency of information processing (eg, rules processing) leads to consumers' positive affective responses (eg, Janiszewski [35] and Gamblin et al [36]) or leads to purchase intentions (eg, Zhang et al [37], Jaud and Melnyk [38], and Wang et al [39]).

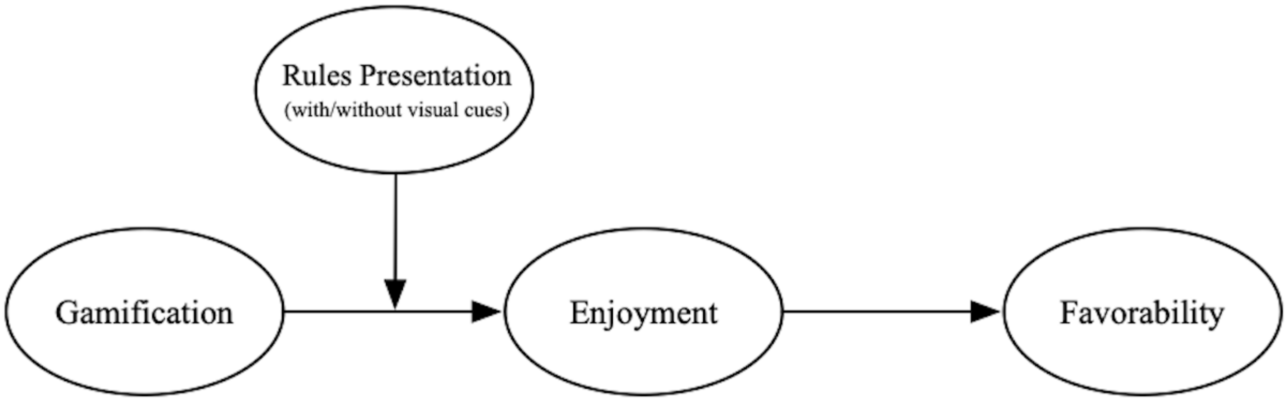
Meanwhile, fluent processes are always involved in visual categorization [40,41]. When faced with experiential-attribute (ie, affective or sensory) targets, consumers are more likely to receive stimuli and respond immediately, without elaborating or reasoning [42].

Therefore, we hypothesized that, if the rules of gamified projects are performed with visual cues (eg, in figurative or other sensory ways), consumers tend to perceive higher enjoyment. On the contrary, however, when the rules are presented in plain and monotonous literal words, consumers perceive less or even no enjoyment from gamified CRM programs. We thus predicted that (H3) visual cues in rules presentation moderate the relationship between gamification and enjoyment. People tend to have a higher level of enjoyment under the condition with visual cues (vs the condition without visual cues).

The conceptual model is illustrated in Figure 1.

Overall, this research aimed to test if consumers have a higher level of favorability to respond in the context of gamification and try to explain why gamification strategy can work. Specifically, we hypothesized that gamification has a positive influence on enjoyment and consumers' favorability toward gamified CRM programs and that enjoyment mediates the relationship between gamification and favorability. Moreover, we also hypothesized that visual cues in rules presentation can moderate the relationship between gamification and enjoyment. People tend to have a higher level of enjoyment under the condition with visual cues (vs the condition without visual cues). We described 3 studies in detail to test our hypotheses. Finally, we addressed the theoretical and managerial implications of this research and put forward some future research directions as suggestions.

Figure 1. Conceptual model.



Methods

Study Design in Study 1

We created 2 videos to introduce the Ant Forest of Alipay. The higher gamification version illustrated the real-life version of Ant Forest. For example, users can gain points by finishing certain assignments or games or stealing from friends. After accumulating enough points, they can turn their virtual plants into real ones. However, the lower gamification version presented a fictitious Ant Forest interface. We deleted all the add-in games. Specifically, users could only accumulate points from conducting eco-friendly behaviors (eg, using public transit) but could not accumulate points from other highly gamified methods (eg, finishing games or interactions with friends). Since the basic rules were retained, we regarded the fictitious version as a lower gamified program. To minimize noise, we kept 2 versions of the same visual designs (eg, images) and presentation length (ie, 30 seconds).

A pretest was first conducted to show that the 2 versions of Ant Forest were not significantly different in relevant factors except for the level of gamification. In the pretest, we told the participants to evaluate the given Ant Forest programs. Participants were randomly assigned to 1 of 2 conditions. We performed a confounding check of brand trust, brand attitude, and brand familiarity (7-point scales; see Multimedia Appendix 1 for details [43-45]). We then asked participants to rate the perceived gamification level. The measurement was adapted from that of Hwang and Choi [23]: "This Ant Forest program entails a game component." (1=Strongly Disagree; 7=Strongly Agree).

After the pretest, we collected a new data sample to conduct our main study. In the main study, we first provided 2 versions of the Ant Forest introduction videos and asked participants to rate their willingness to favor the programs. The measurement was adapted from that of Speed and Thompson [46]: "This form of Ant Forest makes me feel more favorable toward the program." "This form of Ant Forest would improve my perception of the program." "This form of Ant Forest would make me like the program more." (1=Strongly Disagree; 7=Strongly Agree; =.78). Second, to measure enjoyment, we used the scale from Höllig et al [47]: "I would find the program presented in the video game enjoyable." "I would find the program presented in the video game enjoyable and pleasant." "I would find the program presented in the video game enjoyable and exciting." "I would find the program presented in the video game enjoyable and interesting" (1=Strongly Disagree; 7=Strongly Agree; =.81). Third, we asked the participants to rate the perceived gamification level for our manipulation check. Finally, we also performed a confounding check.

Study Design in Study 2

In Study 2, we focused on the relationships among gamification, enjoyment, and favorability and tested if enjoyment plays the role of mediator (H2). We proposed that individuals are more likely to perceive higher enjoyment from a gamified CRM program and in turn have higher favorability toward the program (H2). In Study 2, we created a new stimulus to test the hypothesis. Moreover, to provide generalizability for our results related to H1, we also tested them in this study.

Similar to Study 1, we created 2 videos to introduce a CRM program sponsored by Douyin. Douyin (also known as "TikTok" in western countries) is a popular video-sharing social network service in China. The program is named “Dream Fairy” and aims to donate books to children. The higher gamification version was the real-life version of Dream Fairy in which users can gain points by watching or publishing instant videos, participating in question-and-answer games, or interacting with friends. When they have accumulated enough points, they can make their donations in reality. On the contrary, the lower gamification version presented a fictitious Dream Fairy interface. We deleted all the games. Specifically, users could only accumulate points from watching instant videos or lives and from publishing instant videos. They could not accumulate points from other highly gamified methods (eg, playing games or social interactions). We also kept 2 versions of the same image designs and presentation duration (ie, 30 seconds) to minimize noise in the data. In Study 2, we also performed a pretest and a main study to verify the internal validity.

Study Design in Study 3

In Study 3, we conducted the mediation analysis again as a robustness check and explored the moderation role of visual cues between gamification and favorability.

We proposed that rules presentation moderates the effect of gamification on enjoyment and finally influences individuals’ favorability toward CRM (H3). In Study 3, we provided the rules to participate in a CRM either with or without visual cues. Presumably, people tend to process rules with visual cues more fluently and thus perceive more enjoyment. Therefore, we anticipated that, when rules are presented with visual cues, a higher (vs lower) gamified CRM facilitates higher favorability.

In Study 3, we chose a CRM program called “Protect Pandas” as the stimuli material. This CRM program aims to protect pandas and is sponsored by Weibo, a quite trendy mobile application in China.

Similar to previous studies, we created 2 videos to introduce the CRM program. The higher gamification version was the true version in reality. For example, users can gain points by logging into the app; publishing, reading, sharing, or liking posts; commenting; or interacting with friends. After accumulating enough points, Weibo helps users to plant actual bamboo to feed pandas. On the contrary, the lower gamification version presented a fictitious interface. The higher game elements were all deleted. Users could not accumulate points from social interactions with friends but only from daily routine behaviors in the app (eg, publishing or reading posts). We kept 2 versions in the same image designs and presentation duration (ie, 30 seconds) to avoid noise in the data. A pretest and a main study were also conducted in Study 3.

Ethical Approval

The university institutional review board at Zhejiang Shuren University approved all data collection procedures and scales we used (20221225).

Data Source

All the data in this research were collected in Credamo, which is an online survey platform. The questionnaires were randomly distributed to a registered consumer panel by the platform system, and researchers can collect data in exchange for monetary compensation. All the studies performed in this research were in accordance with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). All participants provided written consent to participate in the research and were informed that they had the ability to opt out.

Results

Results of Study 1

Pretest

We recruited 50 participants from Credamo. The results revealed that there were no significant differences between the 2 conditions for brand trust (lower gamification mean 6.19; higher gamification mean 6.42; P=.17), brand attitude (lower gamification mean 6.04; higher gamification mean 6.22; P=.38), or brand familiarity (lower gamification mean 6.12; higher gamification mean 6.35; P=.41). As expected, levels of perceived gamification were significantly different between the 2 conditions (lower gamification mean 3.87; higher gamification mean 5.91; $F_{1,48}$=31.63, P<.001).

Main Study

We recruited 141 participants from Credamo; 78 (55.3%) were female, and 129 (91.5%) were aged from 21 years to 40 years. All the confounding variables (eg, brand trust, brand attitude, and brand familiarity) showed no significant differences (P=.09, P=.07, P=.19, respectively). Since all the participants were randomly separated into groups, we did not discuss any covariates (eg, age) further. We also performed the manipulation check on the variable of perceived gamification. The result revealed that the levels of perceived gamification were different between the 2 groups (lower gamification mean 4.89; higher gamification mean 5.83; $F_{1,139}$=32.63, P<.001).

We then took enjoyment as a dependent variable and conducted a similar analysis. The result showed that gamification has a positive influence on enjoyment (lower gamification mean 5.44; higher gamification mean 6.04; $F_{1,139}$=21.11, P<.001; partial ^{2}=0.13), which means the higher gamified program leads to higher enjoyment than the lower gamified program.

We finally took favorability as the dependent variable and conducted a similar analysis. The result showed that gamification has a positive influence on favorability (lower gamification mean 5.63; higher gamification mean 6.13; $F_{1,139}$=14.57, P<.001; partial ^{2}=0.09), which means the higher gamified program leads to higher favorability than the lower gamified program.

The results of Study 1 supported H1. The highly gamified CRM program induces more enjoyment and higher favorability.

Results of Study 2

Pretest

A pretest was conducted with 42 participants recruited from Credamo. Participants were randomly assigned to 1 of 2 conditions and were instructed to evaluate the given programs. We also performed a confounding check of brand trust, brand attitude, and brand familiarity. The results revealed that there were no significant differences between the 2 conditions for brand trust (lower gamification mean 5.66; higher gamification mean 5.66; P=.98), brand attitude (lower gamification mean 6.11; higher gamification mean 5.91; P=.40), or brand familiarity (lower gamification mean 6.05; higher gamification mean 6.13; P=.79). However, perceived gamification differed between the 2 conditions (lower gamification mean 4.21; higher gamification mean 5.83; $F_{1,40}$=10.81, P=.002).

Main Study

We recruited 114 participants from Credamo; 55 (48.2%) were female, and all the participants were aged from 21 years to 40 years. We randomly assigned them to view 1 of the 2 videos. After viewing, we first asked the participants to rate the perceived gamification and then asked them to rate the perceived enjoyment (α=.76) and favorability (α=.87) toward the Douyin CRM program. Confounding variables (ie, brand trust, brand attitude, and brand familiarity), as in Study 1, were also checked, and they showed no significant differences between the 2 groups (P=.08, P=.14, P=.12, respectively). All the measures were the same as those in Study 1.

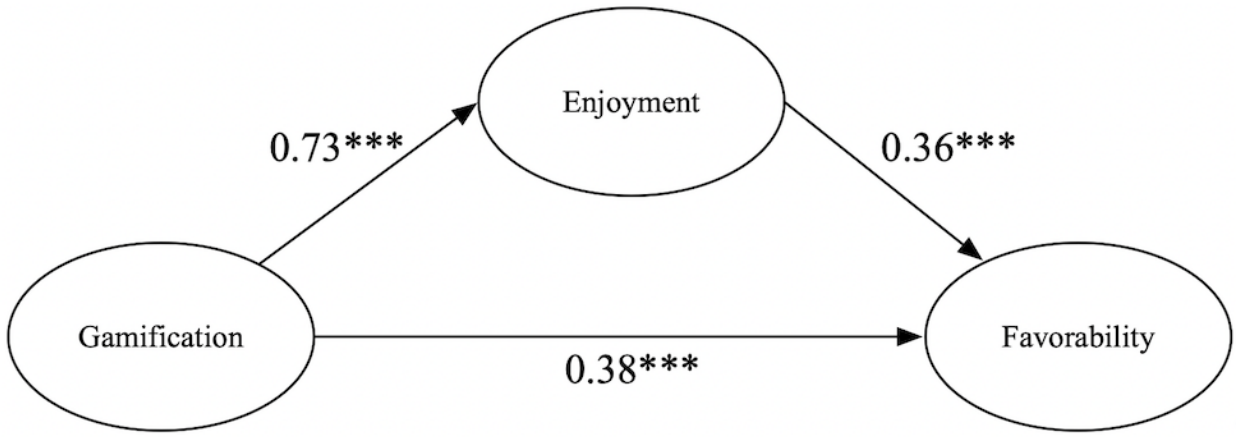
We performed the manipulation check on the variable of perceived gamification in Study 2, replicating the results of the pretest. The 2 videos were significantly different in levels (lower gamification mean 4.36; higher gamification mean 5.77; $F_{1,112}$=33.87, P<.001).

As in Study 1, we conducted a series of analyses of variance (ANOVAs) on the dependent variables. The results showed that gamification positively influenced enjoyment (lower gamification mean 5.21; higher gamification mean 5.94; $F_{1,112}$=19.57, P<.001; partial ^{2}=0.15), with higher gamification leading to more enjoyment. The results also revealed that gamification had a positive impact on favorability (lower gamification mean 5.67; higher gamification mean 6.05; $F_{1,112}$=11.18, P=.001; partial ^{2}=0.09), with higher gamification leading to higher favorability.

To test H2, we conducted a mediation analysis using the bootstrap method (5000 bootstrap samples) in the mediation package of R. The results indicated that the effect of gamification on favorability was fully mediated by enjoyment. As Figure 2 illustrates, the total effect of gamification on favorability was significant (β=.38, P<.001). Controlling for gamification, enjoyment also had a significant effect on favorability (β=.36, P<.001). However, controlling for enjoyment, gamification no longer had a significant influence on favorability (β=.12, P=.17. The indirect effect of gamification on favorability through enjoyment was 0.730.36=0.26 (P<.001), with the 95% CI ranging from 0.16 to 0.63, excluding 0. Thus, H2 was supported.

Study 2 not only reinforced H1 but also gave support to our hypothesis on the mediation role of enjoyment (H2) between gamification and favorability.

Figure 2. Path coefficients of the mediation model. ***P<.001.



Results of Study 3

Pretest

We performed a pretest with 30 participants recruited from Credamo. Participants were randomly assigned to 1 of 2 conditions, and there were no significant differences between the 2 groups in brand trust (lower gamification mean 5.66; higher gamification mean 5.48; P=.58), brand attitude (lower gamification mean 5.55, higher gamification mean 5.73; P=.66), or brand familiarity (lower gamification mean 6.14; higher gamification mean 6.06; P=.84). However, perceived gamification differed between the 2 conditions (lower gamification mean 5.21; higher gamification mean 6.12; $F_{1,28}$=8.62, P=.007).

Main Study

Study 3 used a 2 (gamification: lower, higher) 2 (rules presentation: without visual cues, with visual cues) between-subjects design. We recruited a new sample of 250 participants from Credamo; 128 (51.2%) were female, and all the participants were aged from 21 years to 40 years. In the videos, we first presented the rules (with or without visual cues) for “Protect Pandas” and then showed the interfaces of the program. After viewing, the participants were asked to rate the perceived gamification, enjoyment, and favorability toward the CRM program as in the previous studies. A confounding check was conducted and revealed no significant differences (P=.30, P=.78, P=.70, respectively).

Similar to the results of the pretest, the results of the manipulation check on the variable of perceived gamification showed that the 2 videos were significantly different in levels (lower gamification mean 5.16; higher gamification mean 5.72; $F_{1,248}$=19.48, P<.001).

We first conducted an ANOVA with enjoyment as the dependent variable and gamification and rules presentation as the independent variables. The results confirmed the main effect of gamification on enjoyment (lower gamification mean 4.71; higher gamification mean 5.56; $F_{1,246}$=30.06, P<.001; partial ^{2}=0.10) and the main effect of rules presentation (without visual cues mean 4.86; with visual cues mean 5.43; $F_{1,246}$=13.91, P<.001; partial ^{2}=0.05). These simple effects were also qualified by a significant gamification rules presentation interaction effect on enjoyment ($F_{1,246}$=4.98, P=.03; partial ^{2}=0.02). The planned contrast revealed that, when rules were presented with visual cues, higher gamification led to more enjoyment than did lower gamification (lower gamification mean 4.81; higher gamification mean 6.02; $F_{1,246}$=30.92, P<.001). Meanwhile, when rules were presented without visual cues, there was also a significant difference between the 2 groups (lower gamification mean 4.60; higher gamification mean 5.11; $F_{1,246}$=5.43, P=.02). See Figure 3.

We next performed an ANOVA with favorability as the dependent variable and gamification and rules presentation as the independent variables. The results confirmed the main effect of gamification on favorability (lower gamification mean 5.03; higher gamification mean 5.86; $F_{1,246}$=29.93, P<.001; partial ^{2}=0.10) and the main effect of rules presentation (without visual cues mean 5.21; with visual cues mean 5.72; $F_{1,246}$=11.83, P<.001; partial ^{2}=0.04). These simple effects were also qualified by a significant gamification rules presentation interaction effect on favorability ($F_{1,246}$=5.08, P=.03; partial ^{2}=0.02). The planned contrast revealed that, when rules were presented with visual cues, higher gamification led to more favorable attitudes toward the CRM program than did lower gamification (lower gamification mean 5.11; higher gamification mean 6.29; $F_{1,246}$=30.92, P<.001). Meanwhile, when rules were presented without visual cues, there was also a significant difference between the 2 groups (lower gamification mean 4.95; higher gamification mean 5.44; $F_{1,246}$=5.29, P=.02). See Figure 4.

Figure 3. Mean (SD) enjoyment in the higher gamification group compared with the lower gamification group.

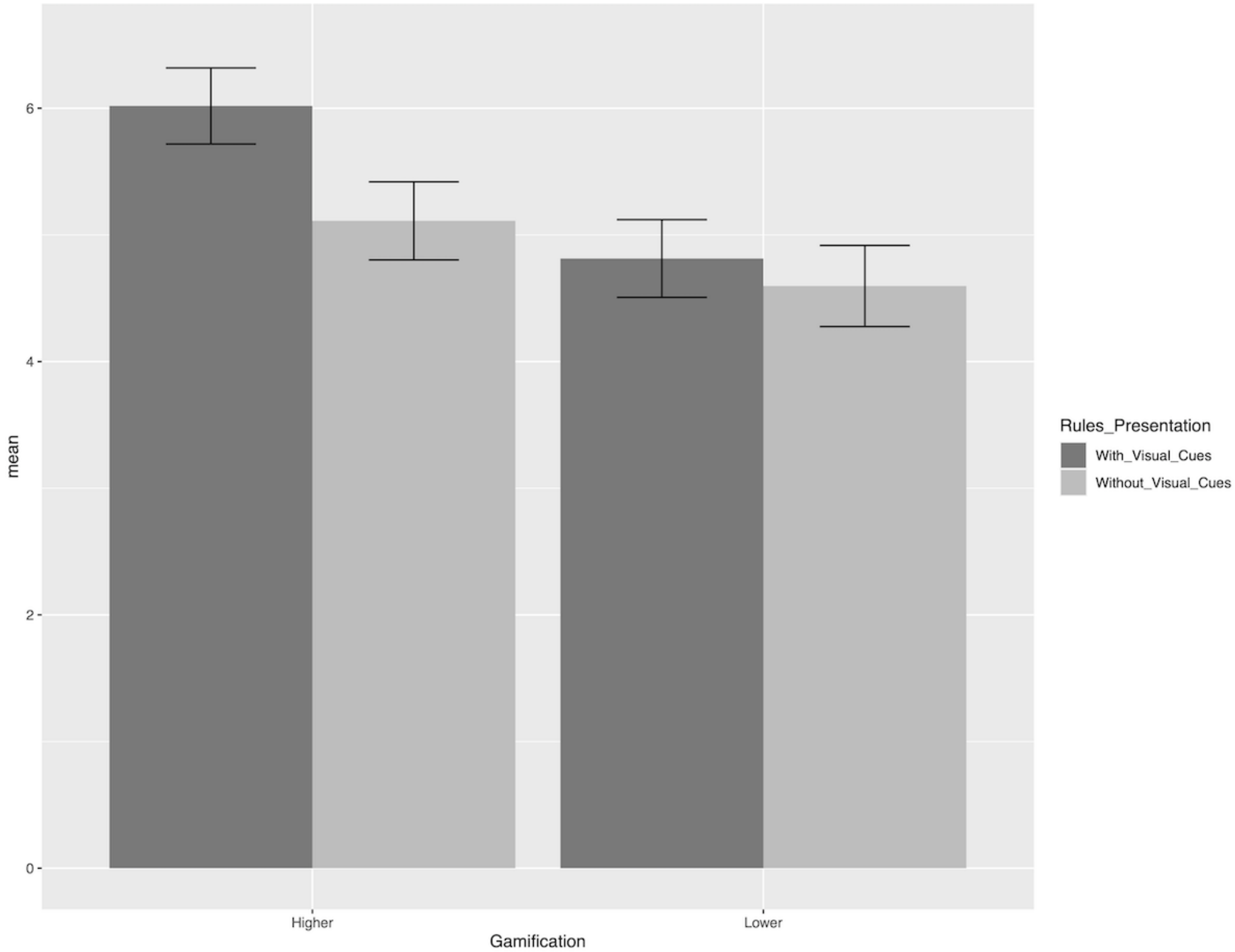
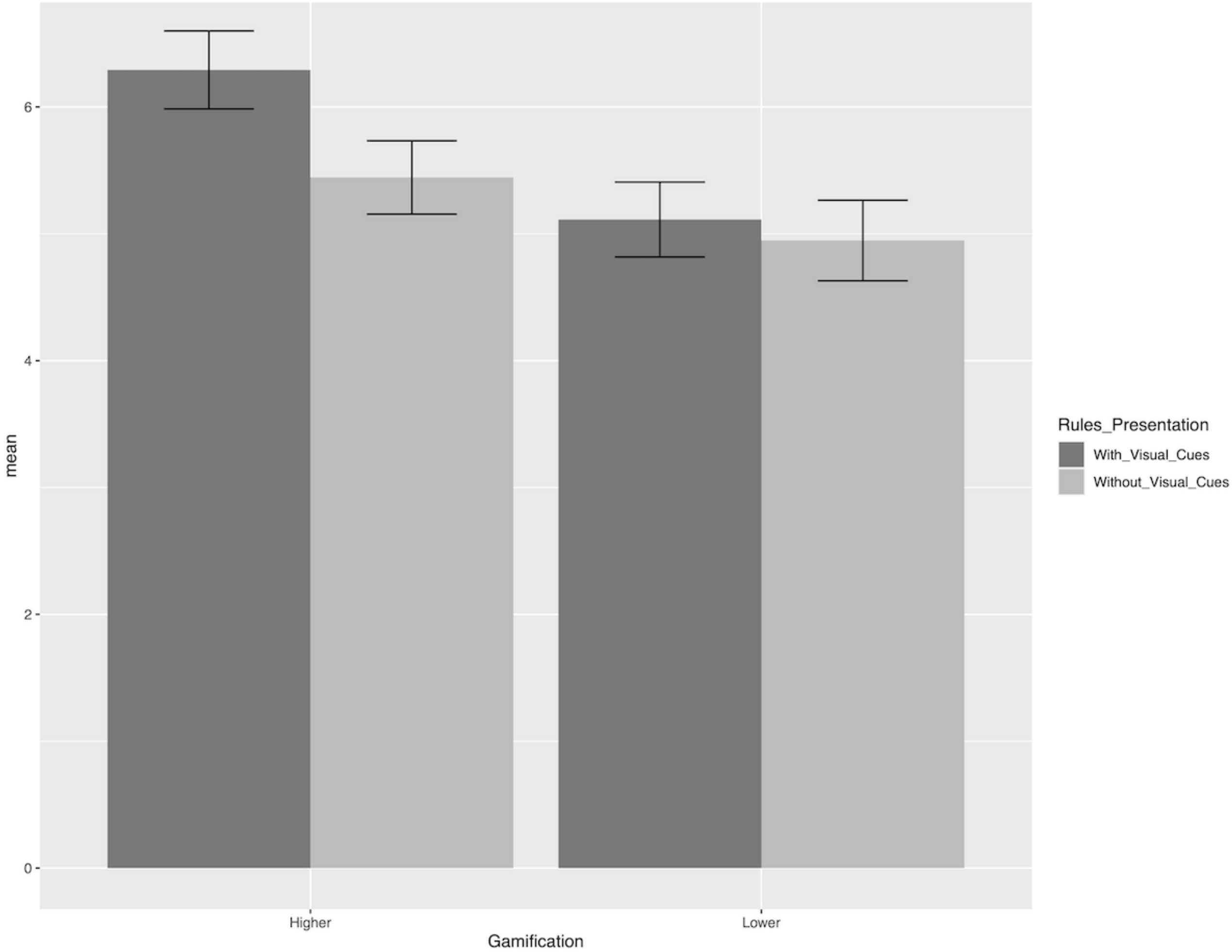


Figure 4. Mean (SD) favorability in the higher gamification group compared with the lower gamification group.



Finally, we estimated our moderated mediation model (in the mediation package of R; 5000 bootstrap samples) to test whether the visual cues in rules representation moderate the underlying process via enjoyment. The model used gamification as the independent variable, enjoyment as the mediator, and visual cues as the moderator. Similar to Study 1 and Study 2, gamification positively influenced enjoyment (β=.51, t_{246}=2.33, *P*=.02). Moreover, the interaction between gamification and visual cues was significant for enjoyment (β=.69, t_{246}=2.23, *P*<.03). Enjoyment, in turn, facilitated favorability (β=.87, t_{245}=30.80, *P*<.001). Visual cues significantly moderated the indirect effect of gamification on favorability via enjoyment (index of moderated mediation: 95% CI –1.12 to –0.10; for rules presentation with visual cues: 95% CI=0.69 to 1.40; for rules presentation without visual cues: 95% CI 0.08 to 0.83). However, the direct path from gamification to favorability was not significant (*P*=.61) nor was its moderation by visual cues (95% CI –0.39 to 0.20).

In summary, the findings from Study 3 supported our hypotheses (H1 to H3). Gamified CRM projects can induce more enjoyment and higher favorability. Importantly, when rules were presented with visual cues, the impact of gamification on enjoyment was more positive than when without visual cues. The results highlight the notion that consumers perceive enjoyment from not only game design elements of the CRM program but also the rules presentation.

Discussion

Across 3 studies, we showed that gamified CRM programs can increase consumers' perceptions of enjoyment and, in turn, enhance their favorability toward the program (Studies 1 and 2). We also showed that the relationship between gamification and enjoyment is moderated by the visual cues of rule presentation (Study 3). Our findings have several implications for marketing research and practice.

Theoretically, our research contributes to the CRM literature by highlighting the impact of gamification. It is not always easy to get consumers' responses to or willingness to participate in a CRM program (eg, Chuah et al [6] and Jun et al [48]). However, in this article, we showed that gamification is an effective alternative for CRM projects to gain more favorability by improving consumers' enjoyment. Moreover, our work adds to the literature exploring the impact of visual design on consumers' psychological mechanisms. The results of our study indicate that, when rules are presented with visual cues, consumers are more likely to perceive higher enjoyment and, in turn, feel greater favorability.

Additionally, the current research yields some implementable managerial implications. On one hand, managers can gamify their CRM programs to enhance consumers' enjoyment and favorability. For example, practitioners embed not only game design elements but also games into their projects. On the other hand, some gamified CRM programs merely present rules in monotonous words (eg, Dream Fairy in Study 2); however, according to our research, practitioners are better to present their rules with visual cues (even in a dynamic way) to induce more enjoyment.

We provide a range of evidence for our model, but there are still some limitations for future research. First, we only discussed the psychological mechanism of enjoyment between gamified CRM programs and favorability. However, there may exist multiple mediators. For example, engagement is another mediator to investigate. Since gamified CRM programs are possibly more interesting than ordinary CRM programs and provide various game design elements with which to interact, consumers may be more easily engaged [49,50]. When highly engaged, consumers are more inclined to believe the cause is connected with their lives [51] and thus are more willing to favor it [52]. Furthermore, engagement may increase the perception of one's personal role in contributing to the cause [18], which evokes an intention to participate. Second, in this article, we performed studies online and merely introduced CRM programs via videos. However, for more strict control and data collection, future studies can choose the context of a laboratory and provide opportunities for participants to conduct operations on certain programs. Finally, as the experience with gamification has not been defined clearly, the current manipulation check is limited. Future studies can develop scales for the gamification experience.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Table measurement items.
[DOCX File , 13 KB - games_v11i1e35756_app1.docx]

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Abbreviations

ANOVA: analysis of variance
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
CRM: cause-related marketing

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Effectiveness of a 5-Week Virtual Reality Telerehabilitation Program for Children With Duchenne and Becker Muscular Dystrophy: Prospective Quasi-Experimental Study

María Rosa Baeza-Barragán[1,2], MSc; Maria Teresa Labajos Manzanares[1], MSc, PhD; Mercedes Cristina Amaya-Álvarez[1], MSc; Fabián Morales Vega[3], MSc; Judit Rodriguez Ruiz[4], MSc; Rocío Martín-Valero[1], MSc, PhD

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Corresponding Author:
Rocío Martín-Valero, MSc, PhD

Abstract

Background: Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD) are neuromuscular diseases. DMD is the most prevalent in children. It affects dystrophin production, reducing the patient's mobility and quality of life. New technologies have become a part of physical therapy in DMD and BMD. During the COVID-19 pandemic, conducting telerehabilitation through virtual reality–based games could help these children maintain their physical abilities.

Objective: This study examined if the use of a virtual platform in a multimodal intervention program changes the results of the 6-minute walk test (6MWT) in children with DMD and BMD. The main objective was to test whether children with DMD and BMD obtain different results on the 6MWT after completing 10 telerehabilitation treatment sessions. The secondary objective was to measure whether other specific motor scales also produce different results after the 10 defined sessions.

Methods: This was a descriptive, open, and quasi-experimental study with a prospective A-B (control-intervention) design. A sample of 12 participants who fulfilled the inclusion criteria followed the program for 5 weeks with 10 telerehabilitation sessions. During the sessions, the participants used virtual reality glasses to train for the treatment goals. All participants were assessed in person before and after the intervention. Analysis was performed using R software according to the different functional assessments performed for each test.

Results: The participants showed a 19.55-meter increase in the 6MWT. Motor function also remained stable according to other scales used to assess it. The North Start Ambulatory Assessment scores were stable in both treatment conditions (P=.20). Furthermore, the timed up and go test results were 0.1 seconds faster in the telerehabilitation condition, and the Motor Function Measure in all of the 3 dimensions showed no significant differences (P=.08). Finally, the Effort Perception Infant scale showed that during the training, fatigue increased in the middle and decreased by the end of the sessions, but the perception throughout the sessions was lower even as the exercise intensity increased.

Conclusions: There were no differences between conventional and telerehabilitation treatments, so the telerehabilitation tool could be used without harming children with DMD and BMD, facilitating their access to therapies and stimulating learning to maintain their functional capacity. Therefore, telerehabilitation in general may be helpful in maintaining motor function in children with DMD and BMD. The learning effect helped reduce the feeling of fatigue in the children during the program.

Trial Registration: ClinicalTrials.gov NCT03879304; https://clinicaltrials.gov/study/NCT03879304

(JMIR Serious Games 2023;11:e48022) doi:10.2196/48022

KEYWORDS

Duchenne muscular dystrophy; telerehabilitation; virtual reality; physical therapy; muscular dystrophy; mutation; muscle; degeneration; telehealth; motor function; digital health intervention; Becker muscular dystrophy; VR

Introduction

Background

Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD) are rare neuromuscular diseases caused by a mutation in the gene that produces dystrophin, which is responsible for maintaining muscle properties [1]. The lack of dystrophin leads to the progressive degeneration of muscle fibers, which become connective tissue and fat [2]. The worldwide prevalence is approximately 0.5 per 10,000 male individuals for DMD and 1 per 3500 male individuals for BMD [3]. The loss of ambulation occurs at a median age of 12 years, and ventilation starts at about the age of 20 years, making it a disabling disease with severe motor sequelae and respiratory and cardiac problems, with a high cost to health [4].

Maintaining function as long as possible is the primary goal of physical therapy for these conditions. To start intervention from the beginning of the diagnosis or to document the evidence of a motor delay, physical therapy is carried out using techniques such as contracture and posture management, as well as aerobic, proprioceptive, coordination, balance, and respiratory work [5]. Children with DMD and BMD have associated disorders such as autism, speech limitations, and behavioral problems in most cases, so the proposed treatment was aimed at treating these associated disorders [3].

The global situation due to COVID-19 has led health professionals to carry out interventions through video calls to support families. The impact of the pandemic, confinement duration, and health care changes could affect the mental health of young people with intellectual disabilities and their environment. Their behavior could be aggravated, and mental disorders could appear [6]. Furthermore, the characteristics of children at advanced stages of DMD and BMD, such as muscle weakness, impaired cough reflex, mucus in the airways, cardiac deterioration, and the very early intake of corticosteroids, may predispose them to severe COVID-19 [5]. A major difference between DMD and BMD is that BMD progresses slower and has a later onset than DMD [5].

The World Confederation for Physical Therapy, in its report on the regulation of clinical practice through digital platforms, summarizes the following benefits: this practice facilitates connection, reduces barriers and waiting times, increases safety, reduces mobility problems, improves user independence, improves flexibility, and lowers costs of care [7]. During this time, the effectiveness of active video games, a game system where the player's movements through the game space are displayed on a television screen, and virtual reality (VR) games, which provide an artificial 3D environment using VR technology, has been demonstrated in the physical rehabilitation of children with disabilities at home [8].

As part of telehealth, telerehabilitation uses telecommunications technologies to control or monitor remote rehabilitation. Its objective is to increase accessibility and continuity of care for vulnerable, geographically remote populations with disabilities, thus saving time and resources for health care providers [9]. In addition, telerehabilitation implementation is feasible, it can be offered to diverse groups of patients, and therapists accept it as an effective model of care for children [10].

The use of VR in physical therapy programs for children can provide a personalized and flexible treatment by allowing us to integrate the child's preferences into the intervention program, improve attention and motivation, and increase sensory feedback [11]. Despite the effectiveness of the programs in general, there are few studies about children with DMD and BMD.

Previous studies have used accelerometers to measure functional tasks and the effectiveness of dynamic arm support at home in young patients with DMD [12,13]. Web-based platforms have also been used to demonstrate respiratory exercises to relatives and provide a satisfaction survey to measure the participation and acceptance of the program [14].

Objectives

The main objective of this study was to test whether children with DMD and BM obtain different results on the 6-minute walk test (6MWT) [15] after completing a multimodal telerehabilitation program of 10 sessions over 5 weeks with VR glasses as a part of the treatment. As a secondary objective, other specific motor scales were used to measure changes after receiving the 10 defined sessions. These scales were the North Star Ambulatory Assessment (NSAA) [16], timed up and go test (TUG) [17], Motor Function Measure (MFM) [18], and Effort Perception Infant (EPInfant) [19], which will be described in the *Methods* section.

The purpose of this study was to examine if the use of a virtual platform in a multimodal intervention program changes the results of the 6MWT in children with DMD and BMD.

Methods

Study Design

This was a descriptive, open, and quasi-experimental study using an A-B design with a prospective control condition and an intervention condition. It was carried out nationally, according to a multicentric scheme.

The principal investigator conducted the sessions with all participants. In all, 3 researchers from the Canary Islands, Madrid, and Almería conducted the pre- and poststudy assessments of the variables. The interviews were conducted by the associate researcher in each department.

All caregivers were notified by email and WhatsApp 1 day before the session was held, to ensure the continuity of the study and its frequency of 2 weekly sessions for 5 weeks.

A control condition and an intervention condition were defined for the entire sample. Both results were compared, and each child was only compared to their own results. Upon the completion of the multimodal physical therapy program, the main researcher performed an outcome assessment and functional assessment of the intervention face to face.

The following sections describes the training carried out with the study participants. Over 5 weeks, the participants passed a pretraining assessment (control condition) and then attended ten 30-minute physiotherapy sessions (intervention condition).

Control Condition

The participants first underwent the control condition, where they performed the functional tests by following a conventional physical therapy program without the use of VR glasses.

Intervention Condition

The participants then underwent the intervention condition of ten 30-minute sessions, which included self-stretching, yoga, aerobic work, breathing and relaxation, mindfulness, and training with VR glasses (Table 1). We used sources on the internet such as videos on YouTube [20] to carry out the guided exercises, as well as music on Spotify. Visual and musical support during the sessions was one of the key factors for the child to want to participate and maintain their attention during the treatment. Cardboard VR glasses sent to each of the participants were also used as support.

Table . Exercises performed during the telerehabilitation sessions.

Type of exercise	Material resources	Time	Example
Aerobic	• Video game • Dancing • Walking • Therapist	Gradual increase in exercise duration from 3 min to 6 min	While watching a video of a walk, the child keeps walking in place.
Respiratory	• Video story • Therapist	10 min	The reading of a visual story with music is used as an opportunity for breathing exercises, prolonged expirations, strengthening of the muscles involved in breathing, deep diaphragmatic inspirations, etc.
Self-stretching	• Music • Therapist • Yoga • Videos	4-5 min	A guided self-stretching session is performed with the therapist following the rhythm of the music.
Relaxation	• Mindfulness • Videos	3 min	Using mindfulness as a tool, we integrate a child's ability to stop, relax, breathe, and disconnect through listening.
VR[a]	• VR glasses • VR videos	6-8 min	Through the VR glasses, the child is required to perform various activities such as swimming, crouching, walking on the spot, or breathing by viewing a VR video.

[a]VR: virtual reality.

The participants used the Zoom (Zoom Video Communications) video call platform to carry out a program of web-based gamification activities. The multimodal physiotherapy treatment, adapted to a virtual platform, was aimed at global work of the child at different levels (respiratory, aerobic, and mental levels), postural re-education, and self-stretching; in addition, gamification, dance, yoga, and meditation were used as tools within the physiotherapy framework [21]. The child performed the intervention alone or with their caregivers. A physiotherapist guided all sessions. Neither the participants nor the caregivers received training or have knowledge of how they were going to perform the exercises.

Recruitment

The recruitment of participants started in March 2021 and was completed in October 2022. Recruitment took place at each child's referring physiotherapy center. To be included in the study, the principal investigator was contacted directly. This investigator's contact information was provided in the study information sheet. Participants who met the inclusion requirements of the study were contacted by a phone call as the first contact and for the clarification of doubts.

The technique used to select the participants was of an intentional, nonprobabilistic nature. The selection was made according to the inclusion and exclusion criteria, and all who met them were included.

Due to the low recruitment capacity (scarce eligible population), convenience sampling was carried out. The allocation process was not randomized. A random sample of 12 individuals was considered significant enough to estimate, with a 95% confidence and an accuracy of within 80 meters, the population mean values with an expected SD of around 134.35 meters. The SD of the control treatment and telerehabilitation was 95 meters. The predicted withdrawal rate was 5% or below. The estimate was made using the GRANMO calculator (Institut Municipal d'Investigació Mèdica) [22].

Inclusion and Exclusion Criteria

Participants were children between the ages of 5 and 15 years with muscular dystrophy (DMD or BMD) who could walk and follow the web-based intervention program; were diagnosed according to the International Classification of Diseases, 10th Revision (code G71-01); and had an NSAA score greater than

20 [23-25]. The characteristics of the participants are shown in Multimedia Appendix 1.

Participants who did not walk were excluded, as well as those with associated heart disease, any fracture or sprain, heart rate >120 beats per minute, or oxygen saturation <89% [15,26,27] and those who did not have internet literacy.

Primary and Secondary Outcome Measures

The primary outcome measure was the change in the 6MWT (time frame: from baseline up to 5 wk) [15]. The 6MWT is a well-established outcome measure in various diseases. It is accurate, reproducible, easy to administer, and well tolerated. The 6MWT is a robust assessment tool for clinical trials, given its ability to assess ambulation quantitatively in a controlled setting.

The following secondary outcome measures were also considered:

- The EPInfant is a perceived child effort measurement scale (time frame: to study completion, 5 wk on average) [19]. It shows 11 numerical descriptors (from 0 to 10), a total of 5 verbal descriptors placed at every 2 intensity levels, and a set of illustrations depicting a boy running at increasing intensities along a bar scale of increasing height following an exponential-type slope from left to right. Higher values correspond to worse results.
- The NSAA is functional scale for children with DMD (time frame: from baseline up to 5 wk) [16]. It is expressed in points and shows the acquisition or loss of functions. Although children with DMD can generally show recognizable adaptations to activities due to the underlying progressive muscle weakness, they may modify their activities to achieve functional goals in slightly different ways. In general, activities receive the following scores: 2 ("Normal")=no obvious modifications to the activity; 1=modified method that achieves the goal independently of physical assistance from others; and 0=unable to achieve the goal independently. The best score is 34 points.
- The MFM measures motor performance (time frame: from baseline to 5 wk) [18]. It has 3 dimensions: D1, standing and transfers (13 items); D2, axial and proximal motor function (12 items); and D3, distal motor function (7 items; 6 of which evaluate the upper extremities).
- The TUG is expressed in seconds (time frame: from baseline to 5 wk) [17]. It shows the time it takes children to stand up, walk 3 meters, return to the seat, and sit down.
- The Vignos Scale ranges from 1 to 10 and assesses lower-extremity function. A score of 1 refers to being able to walk without assistance and 10 refers to being confined to a bed. It is embedded within the MFM data collection [18].

The CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participants' recruitment and progress through the phases of the trial is shown in Multimedia Appendix 2.

Data Analysis

The analysis was organized according to the different functional assessments performed for each test. Analysis was performed using R (R Foundation for Statistical Computing) software. Scores were calculated using the corresponding guidelines. Each variable was analyzed to measure the motor function used: 6MWT, NSAA, TUG, and MFM. In addition, we analyzed the perceived fatigue with EPInfant, including the variation during the course of the sessions and the relationship with the rest of the variables.

The correlation between fatigue and motor function was assessed using the Pearson correlation coefficient. Paired tests were used to account for the inherent dependence and correlation among the variables. The 2-tailed paired t test was used for variables conforming to a normal distribution, whereas the Wilcoxon signed-rank test was used for variables that did not adhere to normal distribution assumptions. The Anderson-Darling and Fligner-Killeen tests were used to evaluate normality and homoscedasticity assumptions, respectively. The Friedman test was used when the evaluation spanned beyond 2 distinct time points. In cases where statistically significant relationships were detected ($P<.05$), we applied the Bonferroni correction method to rigorously examine post hoc relationships. Additionally, 2 linear mixed-effects models (random intercepts) were fitted to evaluate child stress. The first model, M1, does not incorporate an interaction between time and sessions and can be represented as:

The second model, M2, incorporates an interaction and is expressed as:

The above equations apply for patient $j=1...j$.

Ethical Considerations

The project's development followed the World Medical Association Declaration of Helsinki in 1964 and the ratifications of the subsequent assemblies on ethical principles of medical research involving human participants. The researchers in this study agreed that all clinical data collected from study participants would be separated from personally identifiable data to ensure patient anonymity. The researchers collected the patients' clinical data in the study-specific data collection notebook. Each data collection notebook was coded and pseudonymized, thus protecting the patient's identity.

It was guaranteed that the treatment, communication, and transfer of personal data of all participants complied with the provisions of Organic Law 3/2018, of December 5, on protecting personal data and guaranteeing digital rights. The participants were informed about their rights to access, cancel, or oppose the use of their data by emailing the researchers. There was no compensation for participation.

This trial has the approval of the Andalucía Ethics Committee with Portal de Ética de la Investigación Biomédica de Andalucía code 0107-N-20.

All participants were informed, and all signed a paper-based informed consent form in person.

Results

Primary and Secondary Outcome Measures

Overview

Table 2 describes the results for each variable.

Table . Summarized means and SDs of the variables (N=12).

Variable	Conventional treatment, mean (SD)	Telerehabilitation, mean (SD)	Difference, mean (SD)
6MWT[a]	408.24 (115.61)	427.79 (134.40)	19.55 (43.83)
NSAA[b]	0.76 (0.18)	0.71 (0.21)	–0.05 (0.11)
Vignos Scale	2.08 (0.79)	2.25 (1.06)	0.17 (0.39)
TUG[c]	7.70 (3.49)	7.60 (3.75)	–0.10 (0.90)
Total MFM[d]	0.89 (0.10)	0.85 (0.14)	–0.04 (0.13)

[a]6MWT: 6-minute walk test.
[b]NSAA: North Star Ambulatory Assessment.
[c]TUG: timed up and go test.
[d]MFM: Motor Function Measure.

6MWT Outcomes

After completing the conventional treatment and then changing to telerehabilitation, the patients walked an average of 19.55 (95% CI –8.30 to 47.40) meters more. This increase was not significant against the distance walked after the conventional treatment (*P*=.15; Table 3).

Table . Results of the 6-minute walk test (6MWT)[a] (N=12).

6MWT (m)	Conventional treatment	Telerehabilitation	Difference
Value, mean (SD)	408.24 (115.61)	427.79 (134.40)	19.55 (43.83)
Value, median (IQR)	364.50 (323.62 to 459.38)	375.50 (346.88 to 428.75)	15.00 (–5.25 to 37.50)
Value, range	294.00 to 630.00	324.00 to 750.00	–51.50 to 120.00
Value, 95% CI	334.79 to 481.70	342.40 to 513.19	–8.30 to 47.40

[a]Paired *t* test: t_{11}=–1.545, *P*=.15 (not significant).

NSAA Outcomes

The NSAA scores were kept stable at around 73%. Although the score for telerehabilitation decreased (5%, 95% CI –13% to 2%), this decrease was not statistically significant with respect to the conventional approach (*P*=.20; Table 4).

Table . Results of the North Star Ambulatory Assessment (NSAA)[a] (N=12).

NSAA score	Conventional treatment	Telerehabilitation	Difference
Value, mean (SD)	0.76 (0.18)	0.71 (0.21)	–0.05 (0.11)
Value, median (IQR)	0.85 (0.63 to 0.88)	0.68 (0.62 to 0.89)	–0.03 (–0.09 to 0.01)
Value, range	0.44 to 1.00	0.32 to 0.97	–0.26 to 0.09
Value, 95% CI	0.65 to 0.87	0.57 to 0.84	–0.13 to 0.02

[a]Paired Wilcoxon test: *V*=40.000; *P*=.20 (not significant).

TUG Outcomes

The time used in the TUG during the telerehabilitation period was 0.1 (95% CI –0.67 to 0.49) seconds shorter than that during the conventional period. This decrease was not statistically significant (*P*=.72; Table 5).

Table . Results of the timed up and go test (TUG) (N=12).

TUG (s)	Conventional treatment	Telerehabilitation	Difference
Value, mean (SD)	7.70 (3.49)	7.60 (3.75)	–0.10 (0.90)
Value, median (IQR)	6.54 (5.40-9.51)	6.26 (5.27-9.48)	0.22 (0.59-0.21)
Value, range	2.79 to 14.51	2.25 to 14.07	–1.56 to 1.61
Value, 95% CI	5.48 to 9.92	5.22 to 9.99	–0.67 to 0.47

[a]Paired *t* test: t_{11}=–0.370, *P*=.72 (not significant).

MFM Outcomes

Total MFM

Both the total scores and scores for each of the 3 dimensions in the MFM were analyzed. No significant differences were found in the total MFM score between the conventional and telerehabilitation approaches (*P*=.08). Telerehabilitation had an average decrease of 4% (95% CI −12% to 4%; Table 6).

Table . Results of the Motor Function Measure (MFM)[a] (N=12).

Total MFM score	Conventional treatment	Telerehabilitation	Difference
Value, mean (SD)	0.89 (0.10)	0.85 (0.14)	–0.04 (0.13)
Value, median (IQR)	0.95 (0.84 to 0.97)	0.90 (0.77 to 0.96)	0.00 (–0.02 to 0.00)
Value, range	0.74 to 1.00	0.54 to 0.99	–0.44 to 0.02
Value, 95% CI	0.83 to 0.96	0.76 to 0.94	–0.12 to 0.04

[a]Paired Wilcoxon test: *V*=18.500; *P*=.08 (not significant).

D1: Standing and Transfer

No significant differences were found between the conventional and telerehabilitation approaches (*P*=.08). Telerehabilitation had an average decrease of 8% (95% CI −21% to 4%; Multimedia Appendix 3).

D2: Axial and Proximal Motor Function

No significant differences were found between the conventional and telerehabilitation approaches (*P*=.75). The scores remained stable at around 98% (95% CI −3% to 3%; Multimedia Appendix 4).

D3: Distal Motor Function

No significant differences were found between the conventional and telerehabilitation approaches (*P*=.89). Telerehabilitation had an average decrease of 4% (95% CI −15% to 7%; Multimedia Appendix 5).

EPInfant Outcomes

Fatigue was measured for each session (before, in the middle of, and at the end of each session) during the telerehabilitation process. Both fatigue and fatigue evolution were estimated during each session. A clear evolution can be seen in the perception of fatigue throughout the 10 sessions.

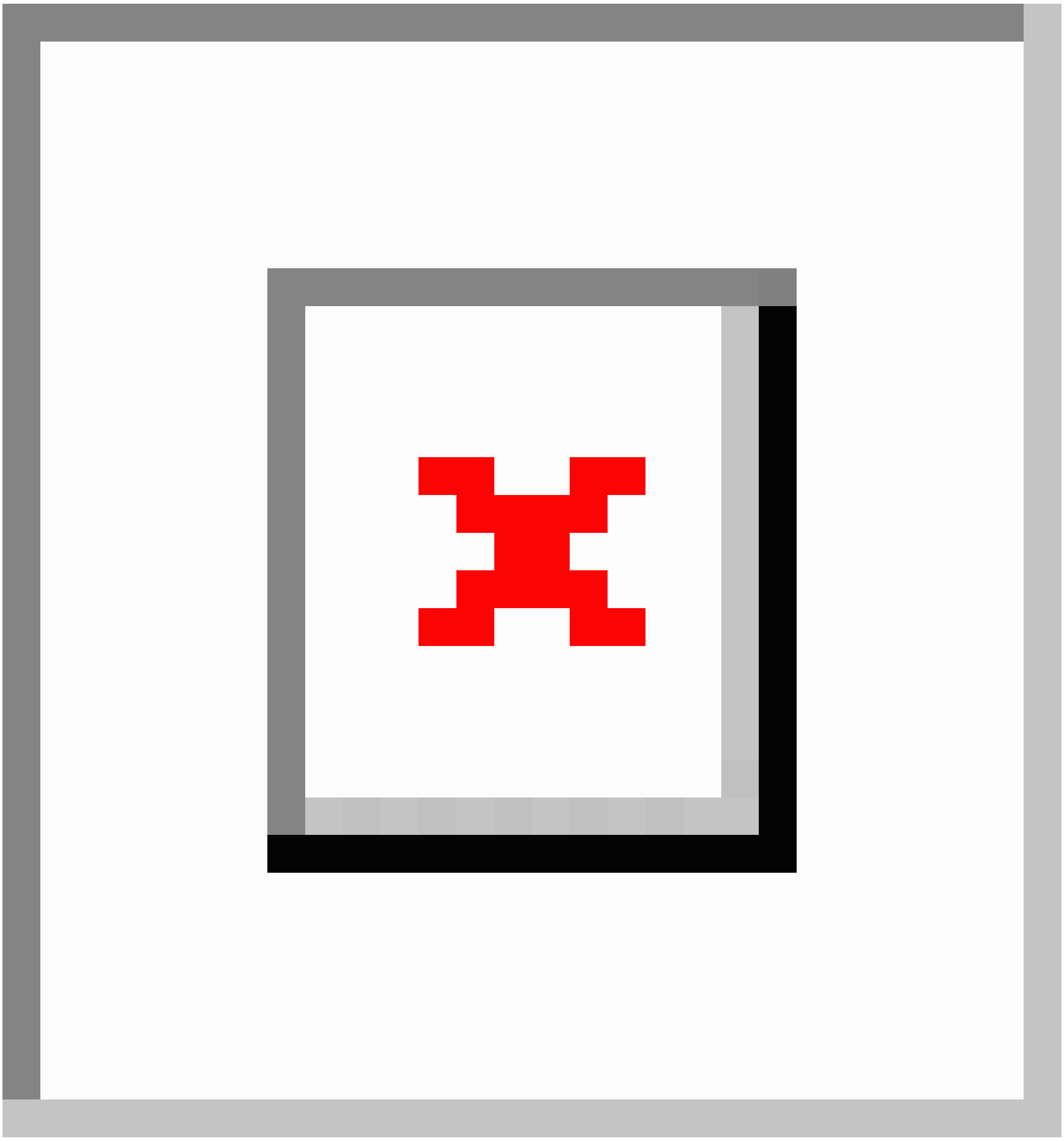
EPInfant Within Sessions

Infant effort significantly changed during the training sessions (*P*<.001; Table 7 and Figure 1). Fatigue peaked during the sessions but decreased by the end.

Table . Effort Perception Infant (EPInfant) score variability within the sessions.

Time point	Data points, n	EPInfant score			
		Range	Median (IQR)	Mean (SD; SE)	95% CI
Before the session	120	0-5	1 (0-3)	1.558 (1.549; 0.141)	1.278-1.838
In the middle of the session	120	0-7	4 (0-4)	3.633 (2.215; 0.202)	3.233-4.033
At the end of the session	120	0-9	2 (0-6)	3.117 (2.554; 0.233)	2.655-3.579

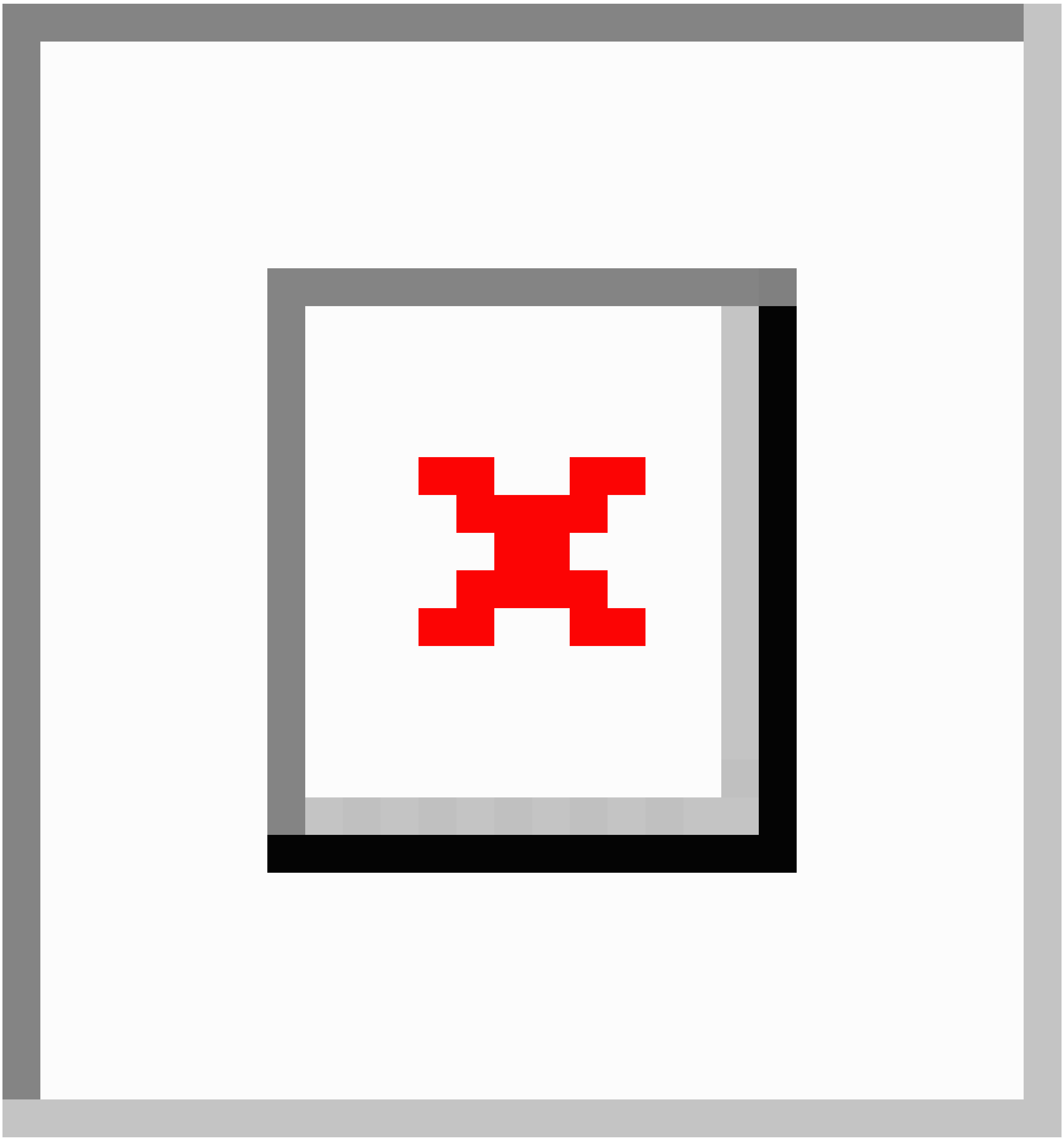
Figure 1. Effort Perception Infant (EPInfant) score variability within the sessions. Friedman test: χ^2_2=104.57, *P*<.001, n=120. Pairwise comparison by Wilcoxon test, with *P* values adjusted by Bonferroni correction. **P*<.05 and *****P*<.0001.



Evolution Throughout the Sessions

Infant effort significantly changed throughout the training sessions (*P*=.02; Figure 2). The highest fatigue peaks occurred during the first session, and fatigue perception was lower starting in the third session, even though the exercise intensity actually increased.

Figure 2. Fatigue perception evolution during the 10 sessions. Friedman test: χ^2_9=19.41, *P*=.02, n=36. Pairwise comparison by Wilcoxon test, with *P* values adjusted by Bonferroni correction.



The *P* value of the comparison between sessions 1 and 10 was statistically significant (*P*=.005), but the Bonferroni-adjusted *P* value was not (*P*=.24). Therefore, there was no significant comparison between the groups after the post hoc analysis.

Linear Mixed-Effects Model

There were significant differences between the different times and sessions (*P*<.05; Figures 3 and 4). The perception of fatigue decreased as the number of sessions increased; the perception of fatigue at the middle and end time points within the sessions was higher than at the beginning.

Figure 3. Linear mixed-effects models for the perception of fatigue. M1: model 1; M2: model 2. *P<.05 and ***P<.001.

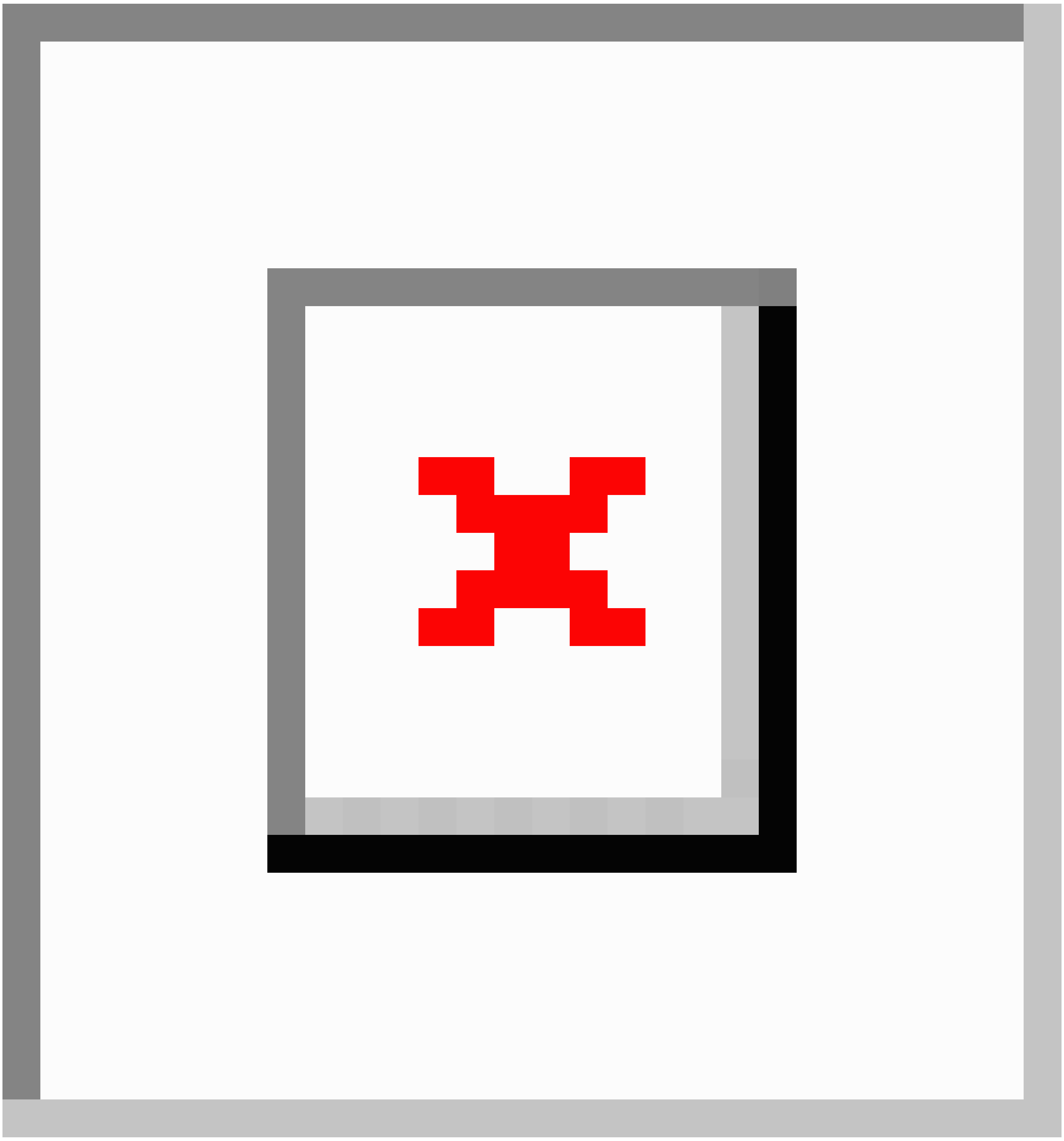
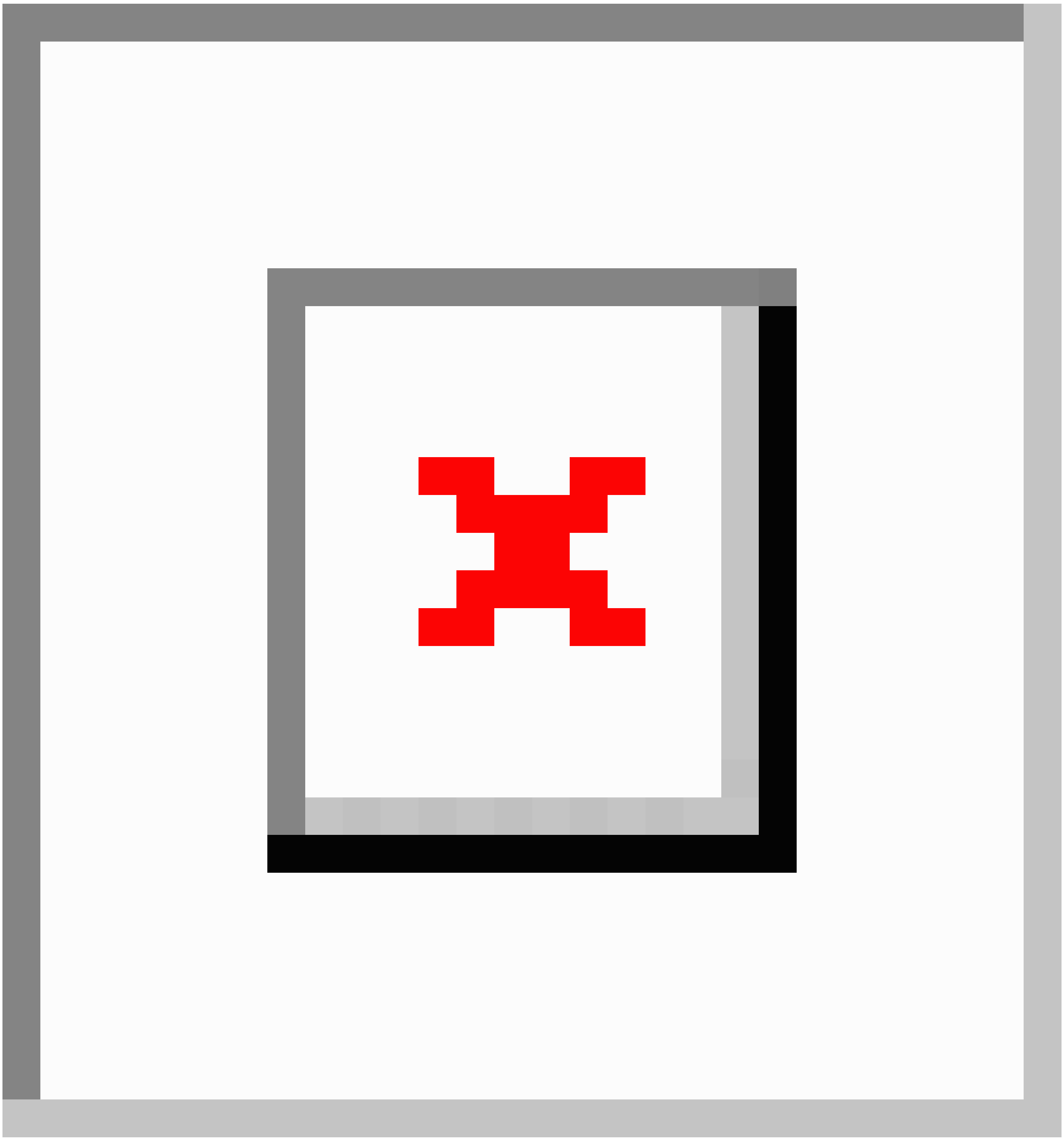


Figure 4. Comparison of 2-to-2 beats (comparing the start of the session to the middle, the middle of the session to the end, and the start of the session to the end. M1: model 1; M2: model 2.



Fatigue Versus Motor Function Correlation

The Pearson correlation coefficient estimates the linear relationship between 2 continuous quantitative variables. The correlation is interpreted as follows: a positive correlation indicates a direct linear relationship between the 2 variables, whereas a negative correlation indicates an inverse linear relationship. The absolute value of the correlation indicates the strength of this association: 0-0.25=no correlation or very low correlation; 0.25-0.50=the association is weak; 0.50-0.75=the association is moderate to strong; and 0.75-1=the association is strong to perfect.

In Figures 5 and 6, the correlation values are shown in the lower-left triangle, and in the upper-right triangle, these values are depicted graphically. Blue color represents a positive relationship, whereas red color represents a negative relationship; furthermore, a larger circle represents a higher correlation.

Figure 5. Correlation matrix between fatigue data (session 1) and motor function (conventional treatment). 6MWT: 6-minute walk test; MFM: Motor Function Measure; NSAA: North Star Ambulatory Assessment; TUG: timed up and go test.

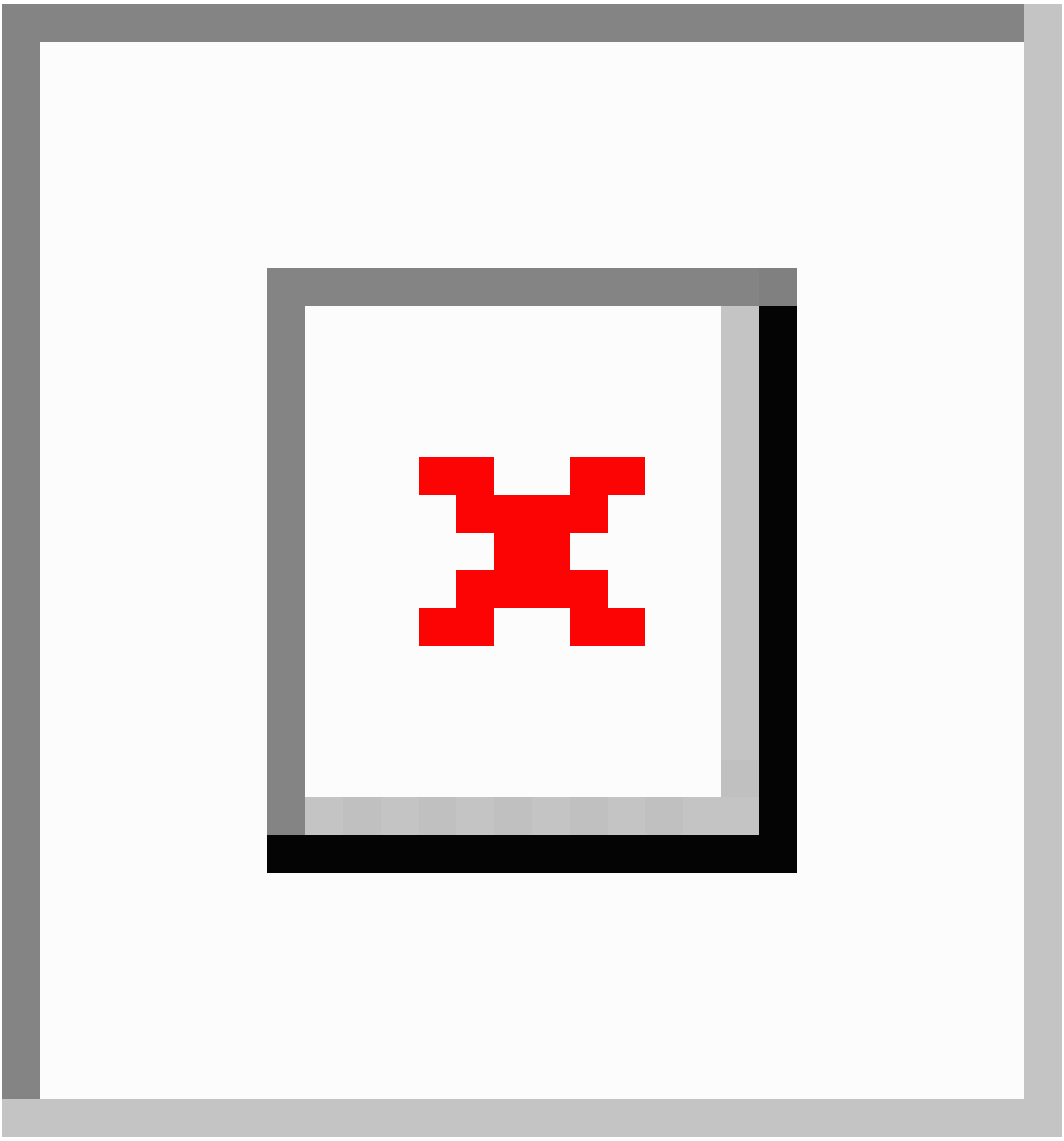
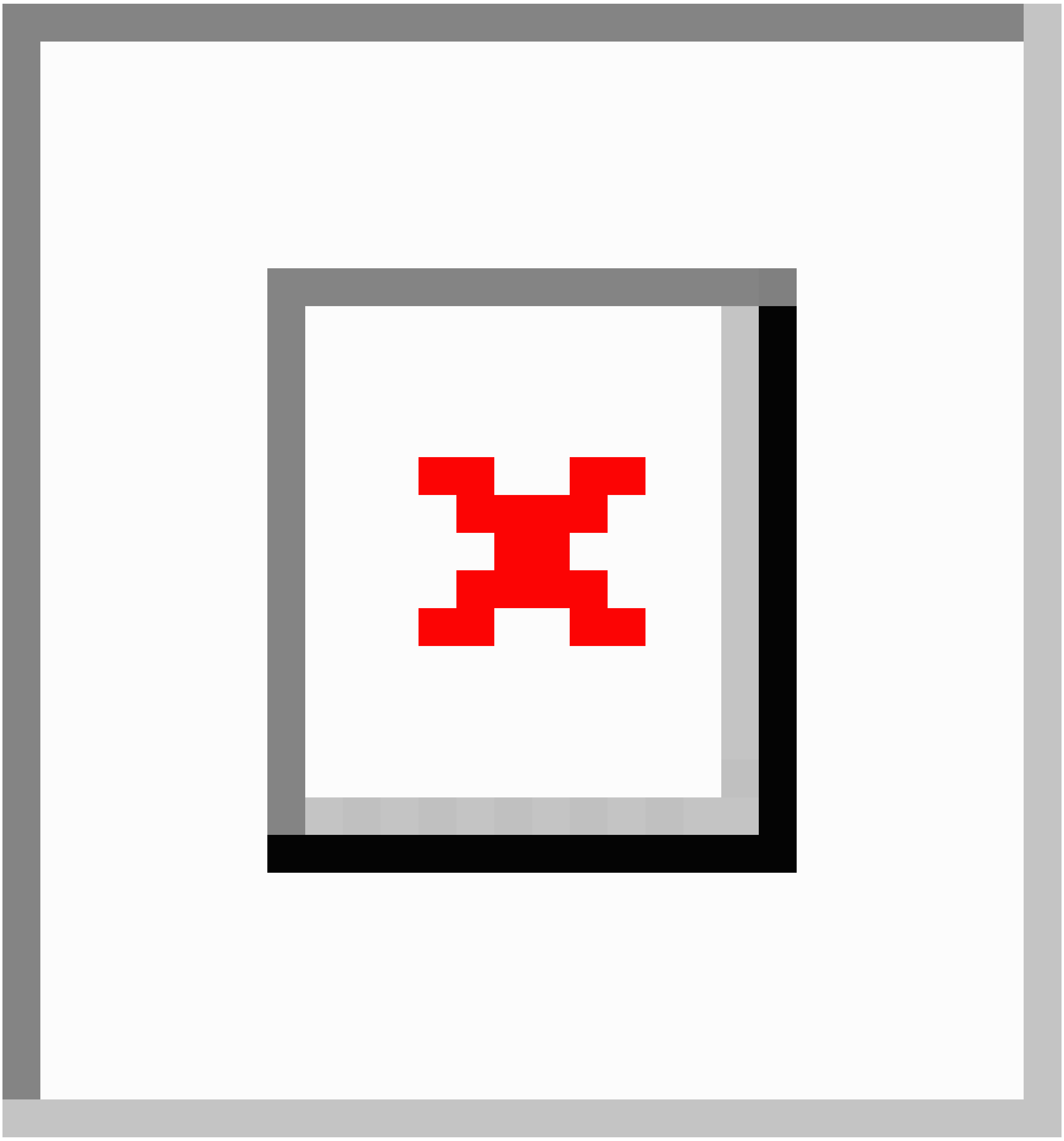


Figure 6. Correlation matrix between fatigue data (session 10) and motor function (telerehabilitation). 6MWT: 6-minute walk test; MFM: Motor Function Measure; NSAA: North Star Ambulatory Assessment; TUG: timed up and go test.



Discussion

Principal Findings

Considering telerehabilitation as a tool for physical therapy in children with DMD and BMD, the results of the functional tests did not show a significant change after 5 weeks of intervention. Although the 6MWT showed a 19.55-meter increase in the distance walked, this finding is not enough to confirm that one treatment is better than the other. However, it does help us understand that by conducting targeted training with children to carry out the test, its results are improved by decreasing the feeling of fatigue throughout the sessions.

The scores for the rest of the functional tests were the same before and after the program. Since the study was about progressive diseases, we can say that it is safe to carry out this type of program for short periods and that the motor skills of the children in the study did not get worse, as shown by the maintenance of the average score on the Vignos Scale.

Comparison to Prior Work

The study of the efficacy of physiotherapy techniques within the framework of neuromuscular diseases is very broad. In a recent systematic review [28], an analysis was carried out on the quality of the studies applied in DMD and the field of study, obtaining some enlightening results on the disease. There are studies on the quality of life and studies that show data on the costs of the disease and mortality [28]. Furthermore, there are studies of the progression and prevalence of the disease and treatment guidelines [4,21,24].

The COVID-19 pandemic physically affected children with DMD and BMD. The study conducted by Tunç et al [29] on the parents of 272 children confirms the significant effects on both the medical care and the patients' physical health. The reason the children did not attend physical therapy centers at the time was concern for contracting COVID-19. Most children did not follow physical therapy throughout the pandemic, and only 6% of the interviewed families had access to a telerehabilitation program at home.

It is well known that an established, continuous physical activity program is needed to maintain functioning in these types of dystrophy. Although the sample of our study was minimal and not limited to the Spanish territory, some of the children lived in towns far from resources and only received therapy once a month. In contrast, other children received weekly physical therapy and other therapies such as hydrotherapy.

Being able to bring physical therapy closer to these children is an achievement within the framework of telemedicine, which should be applied on a more regular basis. In fact, no patients abandoned the therapy during this study. In addition, we observed that the participants learned while performing the exercises, leading to decreased fatigue during the 10 sessions.

The main variable considered in this study was the 6MWT, since research for this disease considers it as a criterion for inclusion in pharmaceutical studies [30]. The NSAA also helped us predict the risk of the loss of ambulation of the participants [31].

Scientific literature supports the use of new technologies as a treatment for children with DMD. Thus, in 2019, de Freitas et al [32] compared performance in a virtual task using interfaces with and without physical contact to identify the use of different devices according to the functionality of the population with DMD. They found that leap motion provided better performance for people with DMD. Similarly, in 2020, Capelini et al [33] conducted a study with 50 individuals with DMD and a control group of 50 healthy individuals using a motor and visual task on a mobile phone. Performance improvement was obtained in a motor learning protocol using a mobile phone. The authors concluded that the use of technology could improve function in people with DMD.

In this study, since there was no control group, the 2 conditions were compared: when the children with DMD and BMD who could walk received the conventional treatment and when they received telerehabilitation. This differs from the study by Kenis-Coskun et al [34], which compared 2 groups with a sample of 19 children, where 1 group followed a telerehabilitation program and the other group performed exercises led through videos. Regarding the duration of the study, we conducted 2 sessions per week for 5 weeks, whereas Kenis-Coskun et al [34] conducted 8 sessions per week for 8 weeks. That study concludes that the telerehabilitation approach led to improvements compared to the group that performed exercises autonomously through the video program. Their conclusion reinforces our opinion that even in telerehabilitation, the presence of the physical therapist during the sessions to adjust the exercises helps to maintain functioning in children with DMD and BMD. The stretching-based program did not lead to clear results that could be implemented in future studies. However, we added aerobic exercises and the child's own work at submaximal levels of physical effort, and the results showed that the functional capacities of these children did not decrease, even though the 19.55-meter increase in the 6MWT was not significant enough to conclude whether the program duration was long enough. In future studies, the programs should be extended for several months to show clearer results.

This program included respiratory exercises that are meant to be fun and designed for autonomous practice. However, some of them needed some family support, mainly to maintain the attention needed to do them. All the children who participated completed the exercises independently and found them to be fun. Sobierajska-Rek et al [5] conducted a study in 2021 where 45 children were instructed to do some exercises at home and then answer a survey. The caregivers explained that the exercises could be carried out at home, although most of the children needed help to be able to do them.

Strengths and Limitations

A positive aspect that we found after carrying out the web-based program is its acceptance by children and their families. All the participants completed the 10 sessions at the indicated time.

The main limitation of this study was the small sample size. Since DMD and BMD are rare diseases, the eligible population was scarce. Furthermore, as the aim was to enroll children who could walk to perform the exercises while guided by the physical therapist as autonomously as possible, many children could not participate due to related cognitive and attention problems.

The second limitation was that we were unable to obtain significant differences between the variables measured. Future studies should assess maintaining the program for a longer time to see if there are significant differences.

The third limitation was regarding the economic aspect. Carrying out the study with glasses that could measure other parameters, such as heart rate, would have made it easier to measure fatigue during the exercises instead of relying on the child's own perception. However, such glasses would be more expensive to send 1 to each participant, limiting participation to those who have a specific type of glasses.

Future Directions

Telerehabilitation should be considered as an additional tool that has come to stay and should be implemented as routine therapy [35]. Since muscular dystrophy is a progressive disease, other types of interventions that manage the maintenance of motor functions instead of their improvement should be considered for future long-term studies. This type of program could be carried out in web-based groups, facilitating fun during physiotherapy training and not just passively stretching the muscles. It would initiate more conscious and active work at home by the child and their caregivers.

Conclusions

Telerehabilitation is a useful tool to bring physical therapy to children who cannot go to a specific place to follow it. Although motor function as measured through the applied scales generally remained the same in the study, we can conclude that there were no significant differences between a conventional physical therapy treatment and a telerehabilitation program applied for 5 weeks. Therefore, this tool could be used without harming children with DMD and BMD, facilitating their access to therapies and stimulating learning to maintain their functional capacity. The learning effect helped reduce the feeling of fatigue in the children during the program.

Future studies should be carried out with a larger sample size and for a more extended period, to show whether a telerehabilitation program sustained over time helps maintain functioning in children with DMD and BMD and perhaps compare the results obtained between children with DMD and children with BMD.

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Data Availability

The 11 videos used to carry out this project can be found on the web [20]. Some cannot be added to the list because they contain children's content.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Characteristics of the participants.
[PNG File, 48 KB - games_v11i1e48022_app1.png]

Multimedia Appendix 2
CONSORT (Consolidated Standards of Reporting Trials) flow diagram.
[DOCX File, 38 KB - games_v11i1e48022_app2.docx]

Multimedia Appendix 3
Results of the Motor Function Measure (MFM), D1: Standing and Transfer.
[DOCX File, 13 KB - games_v11i1e48022_app3.docx]

Multimedia Appendix 4
Results of the Motor Function Measure (MFM), D2: Axial and Proximal Motor Function.
[DOCX File, 13 KB - games_v11i1e48022_app4.docx]

Multimedia Appendix 5
Results of the Motor Function Measure (MFM), D3: Distal Motor Function.
[DOCX File, 13 KB - games_v11i1e48022_app5.docx]

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Abbreviations

6MWT: 6-minute walk test
BMD: Becker muscular dystrophy
CONSORT: Consolidated Standards of Reporting Trials
DMD: Duchenne muscular dystrophy
EPInfant: Effort Perception Infant
MFM: Motor Function Measure
NSAA: North Star Ambulatory Assessment
TUG: timed up and go test
VR: virtual reality

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A Home-Based Exercise Program With Active Video Games for Balance, Motor Proficiency, Foot and Ankle Ability, and Intrinsic Motivation in Children With Chronic Ankle Instability: Feasibility Randomized Controlled Trial

Janya Chuadthong[1,*], MSc; Raweewan Lekskulchai[1,*], PhD; Claire Hiller[2], PhD; Amornpan Ajjimaporn[3,*], PhD

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*these authors contributed equally

Corresponding Author:
Raweewan Lekskulchai, PhD

Abstract

Background: Children with chronic ankle instability (CAI) frequently experience ankle unsteadiness, causing trips, falls, and ankle sprain injuries resulting in poor quality of life. A specific exercise program focused on physical and psychological purposes in children with CAI is needed.

Objective: The purpose of this study was to investigate the feasibility of a 4-week home-based exercise training program using active video games (AVGs) for balance, motor proficiency, foot and ankle ability, and intrinsic motivation in children with CAI.

Methods: Sixty children with CAI (mean age 10, SD 2 years) were randomly assigned to an experimental group (AVG group; n=30) or a control group (CG; n=30). The AVG group played 2 selected video games, Catching Fish and Russian Block, while the CG received the traditional exercise program for CAI. Both programs were scheduled for 30 minutes per day, 3 times per week, for 4 weeks at home. The single-leg stance test was used to assess static balance. The walking forward on a line and standing long jump tests were used to assess motor proficiency. The Foot and Ankle Ability Measure (FAAM) and the Intrinsic Motivation Inventory questionnaire were used to assess foot and ankle ability and intrinsic motivation, respectively. Assessments were conducted at baseline and after 4 weeks.

Results: In the AVG group, the single-leg stand test (eyes open; on floor and on foam conditions), the FAAM (activities of daily living subscale), and intrinsic motivation (interest/enjoyment, pressure/tension, and value/usefulness dimensions) were improved compared with the CG (all *P*<.05). Motor proficiency did not differ between the 2 groups at the end of the 4-week program (*P*=.31 for the walking forward on a line, *P*=.34 for the standing long jump test).

Conclusions: A 4-week home-based exercise training program using AVGs can be beneficial and may be an effective approach for improving balance, foot and ankle ability, and enhancing positive motivation by increasing the interest/enjoyment and value/usefulness dimensions and lowering the pressure/tension dimension in children with CAI that require long-term rehabilitation sessions.

Trial Registration: Thai Clinical Trials Registry TCTR20220727002; https://trialsearch.who.int/Trial2.aspx?TrialID=TCTR20220727002

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KEYWORDS

active video game; children; chronic ankle instability; motivation level; balance training; home-based exercise; video game; feasibility; ankle; instability; kinesiology; balance; exercise; exergame; exergaming

Introduction

Chronic ankle instability (CAI) is a condition characterized by a recurring giving way of the lateral side of the ankle and usually develops after repeated ankle sprains [1]. The indicators of CAI include mechanical instability, perceived instability, and recurrent sprain, which can occur independently or in combination [1]. In children, CAI has been reported in those with a history of ankle sprains or a high BMI and in youth athletes (eg, soccer players and dancers) [2-4]. Children with CAI frequently experience ankle unsteadiness, causing trips, falls, and ankle sprain injuries [4]. To prevent the long-term detrimental impact of CAI on quality of life and activities of daily living, the feasibility of therapeutic exercise programs for children with CAI would appear warranted.

The mainstay of research to date has focused on specific exercise programs in the adult population with CAI [5-11]. For example, Seyedi et al [11] investigated the efficacy of a 4-week progressive home-based balance training program using single-leg stance, crossed-leg sway, single-leg squat, heel raise, and lunge/jump exercises in college students with functional ankle instability. The results demonstrated notable improvements in daily activity following training. Interestingly, scant research attention has focused on developing specific exercise programs in children with CAI [12,13]. To the best of the authors' knowledge, only one study in children with foot and ankle weakness demonstrated that a 24-week high-intensity progressive resistance foot and ankle exercise program could strengthen the affected muscles and enhance the quality of life of children [14].

It is important to note that children commonly show nonadherence and lack of motivation during long-duration in-home physiotherapy training. It has been suggested that this might, in part, be due to the repetitive nature of therapeutic practices [15,16]. Therefore, much attention has recently been paid to the use of active video games (AVGs) or "exergaming" as an alternative method for therapeutic exercise in children with conditions [17,18] such as attention-deficit/hyperactivity disorder [19], type 2 diabetes [20], cerebral palsy [21], cancer [22], and developmental coordination disorder [23]. AVGs are technology-based games that track body movement or reaction to the game with instantaneous visual or audio feedback. It is proposed that this could promote physical and psychological benefits by offering the opportunity to enjoy training [18]. Furthermore, the interactive and engaging nature of the training program could result in promoting adherence and motivation through the player's desire to complete the challenges of the game [7,24].

In children, previous studies have reported the effectiveness of AVG training on physical activity [22], gross motor skills [25,26], balance [26], daily living ability [26], voluntary motor control [27], and dynamic postural stability [28]. However, the effectiveness of AVG training in children with CAI has yet to be investigated. In a previous study at our laboratory, Chuadthong and Lekskulchai [29] compared movement patterns in children with CAI while playing 4 AVGs, including Catching Fish and Russian Block, as well as dancing and running games. The findings suggested that Catching Fish and Russian Block elicited greater specific movement patterns, such as single-leg stance, double-leg stance, and reaching direction, suggesting that these might be effective game-based rehabilitation programs for children with CAI.

Therefore, this study selected these 2 video games (ie, Catching Fish and Russian Block) from Stepmania Coilmix [30] to be used in the AVG training program due to the movement strategies of the games. We hypothesized that an AVG training program would have positive physiological and psychological outcomes in this population. More specifically, this study aimed to investigate the effectiveness of a 4-week home-based AVG exercise training program for improving balance ability, muscle strength of the foot and ankle, and intrinsic motivation in children with CAI.

Methods

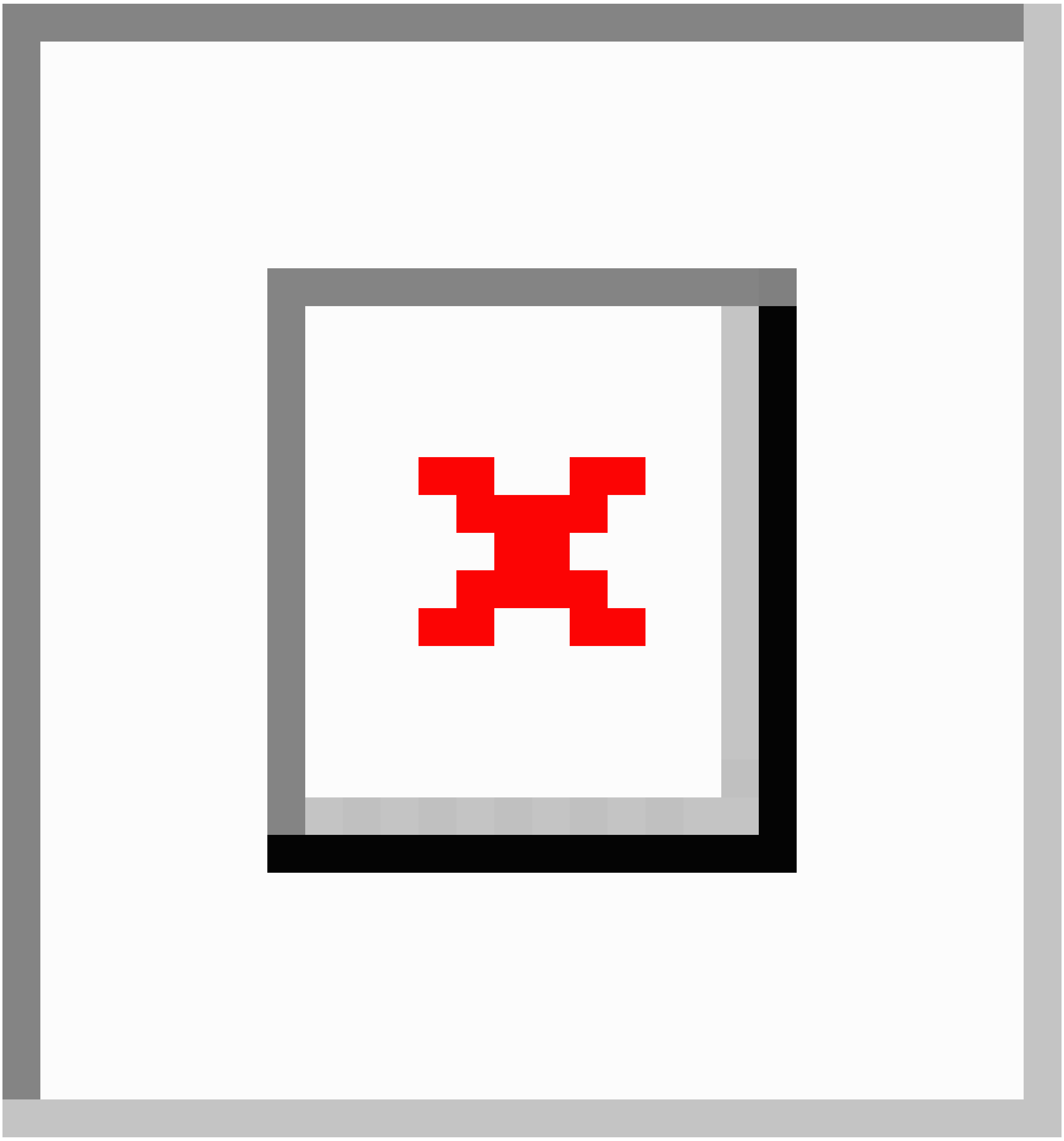
Sample Size

This study calculated sample size estimates from a previous study [3] using G*Power (version 3.1.9.2; Universität Düsseldorf) with a Cohen *f* effect size of 0.7, an α of .05, and a power of 0.8. The calculated sample size was 54 plus 6 for 10% dropout, so a final sample size of 60 participants (30 participants for each group) was needed.

Study Design and Participants

This study was a single-center, assessor-blinded, randomized controlled trial. The participants were matched by age and gender and randomly assigned to either the AVG group (n=30) or the therapeutic exercise program for the control group (CG, n=30) using a computer-generated program. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram of this study is shown in Figure 1. Sixty nonathletic, typically developing children with CAI aged between 7 and 12 years and with BMI between the 5th and 85th percentiles on the US Centers for Disease Control and Prevention growth chart [31] volunteered for the study. Inclusion criteria were (1) a score equal to or less than 25 on the Cumberland Ankle Instability Tool–Youth (CAITY), Thai version [32], (2) recurrent ankle sprain more than 3 months before enrollment, (3) a feeling of giving way at least twice a year, and (4) unilateral ankle sprain at least 1 year before enrollment. Participants were excluded if they had a history of either (1) ankle fracture, ankle surgery, or neurological disorder; (2) health problems such as uncontrolled seizure, asthma, severe heart disease, hearing problems, or visual problems that could not be corrected by using a lens; and (3) current participation in another rehabilitation program for the ankle joint.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study participants.



Ethical Considerations

The study conformed to the Declaration of Helsinki and was approved by the local Institutional Review Board Ethics Committee (MU-CIRB 2020/387.2311). After an explanation of the exercise protocol, testing procedures, and benefits and possible risks of the study, the informed consent form was signed by the parents or guardians and the assent form was signed by the participants.

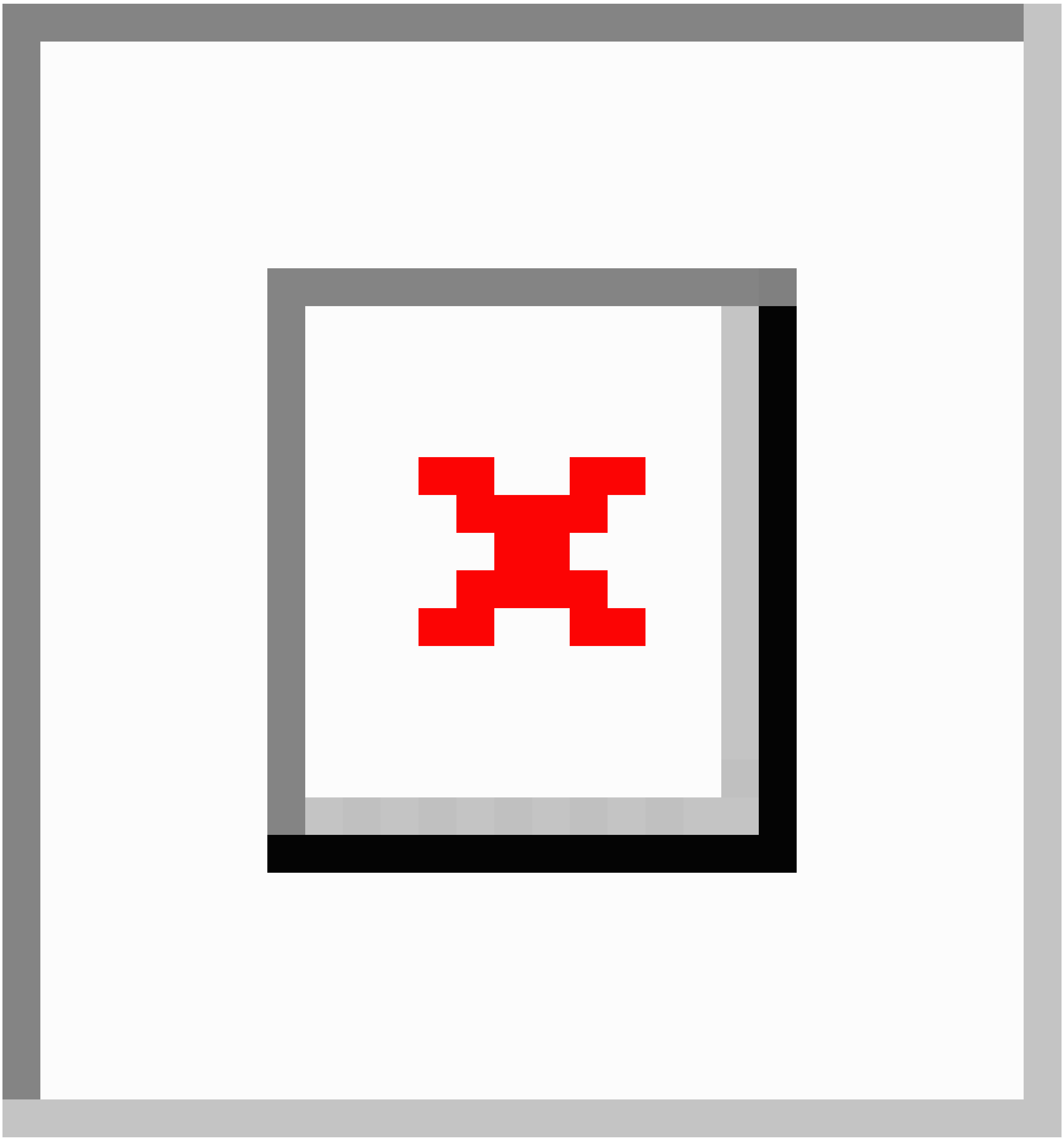
Experimental Procedure

The experimental group performed the AVG exercise program, whereas the CG performed the therapeutic exercise for the CAI program [33]. Both programs were scheduled for 3 sessions per week and 30 minutes per session for 4 weeks at home (a total of 12 exercise sessions). The 30-minute CG and AVG exercise programs consisted of a 5-minute active warm-up, a 20-minute main exercise, and a 5-minute cooldown. To assess compliance with the study protocol, the researchers followed up with participants once a week with a phone call. Balance ability tests and ankle instability questionnaires were evaluated at week 0 and week 4. The Intrinsic Motivation Level (IML) questionnaire was assessed each week over the course of the 4-week program [34].

Therapeutic Exercise Program for CAI (CG)

The design of the exercise program used in this study was adapted from the Star Excursion Balance Test (SEBT) [28]. Briefly, participants were asked to stand on one leg and then slowly reach with the other leg in different directions. This involved reaching in the anterior posteromedial and posterolateral directions as far as possible, touching down along the guideline, and then returning to the starting position (Figure 2). Each direction was completed as a separate trial. Participants were asked to perform 10 trials in each direction for 2 rounds with a 5-minute rest between rounds (for a total main exercise duration of around 20 minutes). Participants used their affected limbs first and then changed to the other limb. The program was designed to gradually increase the reaching distance of the leg (in centimeters) every week (by 50%, 60%, 70%, and 80% of the baseline value in weeks 1, 2, 3, and 4, respectively).

Figure 2. Outline of the therapeutic exercise for chronic ankle instability.

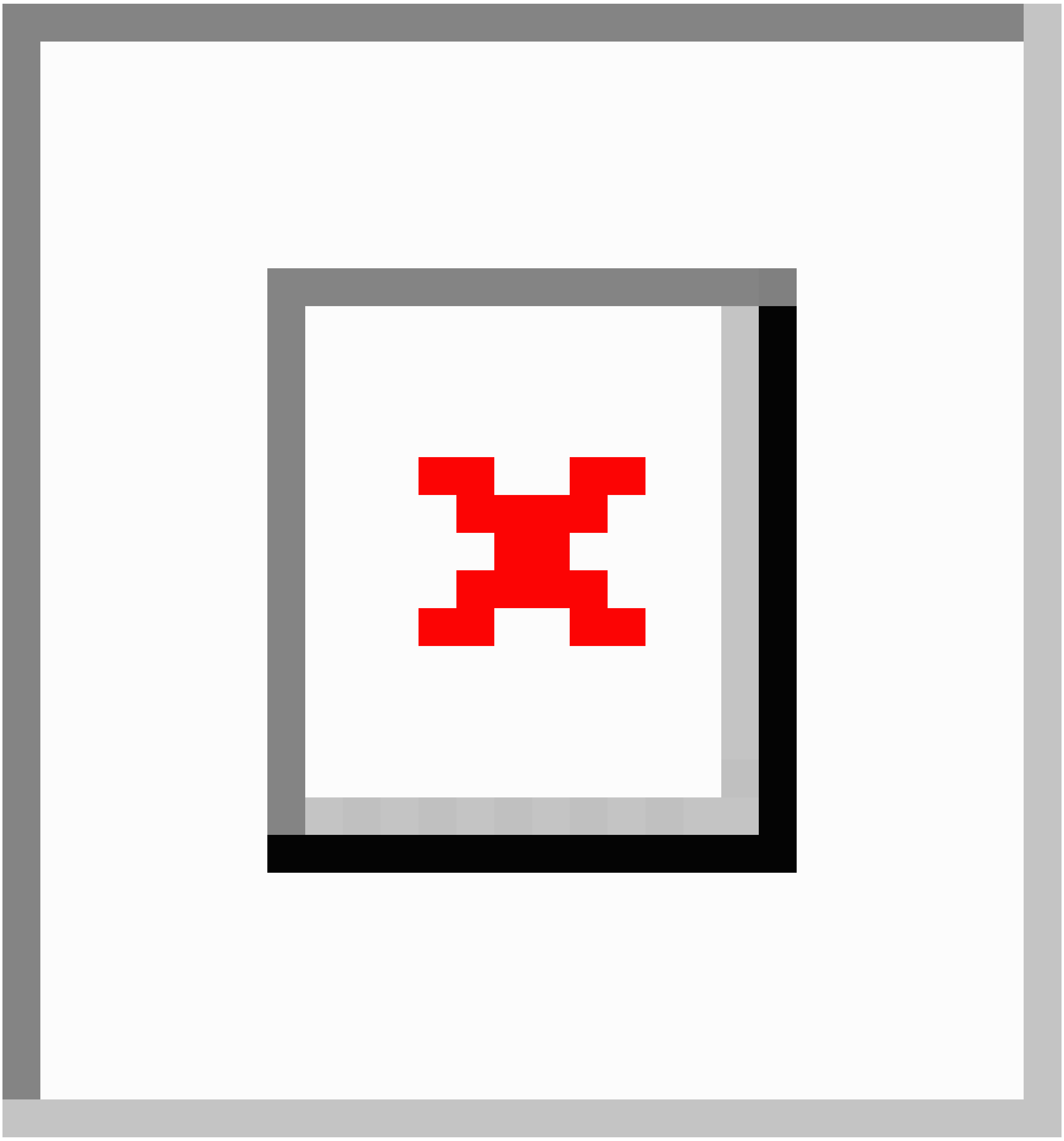


AVG Exercise

The AVG program (Figure 3) comprised 2 selected video games (ie, Catching Fish and Russian Block) from Stepmania Coilmix, a cross-platform rhythm video game and engine with a wireless dance mat [30]. In Catching Fish, participants stood in the center of the mat before starting the game, then moved their feet either in the left or right direction in response to the game (ie, they pressed the corresponding arrows to catch the yellow or red fish). Participants had to continue playing the game as long as possible, with 4 chances to obtain a higher score. Similarly, for the Russian Block game, participants stood in the center of the mat before starting, then moved their feet in the left or right direction to change and manipulate the shape of the falling Tetromino piece shown on screen. To challenge the players, the piece will be moved faster, and it will become more difficult to correct the position. By the end of the game, the total score is shown.

The total exercise duration for the 2 games was approximately 20 minutes. If one of the games ended before 10 minutes, participants were required to start playing again from the beginning. For convenience and to promote adherence, the AVG devices were set up in the participants' homes. The researchers provided instructions and demonstrations until the parents and children could operate the device correctly with no assistance.

Figure 3. Outline of the active video games. (A) Catching Fish; (B) Russian Block.



Outcome Measurements

Static Balance Tests

A single-leg stance test (SLST) was used to assess static balance. Participants were asked to stand on their affected limb and flex the hip and knee joints of the unaffected limb to 90 degrees for up to 30 seconds [35]. The tests were assessed in 4 conditions, including standing with eyes open (EO) or eyes closed (EC) on a stable surface (EO-floor and EC-floor) or a foam surface (EO-foam and EC-foam). The start time was when the foot was lifted off the floor. The test was stopped when any of the following occurred: (1) 30 seconds expired, (2) there were changes in the position of the weight-bearing foot, (3) any body part except the weight-bearing foot touched the floor, and (4) the participants opened their eyes during the EC trials. The test was measured 3 times. The test-retest reliability of the test was assessed and ensured using the intraclass correlation coefficient

(ICC). We used the ICC (3,1) type and found that ICC was 0.793.

The Bruininks-Oseretsky Test of Motor Proficiency

The balance subtests (ie, walking forward on a line test and standing long jump test) of the Bruininks-Oseretsky Test of Motor Proficiency, second edition (BOT-2) [36,37] were used to assess functional balance and muscle strength. The ICC of the BOT-2 was 0.789.

For the walking forward on a line test, participants stood with feet together and hands on hips, with the preferred foot on and parallel to the line. This test was conducted one time but allowed for a second time if a participant did not achieve the maximum score of 6 correct steps. The primary investigator recorded the number of correct steps, up to 6. An incorrect step was recorded when the participant either stepped off the line, failed to keep hands on hips, or stumbled or fell.

For the standing long jump test, participants were asked to stand behind the start line, then jump forward as far as possible and try to land on their feet. This test was conducted one time; however, if the participant stumbled or fell, a second attempt was conducted. The researcher recorded the distance (in cm) from the start line to the heel.

Ankle Instability Questionnaire

The Foot and Ankle Ability Measure (FAAM) questionnaire is a commonly deployed diagnostic tool to assess foot and ankle ability for participation level [38,39]. It contains 2 subscales, one including 21 items on activities of daily life (FAAM-ADL) and the other 8 items for sports (FAAM-Sport). All participants rated their current level of difficulty when performing various tasks (eg, standing, walking up and down hills, and going up and down stairs for FAAM-ADL and running, jumping, and cutting or lateral movements for FAAM-Sport) with one response that most closely described their condition within the past week. If an activity was limited by something other than their foot or ankle, the question was marked not applicable (4=no difficulty, 3=slight difficulty, 2=moderate difficulty, 1=extreme difficulty, 0=unable to do, and N/A=not applicable). Percentage scores were obtained by converting item score totals ranging from 0 to 84 for the ADL subscale and from 0 to 32 for the sports subscale. A score below 90% on both subscales signifies functional ankle instability in participants. Higher scores indicate better self-reported function.

Intrinsic Motivation Inventory Questionnaire

The Intrinsic Motivation Inventory (IMI) is a multidimensional questionnaire used to assess the participant's subjective perception of a target activity [34,40]. It uses a 7-point Likert scale (ranging from 1=strongly agree to 7=strongly disagree) [41]. This questionnaire assesses 5 dimensions: interest/enjoyment; perceived competence; effort/importance; pressure/tension; and value/usefulness. The mean IMI scores were calculated for each dimension. According to a previous study conducted at our laboratory, the IMI is feasible and understandable for children aged 7 years without any indications, since the questions consist of simple words and are easy to understand [29]. However, to ensure correct use, parents and children practiced under the supervision of an investigator before going home. For the first use, the investigator visited each child's home to supervise them. Later, any problems with the use of the questionnaire were noted by the parents in the child's logbook. Furthermore, the investigator called once a week to assess their compliance with the study protocol.

In the child's logbook, feasibility was recorded as the rate of recruitment, retention, and adherence to the training intervention; safety was also recorded as the number of adverse events during testing or training.

Statistical Analysis

Shapiro-Wilk tests were carried out to examine the normality of the data, and all data were found to be suitable for parametric testing. In addition, the sphericity of data was considered using the Mauchly test of sphericity; where the sphericity assumption was violated, Greenhouse-Geisser corrections were applied. Independent 2-tailed *t* tests were performed to compare the means and differences of each dependent variable at the baseline assessment. A 2-factor mixed model ANOVA was used to evaluate the effect of treatment group and time for the SLST, functional balance and strength test, and FAAM questionnaire. A repeated measure ANOVA was used for the IMI questionnaire. Any interactions between group and time were revealed using post hoc 2-tailed paired *t* tests with a Bonferroni correction to determine any differences within each group between the time points. The observed effect size was expressed as partial η squared (ηp^2), with values of 0.1-0.29, 0.3-0.49, and >0.50 representing a small, medium, and large effect size, respectively [42]. The change score was calculated from the difference between data from week 4 minus data from week 0 using independent 2-tailed *t* tests. A $P<.05$ was considered statistically significant.

Results

Demographic characteristics and screening tests of participants are displayed in Table 1. Independent 2-tailed *t* tests showed no significant differences between the AVG and the CG at week 0 at the $P>.05$ level.

Table . Baseline characteristics of the active video game (AVG) group and the control group (CG), which received therapeutic exercise for chronic ankle instability (n=30 for each group). Data were analyzed with an independent 2-tailed *t* test. The significance level was set at *P*<.05.

Characteristics		AVG group	CG	*P* value
Gender, n				.43
	Boy	14	11	
	Girl	16	19	
Age (years), mean (SD)		10 (2)	10 (2)	.51
Weight (kilograms), mean (SD)		32.8 (9.6)	34.0 (11.1)	.68
Height (centimeters), mean (SD)		135.2 (11.7)	136.7 (11.9)	.62
Side of chronic ankle instability, n				.43
	Right	20	17	
	Left	10	13	

For the SLST, the mixed model ANOVA tests revealed significant interactions between groups for EO-floor ($F_{1,58}$=7.11; *P*=.004; ηp^2=0.02) and EO-foam ($F_{1,58}$=7.80; *P*=.002; ηp^2=0.03). Further post hoc analysis revealed that the AVG group had higher values than the CG for EO-floor (*P*=.03) and EO-foam (*P*=.01) at week 4. In addition, the differences in change score between groups indicated that the AVGs elicited a change in EO-floor (95% CI=−8.01 to 0.71; *P*=.04) and EO-foam (95% CI=−7.47 to 0.05; *P*=.03) over the CG at week 4. However, there were no changes in EC-floor between time and groups for either group (*P*=.44) (Table 2).

Table . Observations from the single-leg stance test (SLST) with eyes open (EO) and eyes closed (EC) on floor and foam; the balance and strength subtests of the Bruininks-Oseretsky Test (BOT-2), including the walking forward on a line test and standing long jump test; and the Foot and Ankle Ability Measure (FAAM) for activities of daily life (ADLs) and sports at baseline (week 0) and week 4 in the active video game (AVG) exercise group and control group (CG), which received therapeutic exercise for chronic ankle instability (n=30 for each group). The significance level was *P*<.05.

Variables		AVG group			CG		
		Week 0	Week 4	Change score	Week 0	Week 4	Change score
SLST (seconds), mean (SE)							
	EO-floor	24.6 (1.2)	25.3 (1.1)	0.7 (1.3)	22.2 (1.4)	19.3 (1.6)[a]	−2.9 (1.7)[b]
	EC-floor	8.8 (0.9)	9.9 (1.1)	1.1 (1.0)	8.7 (1.0)	8.2 (1.1)	−0.5 (1.0)
	EO-foam	15.9 (1.4)	18.0 (1.4)	2.1 (1.3)	13.1 (1.4)	11.5 (1.3)[a]	−1.7 (1.4)[b]
	EC-foam	3.1 (0.2)	3.6 (0.3)	0.5 (0.3)	3.1 (0.2)	3.3 (0.2)	0.2 (0.2)
BOT-2							
	Walking forward on a line (steps), mean (SE)	5 (0)	6 (0)	0.7 (1.7)	5 (0)	6 (0)	0.4 (1.4)
	Standing long jump (centimeters), mean (SE)	107.9 (4.9)	108.5 (4.8)	0.6 (3.2)	103.6 (4.4)	106.8 (2.9)	3.2 (3.1)
FAAM (%), mean (SE)							
	FAAM-ADL	87.2 (1.3)	91.3 (1.1)[c]	4.3 (0.9)	82.2 (2.1)	84.1 (2.1)[a]	2.0 (1.1)[b]
	FAAM-Sports	89.6 (1.9)	91.5 (1.4)	1.9 (2.1)	83.7 (3.0)	87.1 (2.4)	3.3 (2.8)

[a]Significant difference between the AVG group and the CG at week 4 using mixed model ANOVA.

[b]Significant difference between the AVG group and the CG for change score using independent 2-tailed *t* test.

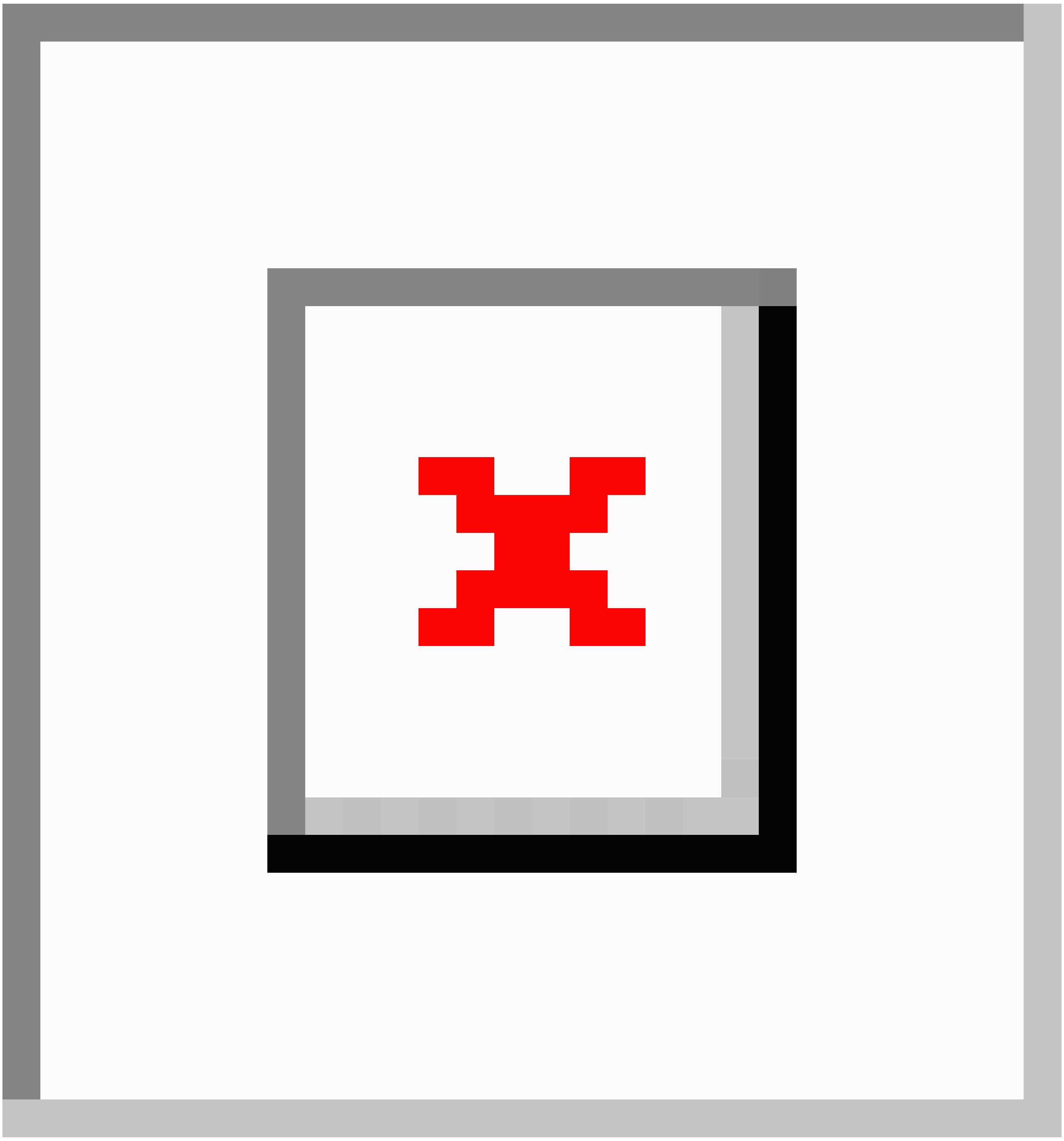
[c]Significant difference between week 0 and week 4 using mixed model ANOVA.

Regarding the BOT-2, including the functional balance and strength test, there were no significant interactions between time and group on the walking forward on a line (*P*=.31) and the standing long jump test (*P*=.34) in both groups (Table 2).

For the FAAM-ADL, the mixed model ANOVA tests revealed significant interactions between groups ($F_{1,58}$=6.77; *P=.01*; ηp^2=0.56) where the FAAM-ADL values for the AVG group were greater than those for the CG at week 4 (*P*=0.01). Also, significant interactions between times were found ($F_{1,58}$=19.03; *P*<.0001; ηp^2=0.25) in the AVG group, but not in the CG. The AVG group increased mean percentage on the FAAM-ADL from week 0 to week 4 (*P*<.001). Moreover, the differences in change score between groups indicated that the AVG group showed a change in percentage on the FAAM-ADL (95% CI−5.16 to 0.445; *P*=.04) over the CG at week 4. However, there were no changes in FAAM-Sports between time and group for either group (*P*=.69) (Table 2).

For the IMI, A 2-way repeated-measures ANOVA determined an effect of group for the interest/enjoyment ($F_{4,116}$=2.59; *P*=.04; ηp^2=0.08), value/usefulness ($F_{4,116}$=2.71 *P*=.03; ηp^2=0.09), and pressure/tension ($F_{4,116}$=2.50, *P*=.04, ηp^2=0.08) dimensions. Post hoc pairwise comparisons using Bonferroni correction showed a significantly greater score for interest/enjoyment and value/usefulness on the IMI in the AVG group compared to the CG (AVG group vs CG: 7, SD 0 vs 6, SD 0 for interest/enjoyment, *P*<.001 and 6, SD 0 vs 5, SD 0 for value/usefulness, *P*=.005) at week 2. Additionally, at week 4, the AVG group had a lower score for pressure/tension on the IMI than the CG (AVG group vs CG: 1, SD 0 vs 2, SD 0; *P*<.001). Significant interactions for time were found in the CG ($F_{4,116}$=4.39; *P*=.002; ηp^2=0.17) but not in the AVG group. The CG had increased perceived competence scores from baseline to week 4 (baseline vs week 4: 5, SD 0 vs 6, SD 0; *P*=.005) and week 1 to week 4 (week 1 vs week 4: 5, SD 0 vs 6, SD 0; *P*<.001). There were no significant differences observed between the group and time on any other dimension of the IMI (*P*>.05) (Figure 4).

Figure 4. Observations from the intrinsic motivation inventory questionnaire at baseline, week 1, week 2, week 3, and week 4 in the active video game (AVG; n=30) exercise group and the control group (CG; n=30), who received therapeutic exercise. The data are shown as the mean (SEM). **P*<.05; repeated measures ANOVA.



Exercise adherence was measured using the child's logbook. All participants performed 100% of the exercise as per each week's exercise protocol. Furthermore, there were no reports of harm or injury occurring during training in either the AVG group or the CG.

Discussion

Principal Findings

The major finding of this study provides evidence that a 4-week AVG home-based exercise training program can have a positive and significant therapeutic effect on children with CAI as determined by improving static balance, foot and ankle ability, and key measures of intrinsic motivation (ie, interest/enjoyment, pressure/tension, and value/usefulness).

For balance control, after 4 weeks of the training program, the AVG group could perform the SLST with EO on a stable surface as well as on a foam surface better than those who performed the traditional CAI program. When playing video games, children learn how to act and respond to the game scenario promptly, which is considered to enhance sensorimotor learning after training [43]. Moreover, the improvement of balance following the AVG training could be related to the movement strategies inherent in the games. The games provide visual feedback via a variety of visual-perceptual processing challenges and prompt lower-extremity muscle responses to control posture and balance. The results of this study support previous findings that have demonstrated the effectiveness of using visual feedback tools as a therapeutic training modality [28,44-46]. For example, Kim and Heo [44] reported the benefits of 4 weeks of balance exercise using the Wii Fit Plus program (30 minutes, 3 times a week) for improving static balance in people with functional ankle instability. Moreover, Fitzgerald et al [28] found that a therapeutic exergaming system showed an improvement in postural stability when compared to a group doing similar balance training without the game system. Therefore, this study offers further support for using an AVG visual feedback training program as an effective modality for improving the balance of children with CAI.

The results of this study showed no significant difference in the subtest of the BOT-2 for functional balance, measured by walking forward on a line, and for leg muscle strength, measured by a standing long jump, in the AVG group and the CG after 4 weeks of training. This might be caused by either the movement patterns of the AVGs (moving feet to the left or right) and the traditional CAI program not being potent enough or the period of the exercise program (4 weeks) being too short to improve functional balance and lower-extremity strength.

This study revealed that foot and ankle ability measured by the FAAM-ADL in the AVG group improved after the 4-week training, and interestingly, it was greater than the CG. This result is congruent with the results of Punt et al [47], who found an improvement in foot and ankle ability during a 6-week follow-up of users of the Wii Fit game (twice per week, for 30 minutes per session) in lateral ankle sprain patients. Perceived instability of the foot and ankle has been reported to be associated with decreased health-related quality of life in individuals with CAI [43]. Thus, the exercise program with AVG could be used as exercise therapy to increase foot and ankle ability and might provide a better quality of life in children with CAI.

The participants' subjective perception of the program was assessed every week. Notably, in week 2, the perception of interest/enjoyment was increased in the AVG group, whereas the perception of value/usefulness was decreased in the CG. Interestingly, the perception of pressure/tension was increased in the CG and greater than the AVG group at week 4. These results are consistent with previous findings [28,45,48] that reported that a video game–based rehabilitation approach could provide a greater intrinsic motivation level to engage in the activity for a longer period of time when compared to a group doing similar balance training. These results might explain that increased interest and enjoyment may have occurred due to the achievable challenges provided by the games (ie, Catching Fish and Russian Block) and the subsequent feelings of achievement when each game level was completed. By contrast, in the traditional CAI program, there was no feedback mechanism during the exercises. The participants simply had to count the number of repetitions and sets performed, and this might have contributed to the reduction in value/usefulness levels, as well as the pressure/tension level increasing during the program. It is noteworthy that the results of this study illustrated that effort/importance slightly declined after 2 weeks and was still declining in week 4. It may be possible that the children became accustomed to the exercise program, as they had to repeat the same exercise again and again to achieve the aim of the intervention. This result is consistent with the findings of previous research that reported nonadherence and lack of motivation in long-duration training in home-based therapeutic practices [15,16].

Furthermore, the protocol and training intervention using the AVG program has been shown to be feasible, as indicated by the retention and adherence of participants. The safety of the program is evidenced by the lack of adverse events reported. This suggests that the design and progression of the training had an appropriate intensity and the interactive video game did not present any harm. Therefore, the above results suggest that AVG programs provide an engaging and interactive environment that results in less fatigue, more relaxation, and enhanced adherence throughout the rehabilitation period.

Limitations

There are some limitations to this study. First, observations were not obtained in a controlled laboratory environment. However, the researchers gave instructions, set up the exercise environment at the participants' homes, and made telephone calls to give reminders to the participants. Second, the relatively small sample size may not be representative of the characteristics of the broader population of children with CAI. Third, follow-up measurements are required so that the longitudinal effects of the AVG program can be better understood. Lastly, a 4-week program is a relatively short intervention period. Thus, further studies would appear warranted to determine the effects of a longer-duration AVG training program.

Conclusions

This study found that children with CAI showed significant improvements in single-leg standing, foot, and ankle ability measured by the FAAM-ADL and intrinsic motivation in the interest/enjoyment, pressure/tension, and value/usefulness dimensions after following a home-based exercise program with AVGs. Furthermore, it was discovered that playing video games while exercising comprised a visuomotor feedback task that was lacking in the therapeutic exercise program. Thus, visual feedback while exercising with AVGs may be an effective way to improve balance ability, especially in the EO condition. This highlights that AVGs focused on balance exercises can be beneficial and may be an effective approach for improving balance and enhancing positive motivation in children with CAI who require long-term rehabilitation sessions.

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Authors' Contributions

JC conceptualized and designed the study, performed data collection, analyzed the data, interpreted the results, and wrote the first draft of the manuscript; RL and AA contributed to the conception and design of the study, performed the statistical analysis, interpreted the results, and drafted the manuscript; CH contributed to the conception and design of the study and supervised the study. All authors have read and approved the final version of the manuscript and agree with the order of presentation of the authors.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File, 1250 KB - games_v11i1e51073_app1.pdf]

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Abbreviations

ADL: activity of daily life
AVG: active video game
BOT-2: Bruininks-Oseretsky Test of Motor Proficiency, second edition
CAI: chronic ankle instability
CAITY: Cumberland Ankle Instability Tool-Youth
CG: control group
CONSORT: Consolidated Standards of Reporting Trials
EC: eyes closed
EO: eyes open
FAAM: Foot and Ankle Ability Measure
ICC: intraclass correlation coefficient
IMI: Intrinsic Motivation Inventory
IML: Intrinsic Motivation Level
SEBT: Star Excursion Balance Test
SLST: single leg stance test

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Original Paper

Finding Effective Adjustment Levels for Upper Limb Exergames: Focus Group Study With Children With Physical Disabilities

Martina Eckert[1*], PhD, ING; Beatriz Domingo Soria[2*], PT; Noelia Terroso Gil[2*], PT

[1]Group of Acoustics and Multimedia Applications, Department ot Audiovisual Engineering, Universidad Politécnica de Madrid, Madrid, Spain

[2]Department of Physiotherapy, Primary School, Centro de Educación Infantil y Primaria Pinar de San José, Madrid, Spain

[*]all authors contributed equally

Corresponding Author:
Martina Eckert, PhD, ING
Group of Acoustics and Multimedia Applications
Department ot Audiovisual Engineering
Universidad Politécnica de Madrid
Calle Alan Turing 3
Madrid, 28031
Spain
Phone: 34 91 067 87 62
Email: martina.eckert@upm.es

Abstract

Background: We developed the Blexer system consisting of a database and a web interface for therapists that can host different types of adaptive and personally configurable virtual reality exergames based on Kinect (Microsoft Corp) motion capture to provide entertaining exercises for children with motor disabilities. It allows for parameter adjustment and the monitoring of results remotely, thereby providing a useful tool to complement traditional physical therapy sessions with home exercises.

Objective: The aim of this study was to observe the motor benefits achieved through the use of a video exergame and the importance and implications of correctly setting the game's difficulty parameters.

Methods: This was an observational case study of 6 children with different physical disabilities receiving physical therapy at school combined with the use of a fully configurable exergame under research that forms a part of the Blexer environment. The game integrates 4 repeatedly appearing upper limb exercises with individually adjustable difficulties (intermittent arm rising, arm forward and backward movement, rising and holding of one arm, and trunk control in all directions). The outcomes were 3 assessments of 2 efficacy measures: Box and Block Test and Jebsen Taylor Hand Function Test.

Results: A total of 5 children with cerebral palsy (mean 8.4, SD 2.7 years; Gross Motor Function Classification II—2/5, 40%; III—2/5, 40%; and IV—1/5, 20%) and 1 child with obstetric brachial plexus palsy (aged 8 years; Mallet Classification III) received between 8 and 11 sessions of training (10-20 minutes per session), depending on age, motivation, and fatigue. Significant associations were observed between game parameter settings and improvements in motor function, on the one hand, and between the type of improvement and disability severity, on the other: with adjusted game parameters *goal* and *time* in the range of 70% to 100%, only less affected children improved in the Box and Block Test (+11 blocks vs −1 block), and more affected children improved more in the Jebsen Taylor Hand Function Test (+90 seconds vs +27 seconds).

Conclusions: When defining the difficulty parameters for an exergame, we suggest a classification in levels ranging from *very easy* to *very hard*. For practical use, we suggest setting the difficulty for the player to an *easy* or *medium* level rather than high-commitment goals, as this leads to a longer playtime with more fun and, therefore, seems to improve the results of the game and, consequently, mobility.

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KEYWORDS

rehabilitation; physical therapy; cerebral palsy; obstetric brachial plexus palsy; serious games; exergames; Kinect

Introduction

Background

Cerebral palsy (CP) and obstetric brachial plexus palsy (OBPP) are 2 of the pathologies that most frequently cause problems in the upper limbs in children and adolescents. According to the International Classification of Functioning, Disability, and Health (ICF), these problems affect corporal structure and function, limiting, in many cases, activities of daily living [1]. CP is considered a global disorder because of a permanent and nonprogressive lesion in the brain, before its development is complete, producing alterations in tone, posture, and movement, resulting in functional limitations and other associated alterations [2,3]. OBPP is generally caused by an elongation of the brachial plexus during childbirth, although it can also have an intrauterine, genetic, or postural origin. Alterations range from nerve conduction impairment to total rupture of anatomical structures [4,5]. Common problems of both pathologies are muscular atrophy and weakness, imbalance, alteration of the coordination of different muscle groups, secondary joint pathology, and decreased general use of the arms and hands in daily activities [6,7].

Regarding the different conservative treatments for both pathologies, we found that different systematic reviews proposed repetitive, challenging, high-intensity, and motivational interventions [5,6,8,9].

When analyzing the interventions that are considered effective in CP, we found that training with video games or virtual reality (VR) is among the interventions for which there is promising evidence suggesting possible effectiveness [8]. In OBPP, VR associated with other therapeutic strategies is also considered significantly more effective than conventional physical therapy programs [4,10]. Therefore, serious games and VR are considered promising interventions in both conditions.

Systematic reviews that analyzed the effectiveness and clinical utility of VR interventions indicated that motion capture devices have beneficial effects in the rehabilitation of patients with neurological disorders, achieving high levels of compliance, motivation, and commitment that can help improve one or more levels of ICF. The greatest benefits were found in domain 1 of the ICF, being effective in improving upper extremity function, hand coordination, balance function, gait, and postural control. In addition, benefits are associated with aspects such as participation in the community and improvements in psychological and cognitive functions [5,9,11-13].

The benefit of video games is that they offer immediate feedback and rewards that stimulate the brain so that the user wants to play more. Providing challenging and fun environments that keep the player motivated increases the number of repetitions of certain movements compared with conventional therapy. Thus, neuroplastic changes and cortical reorganization, which could produce improvements in performance, are elicited [14,15]. The use of these types of games encourages participants to direct their attention to an external focus, which helps them to learn faster and more accurately than requests from an internal focus [16].

As for motion-controlled video games, most studies use Kinect devices (Microsoft Corp) along with commercial video games, which provide accessibility and portability and are low cost. However, these video games do not address the specific needs of patients who sometimes cannot perform the required movements quickly or efficiently enough to succeed during play. Therefore, different reviews point to the advantages of specifically designed games that provide appropriate challenges and adapt to the player's speed and quality of movement, thus avoiding boredom and frustration. However, the negative aspect is that commercially available mainstream video games cannot be personalized and that there are still very few offers for therapeutic video games, which are quite expensive [11-13,17-20].

Some commercial solutions we found are the MIRA software platform (MIRA Rehab Limited), [21], VirtualRehab (Evolv) [22], and REHABILITY (Imaginary SL) [23], all of which seem quite complete, but it is not clear from the information provided on the web pages how and to what extent the different exercises involved in the games are configurable for each user.

The common opinion of researchers is that games should complement therapy with both options, accompanied by a professional or used at home [9,12,24]. In any case, it is recommended that computer-based training be followed by the practice of activities in the physical environment to ensure adequate perceptual adjustment and the transfer of the benefits of training to activities of daily living performed in a real environment [24].

Objectives

The purpose of this study was to observe how much influence the adjustment of the games' objectives has on the child's performance in upper limb movements. We suppose that there is a small range of adjustments that ensures that the challenge for the child is neither too low (leading to boredom) nor too high (leading to frustration). Therefore, we wanted to prove the hypothesis that the optimal settings (of the goal and the time parameters) are those that ensure that the goal can be reached within the given time limit. Furthermore, the aim was to derive some practical adjustment rules from our results that could be useful for our and other similar configurable games.

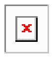
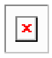
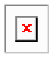
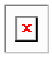
Methods

Therapeutic Video Game Environment

The Blexer system has been described in detail in various previous publications [25,26]. It consists of a database and a web platform that integrates different video games and is accessible only to clinicians. On the user side, a PC with a motion capture camera (Kinect X360, Microsoft Corp) is required. The PC hosts one or more games and a middleware [27] that acts as a communicator among the camera, the database, and the games. It provides the games with motion data, downloads the game settings established by the clinician, and uploads the users' results after each play to the database.

The game used in this study, Phiby's Adventures (version 1), is a semi-3D third-person video game extensively described in the study by Eckert et al [26]. The main character, Phiby, is a small amphibian that must be helped to get out of a valley, which is represented by a modular 2D map with 16 × 8 cells. The cells are connected through different obstacles such as rivers, trees, lakes, or trunks that Phiby must pass while finding its way out of the valley. Each obstacle is an independent exercise scene (refer to the description provided in Table 1) that needs arm and trunk movements of different intensities to pass through. The logs obtained from chopping the trunks can be used to build bridges or huts. A hut allows the player to rest and to save the game state for resuming from that point in the next session. With the aim of increasing the player's interactivity and decision-making, they are given an option to freely choose the path to follow and, therefore, take the obstacles they like. By passing through the cells, the areas of the map are gradually discovered and can be visualized through an arm movement. The 4 exercise scenes have adjustable difficulty parameters (objective and time limit), as explained in Table 1. An initial calibration measures the players' range of movement for adapting the game to their capacities.

Table 1. Overview of the 4 exercises inherent in the video game.

Exercise	Description	Abilities to train	Pictures
Chop the wood	Exercise using the affected limb: this exercise provides a specific activity for the use of the affected side in which maximum shoulder flexion is requested based on the initial calibration. The child works on support and shoulder girdle stability to keep the axe elevated until it is loaded as well as on arm speed to lower the axe and split the wood. The amount of wood to split (=number of arm lifts) and the time limit to achieve all can be modified.	• Proximal arm movement (shoulder flexion) • Movement speed • Initiation of use of assisting hand • Reaches • Endurance • Stabilization of the shoulder and shoulder girdle	
Dive and eat	Trunk control exercise: in this exercise, the objective is to catch some of the pieces of plankton floating in the water. The player controls the direction of the fish with their trunk movements. It favors trunk control and can be performed in a sitting or standing position. The number of planktons to catch and the time limit can be modified.	• Trunk control and stability	
Row the boat	Symmetrical movement exercise of upper extremities: in this exercise, the symmetrical use of both upper limbs is proposed, and the objective is to row a boat until reaching the opposite bank of the river. The speed of the boat depends on the speed of the user's movements. The distance to travel (=number of arm movements) and the time limit can be adjusted.	• Proximal movement of the arm (shoulder flexion-extension) and elbow • Movement speed • Initiation of use • Hand and arm coordination • Execution flow of bimanual activities	
Climb the tree	Alternated movement exercise in upper limb abduction: this exercise involves alternating movements of the arms in abduction, and the objective is to reach the top of a tree to see the valley. The parameters to be modified are the height of the tree (=number of arm movements) and the time limit.	• Proximal arm movement (shoulder abduction and flexion) • Movement speed • Initiation of use • Reaches • Hand and arm coordination • Execution flow of bimanual activities	

Study Design and Participants

This case study was jointly driven by the Research Center for Software Technologies and Multimedia Systems for Sustainability of the Universidad Politécnica de Madrid (UPM) and the Public School CEIP (Centro de Educación Infantil y Primaria) Pinar de San José in Madrid. UPM developed the Phiby's Adventures video game and the Blexer-med web platform used in this study. The game is connected to the platform, which allows for the adjustment of the difficulty of the game parameters and the supervision of the results for each participant.

CEIP Pinar de San José is an integrative primary school (5-12 years) with 28 pupils (out of 950) having motor disabilities (13 CP, 2 OBPP). Informed consent was obtained from the parents and children involved in this study.

Inclusion criteria for the study were the following: being a scholar receiving physiotherapy care at the Pinar de San José school, being aged between 5 and 12 years, having a major functional impairment of an upper limb because of CP or OBPP, and being able to understand and follow the game. Exclusion criterion was poor trunk control that prevents activity from being performed in a freely seated position. The children were classified based on their functional level according to the *Gross Motor Function Classification (GMFCS)* [28], *Manual Ability Classification System (MACS)* [28,29], and *Mallet Classification* [30,31].

Intervention

Initially, several instructional sessions were conducted for 8 weeks to familiarize the children with the dynamics of the game. Then, the intervention took place for 6 weeks, using the game as a part of the usual 45-minute physiotherapy sessions (2 or 3 times a week), for approximately 10 to 20 minutes, according to age, motivation, and fatigue. In the remaining time, they received the usual physiotherapy treatment. They also continued with activities and therapies outside school.

During the instructional sessions conducted before the intervention, all the children played with the same default difficulty adjustments, which were 60 seconds time limit per exercise with the following goals: chopping 60 trunks, climbing up 100 meters, catching 10 planktons diving, and rowing 100 meters. After these sessions, the objectives of each game were adjusted individually for each child according to our subjective observations during training and with the intention to provide affordable challenges.

During the intervention, physiotherapists constantly supervised the children and verbally motivated them. They were allowed to vary their pose (sitting or standing) depending on their abilities and how they felt that day; however, all participants selected their favorite posture once and then always played in the same way and without any physical help from the therapists. Depending on the results observed, that is, considering whether the objectives were achieved and how quickly or whether the children were bored or stressed, the difficulty of each exercise was readjusted after each session to maintain the challenge. In the case of being tired or unmotivated, the goals were lowered, whereas they were raised when improvement or low challenge was observed. The time limit was kept constant at 60 seconds in all exercises. These decisions were based on subjective observations (of movements and mood) as the objective results (time needed for an exercise and score) were not graphically presented on the web at that moment. They could be revised in form of tables, but this was not useful for making instantaneous objective decisions. All the children were able to complete the activity.

Data Analysis of the Exercise Results and Jebsen Taylor Hand Function Test and Box and Block Test Assessments

The web platform receives the following for each exercise: its difficulty parameters (objective and time limit), the time stamps of entering and leaving, and the score reached. We analyzed the *relative* scores for each type of exercise, that is, the percentage of movements in relation to the objective established by the therapist, and correlated these data with the outcomes of 3 evaluations: previous evaluation (*Vp*) 8 weeks before, initial evaluation (*Vi*) immediately before, and final evaluation (*Vf*) immediately after the intervention. Between Vp and Vi, conventional therapy was performed, and after Vi, the game was used as a part of the therapy sessions for 6 weeks.

The assessments were made using the Box and Block Test (BBT) [32] (counting the number of blocks put from one part of the box to another; the more blocks, the better the result) and the Jebsen Taylor Hand Function Test (JTHFT) [33] (measuring the time required to perform 7 activities; the quicker, the better the result). Both tests have demonstrated reliability, especially for measuring changes that focus on improving hand dexterity and function in children with CP after intensive intervention. The reliability and responsiveness of these tests are better for short evaluation periods [18,19].

Statistical calculations were performed using SPSS software (version 26; IBM Corp). Descriptive statistics were used to summarize baseline characteristics and feasibility data. We used the Levene test to assess the normality of data distribution. Differences of means were calculated and proved by 2-tailed significance tests, and the differences were considered statistically significant at $P<.05$.

Ethics Approval

This study was approved by the Universidad Politécnica de Madrid (UPM) ethics committee and also complied with the Declaration of Helsinki.

Results

Study Design and Participants

For the study, 54% (15/28) of the children aged 5 to 12 years were screened for eligibility among the ones receiving physical therapy support at the Public School CEIP Pinar de San José in Madrid. Out of these, 47% (7/15) met all inclusion criteria and 7% (1/15) had to be excluded because of poor trunk control and inability to maintain stability during play without external aids; so finally, the analysis group was reduced to 6 children (Table 2). The mean age of the participants was 8.3 (SD 2.4) years; 5 (83%) children with CP were aged 8.4 (SD 2.7) years, and 1 (17%) child with OBPP was aged 8 years. We used the following code to identify the participants: *CP/OBPP+age+hand+group.*

The participants were divided into 3 groups based on the results of the functional classifications of GMFCS, MACS, and Mallet (Table 2):

1. Group 1: CP (GMFCS ≥III, MACS ≥III; 3/6, 50% participants)
2. Group 2: CP (GMFCS<III, MACS <III; 2/6, 33% participants)
3. Group 3: OBPP (Mallet III; 1/6, 17% participants)

The participants in group 1 had a lower functional level, with an average age of 7 (SD 2.6) years. The participants in groups 2 and 3 presented a similar profile with higher functional levels in both gross and fine motor skills; therefore, these 2 groups were merged into group 2+3 (average age: 9.7, SD 1.5 years). Thus, 2 homogeneous groups of 3 children each were formed, considering similar functionality and age.

Table 2. Details of the participants' age, sex, diagnosis, affected hand, playing position, motor function ratings, and assigned group.

ID	Age[a] (years)	Sex	Diagnosis	More affected hand	Play position	Classification			Group
						GMFCS[b]	MACS[c]	Mallet	
CP5L1	5	Female	CP[d]	Left	Seated	IV	III	N/A[e]	1
CP6R1	6	Male	CP	Right	Seated	III	III	N/A	1
CP10R1	10	Male	CP	Right	Standing	III	III	N/A	1
CP10L2	10	Male	CP	Left	Standing	II	I	N/A	2
CP11R2	11	Female	CP	Right	Standing	II	I	N/A	2
OBPP8R3	8	Female	OBPP[f]	Right	Standing	N/A	N/A	Mallet III	3

[a]Age, mean (SD): all=8.3 (2.4) years; CP=8.4 (2.7) years; group 1=7.0 (2.6) years; group 2+3=9.7 (1.5) years.

[b]GMFCS: Gross Motor Function Classification.

[c]MACS: Manual Ability Classification System.

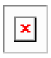
[d]CP: cerebral palsy.

[e]N/A: not applicable.

[f]OBPP: obstetric brachial plexus palsy.

Intervention

On average, 9.8 (range 8-11) sessions were conducted per participant, adjusting the duration of each session according to age, motivation, and fatigue. Given the fact that each player needed individual adjustments of the time limit and the objective of an exercise, comparisons could be made only through relative values; therefore, we defined 2 variables that represent the results as percentages of what was achieved in relation to what was configured: pct_{goal} (percentage of goals, equation 1) is the number of movements performed in relation to the objective established by the therapist and pct_{time} (percentage of time, equation 2) is the time needed to finish the exercise in relation to the time limit set.



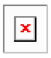


Table 3 presents the individual results that the participants obtained for each exercise during the intervention sessions.

For analyzing how well the target values of the exercises were adjusted in each session according to the child's abilities, pct_{goal} and pct_{time} were plotted over time. The aim was to avoid excessive exertion and under exertion and to achieve the highest possible level of motivation. Figure 1 shows 4 examples of the performance of different players in different exercises, comparing the time and score achieved during the intervention.

Participant CP5L1 achieved a 100% score on the rowing exercise (Figure 1, top left) in less than half the time, and our observation was that the child quickly became bored. The plot on the right side of the top row in Figure 1 shows the opposite situation for the same child during the dive exercise: 100% of the time limit was almost always used but to no avail, and we also observed difficulties and frustration. However, in this case, it was not possible to set an easier target because it was already set at the minimum value. The third case (CP6R1 in the climbing exercise) shows a good balance between the score obtained and time taken, with both percentages being similar and mostly close to 100%. The child also played with fun and seemed challenged. The fourth case, CP10L2 in the chopping exercise (Figure 1, below right), shows a readjustment situation: the first 16 exercises were completed with a high goal and a short time limit so that the goal was almost never reached in the given time. We observed stress and reduced the goal (keeping the time limit the same), resulting in a setting that allowed reaching the goal 100% and in a short time.

The graphical representation of all individual results from Table 3 is shown in Table 4 and in the graph in Figure 2. It shows a group of settings in the top right where both the score and the time spent are high (between 70% and 100%). Very few cases had settings that resulted in very low scores or high scores obtained in a short amount of time (blue and yellow outliers). Accordingly, and also considering our observations of the children during play, we classified the setting ranges from *very easy* to *very hard*. To do this, we divided each axis into thirds.

Table 3. Individual playing results, relative to the adjustments.

Participants	Chop		Row		Dive		Climb	
	pct_{goal} [a] (%)	pct_{time} [b] (%)	pct_{goal} (%)	pct_{time} (%)	pct_{goal} (%)	pct_{time} (%)	pct_{goal} (%)	pct_{time} (%)
Group 1, value								
CP5L1	62	94	100	36	12	94	32	96
CP6R1	74	94	92	79	22	91	66	90
CP10R1	75	97	82	73	34	84	72	97
Group 1, mean (SD)	70 (6)	95 (1)	91 (7)	63 (19)	23 (9)	90 (4)	57 (18)	94 (3)
Group 2+3, value								
CP10L2	98	52	95	75	48	93	66	97
CP11R2	93	59	92	67	70	90	77	88
OBPP8R3	89	85	78	75	88	78	72	81
Group 2+3, mean (SD)	93 (4)	66 (14)	88 (8)	72 (4)	69 (16)	87 (7)	72 (4)	89 (7)
All participants, mean (SD)	82 (13)	80 (18)	90 (8)	67 (14)	46 (26)	88 (6)	64 (15)	92 (6)

[a] pct_{goal}: percentage of points obtained with respect to those established.

[b] pct_{time}: required time percentage of set time limit.

Figure 1. Four examples of different player experiences. Top left: easy play (100% goal achieved in a very short time). Top right: difficult play (100% time consumed but nearly no hits). Bottom left: challenged play (high percentage of goals, high time consumption). Bottom right: initially difficult play, finally easy play. The following code was used to identify the participants: CP/OBPP+age+hand+group.

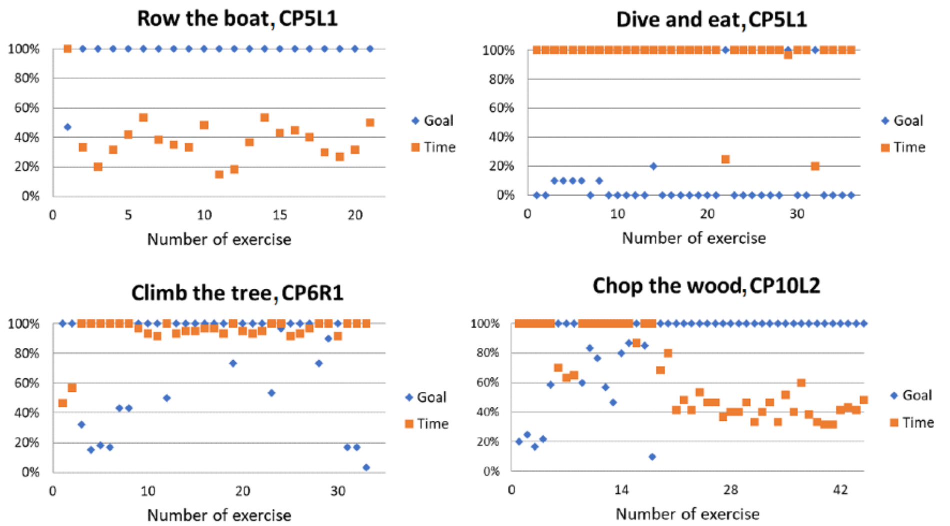


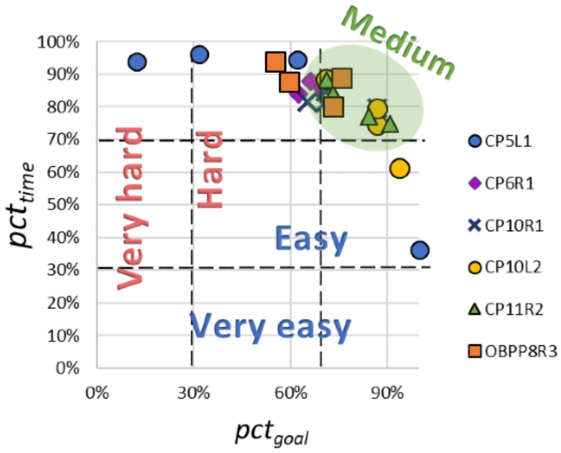
Table 4. Relation between playing time, score, and adjusted game difficulty level.

pct_{time} [a]	pct_{goal} [b]	Game difficulty level
≤30%	>pct_{time}	Very easy
>30% and ≤70%	>pct_{time}	Easy
>70% and ≤100%	>70% and ≤100%	Medium
>pct_{goal}	>30% and ≤70%	Hard
>pct_{goal}	≤30%	Very hard

[a] pct_{goal}: percentage of points obtained with respect to those established.

[b] pct_{time}: required time percentage of set time limit.

Figure 2. Graphical representation of all individual results for all exercises. Adjustment of time and objective. The following code was used to identify the participants: CP/OBPP+age+hand+group.



Data Analysis of the Exercise Results and JTHFT and BBT Assessments

Table 5 presents the data of the individual results of the 3 evaluations, and Figure 3 is a visualization of these values showing the improvement in both tests.

In addition, the graph in Figure 4 has been created to perform a visual analysis of the relation of the JTHFT ratings with the BBT scores for each participant. We added a hull around the 3 evaluations to show at first glance how much a child improved between assessments: the larger the shape, the more the results differed between the JTHFT and BBT. A very horizontal slant indicates better performance in the BBT, and a vertical slant indicates more improvement in the JTHFT. Round shapes indicate few differences between both assessments, and a slant toward 45° indicates that the improvements were similar.

Table 5. Individual results of 3 evaluations with the Jebsen Taylor Hand Function Test (JTHFT) and Box and Block Test (BBT).

Participants	JTHFT (seconds)					BBT (number of blocks)				
	V_p[a]	V_i[b]	V_f[c]	$V_i - V_p$	$V_f - V_i$	V_p	V_i	V_f	$V_i - V_p$	$V_f - V_i$
Group 1, value										
CP5L1	473.1	526.6	509.4	53.5	−17.2	9.0	11.0	8.0	2.0	−3.0
CP6R1	719.5	627.5	464.7	−92.0	−162.8	12.0	17.0	16.0	5.0	−1.0
CP10R1	949.4	732.7	645.3	−216.8	−87.4	2.0	3.0	4.0	1.0	1.0
Group 1, mean (SD)	714.0 (194.49)	628.9 (84.14)	539.8 (76.81)	−85.1 (110.42)	−89.1 (59.46)	7.7 (4.19)	10.3 (5.73)	9.3 (4.99)	2.7 (1.70)	−1.0 (1.63)
Group 2+3, value										
CP10L2	157.4	162.1	133.6	4.7	−28.5	25.0	25.0	40.0	0.0	15.0
CP11R2	206.3	164.4	115.3	−41.9	−49.1	31.0	33.0	38.0	2.0	5.0
OBPP8R3	65.9	58.4	55.5	−7.5	−3.0	50.0	49.0	62.0	−1.0	13.0
Group 2+3, mean (SD)	143.2 (58.17)	128.3 (49.42)	101.4 (33.37)	−14.9 (19.73)	−26.9 (18.87)	35.3 (10.66)	35.7 (9.98)	46.7 (10.87)	0.3 (1.25)	11.0 (4.32)
All participants, mean (SD)	428.6 (349.9)	378.6 (284.4)	320.6 (248.7)	−50.0 (95.02)	−58.0 (59.2)	21.5 (17.6)	23.0 (16.5)	28.0 (22.5)	1.5 (2.1)	5.0 (7.5)
Between groups										
Difference of means	−570.83	−500.6	−438.4	−70.2	−62.3	27.66	25.34	37.4	2.33	−12
P value	.02	.002	.002	.41	.23	.03	.04	.01	.19	.02

[a]V_p: previous evaluation.

[b]V_i: initial evaluation.

[c]V_f: final evaluation.

In addition, we assembled the evaluation data with exponential trend lines to demonstrate the correlation between them. The resulting curves from the 2 initial assessments did not differ, indicating that the children's mean scores were very similar.

However, the curve of the third assessment stood out significantly, showing a more vertical slope, indicating that there were greater differences between JTHFT and BBT in this final assessment, pointing to an improvement in skills owing to the games.

Figure 3. Visual comparison between the 3 evaluations with the Jebsen Taylor Hand Function Test (JTHFT) and Box and Block Test (BBT). Vf: final evaluation; Vi: initial evaluation; Vp: previous evaluation.

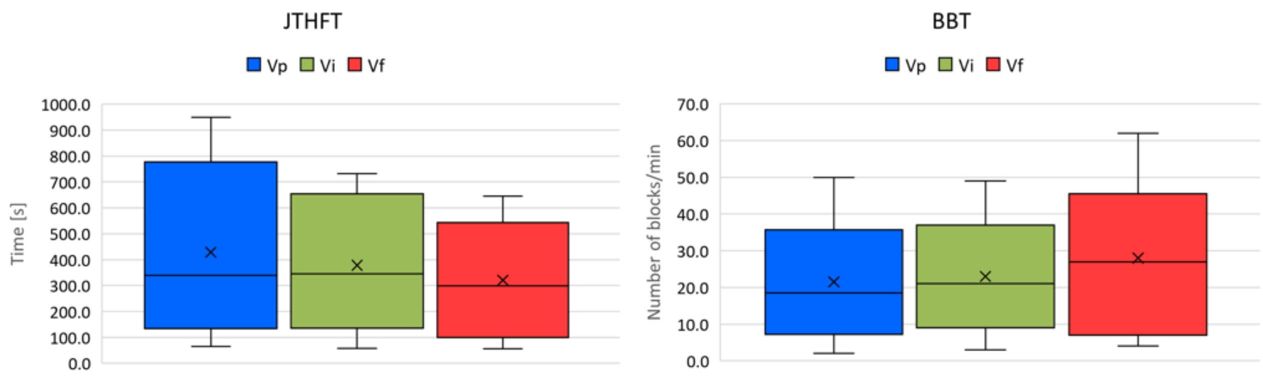
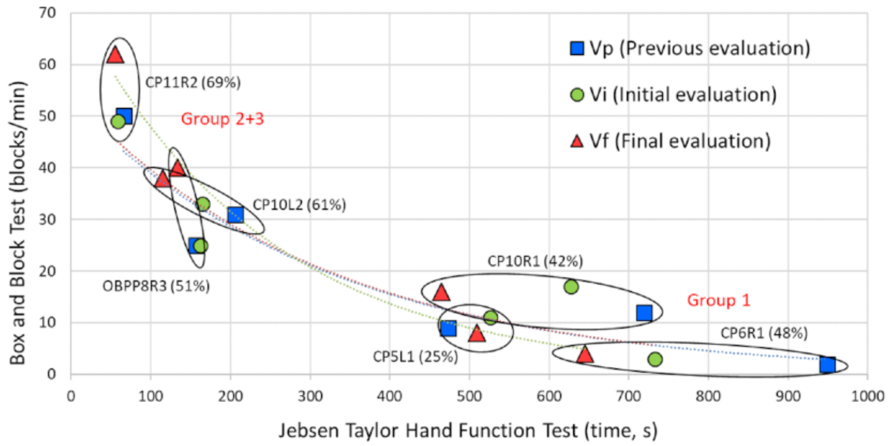


Figure 4. Visualization of the dependencies between evaluations, test types, and groups. Within parentheses, the percentage of time played with easy and medium adjustment of the game parameters is given. The following code was used to identify the participants: CP/OBPP+age+hand+group.



Discussion

The main finding of this study is the categorization of the parameter adjustments into 5 levels of difficulty, which may be of high interest to a therapist who has to decide on the configuration of different exercises. Here, the *easy* and *medium* levels seem to be the most effective, as the final assessment tests show greater improvements for those children who played longer in these adjustment ranges.

Participants

The number of children in this study seems small at first glance, but given our conditions (being a common primary school that integrates 28 children with very different types of physical disabilities), we were fortunate to find 6 children of similar conditions and age and that they were allowed to participate in this study. However, their physical abilities were different because of different degrees of affection, so we decided to analyze them in 2 homogeneous subgroups of the same size, which turned out to be a positive decision, as can be observed from the results.

Intervention

Table 3 presents the results of play for each child and each type of exercise as relative values between the scores and the adjustments. In this way, it was possible to quickly observe in which cases the parameter settings led to better results (the higher the percentage, the more appropriate the parameter adjustment was to the child's capacity). The graphical representation of these values (refer to the graph in Table 4) led to a distinction of 5 levels of difficulty ranging from *very easy* to *very hard* and reveals that most exercises were played with settings that led to achievements of 70% to 100% for both values (upper right part of the graph in Table 4). This means that the objectives were achieved in most cases and that the time given was sufficient, neither too short nor too long. We also observed that in those cases, the children played with more fun and enthusiasm. In the other ranges, they performed worse and felt frustrated or bored. When the time limit was not considered a challenge, as the highest score could be achieved without much effort, the setup seemed too easy. When the goal of an exercise could not be achieved within the given time limit, the participants became stressed and frustrated, so adjustments were probably too difficult. These observations led us to consider the range between 70% and 100% as a *medium* difficulty level, which could be the optimal range of adjustment.

Figure 1 visualizes 4 typical cases showing cases of play that were too easy, too hard, and just right. Participant CP5L1 achieved a 100% score in less than half of the given time limit, so this could be considered a *very easy* adjustment. In the diving exercise, the same child needed the full amount of time given but was unsuccessful, so the configuration appeared to be *very hard*. CP6R1 achieved the score within the given time, so the configuration of this exercise was considered well suited for this child; we would call it an optimal setup. CP10L2, in the beginning, required the entire time given and achieved very low scores. After readjustment, the child never failed and quickly achieved the goal. Both situations were not ideal, too difficult at first and too easy afterward.

During the intervention, adjustments were made to the parameters of the game based on subjective observations because at that time, the therapist did not have a graphic display of the results available on the web. The adjustments made were expected to be optimal; however, subsequent analysis showed that not all children received an adequate adjustment to their abilities. For example, we noticed an incorrect setting for the participant CP5L1, both in the training sessions and in the intervention sessions, which could possibly have been avoided. Therefore, we consider it crucial that a therapist has an *objective* measure to verify whether a game setting is well adjusted for each participant. We are convinced that if we had had a tool that showed the range in which a child was playing, our adjustments would have been made more quickly and accurately.

In addition to the general results, it is worth mentioning some differences among the 4 types of exercises (or minigames) inherent in the game. Of them, 3 (75%) are aimed at arm movements (rowing, climbing, and chopping), and the child can fully concentrate on them because the avatar does not change its position when the child's position changes. Instead, the dive exercise is fully controlled in 3D; that is, each corporal movement translates into a change in the position of the avatar in the virtual space. This exercise was created to train trunk stability; however, it turned out to be the most difficult to control, especially for the youngest and most affected children. Therefore, this exercise produced frustration in some cases, especially for CP5L1. Here, we set the goals to low values, because we noticed that children avoided this exercise. They liked the chopping exercise best, which has a great animation with a sparkling axe and logs falling to the sides. Climbing and rowing were the 2 easiest exercises, and the children got much faster after learning how to do them.

Data Analysis of the Exercise Results and JTHFT and BBT Assessments

The results obtained in the 3 evaluations of the JTHFT and BBT showed clear improvements for almost all children, especially between V_i and V_f (before and after the intervention with the video game): a reduction in time for the JTHFT and an increase in the number of blocks for the BBT (refer to the column $V_f – V_i$ in Table 5).

The results of group 1, which includes children with lower capacities, clearly differ from those of group 2+3, which can be observed in the difference in mean values for both groups. Group 1 had longer times for the Jebsen tests and moved fewer blocks in the BBT (3 to 5 times fewer blocks). The difference in means can be considered significant despite the small sample size; after checking for normality through Levene test, all P values were <.05 for the 3 assessments (JTHFT: V_p, P=.02; V_i, P=.002; and V_f, P=.002; BBT: V_p, P=.03; V_i, P=.04; and V_f, P=.01).

However, the improvements in both tests achieved through the intervention were different: group 1 improved their results in the JTHFT more than group 2+3. In V_f, the average times achieved were about 5 times longer, but the improvement compared with V_i was 89.1 seconds, which was 3 times better than the improvement of group 2+3 (26.9 s). For the BBT, this was the other way around: after the intervention, group 2+3 achieved moving 11 blocks more than those moved before the intervention (+13%), whereas group 1 did not show any improvement caused by the game or related to the game.

An important correlation can be observed when contrasting the data obtained from the BBT and JTHFT evaluations with the time they played in the *easy* or *medium* difficulty range. As can be observed in Figure 3, the children who played most of the time with this configuration (refer to the percentages within parentheses) were the ones who achieved the best evaluations in either the BBT or JTHFT.

Looking at the individual cases, it can be observed that the improvement between the initial and final BBT ratings is best for CP11R2 (who played 69% of the time with *easy* or *medium* settings) and very high for OBPP8R3 (who played 51% of the time on *easy* or *medium*). CP10L2 played 61% of the time at those ranges and improved similarly in the BBT and JTHFT. CP10R1 (42%) and CP6R1 (48%) improved more in the JTHFT. Finally, CP5L1 unfortunately had *very hard* settings for her abilities, and as a result, she was the only child who did not improve, neither in the BBT nor in the JTHFT. As explained before, the reason was probably the young age and the general difficulty of the diving exercise, which was already set to the minimum possible goal for this child.

From these results, we understand that a correct adjustment range generates a certain challenge that leads to a longer playing time and highly motivates the player to reach the goal (a fact frequently mentioned in the literature and also called “flow” [34,35]). This is optimal from the therapeutic point of view, as overexertion and underload are avoided while achieving the highest possible level of motivation.

Comparing our proposed level adjustment in Table 4 with the generally published guidelines for game level adjustment, we observe a great coincidence. For example, Sepulveda et al [34] presented the ratio between player performance (*Cp*) and expected performance (*Ep*), as a method to measure the general performance or quality of adjustment:

$$Performance = Cp / Ep \quad (3)$$

A value next to 1 means that the challenge is appropriate for the player, and with an error range set to 0.2, a value <0.8 indicates the game is too difficult and a value >1.2 means the game is too easy. If we apply this formula to our data, the relation pct_{goal} / pct_{time} would be equivalent to *Cp*, with *Ep=1*, the ratio expected and desired by the therapist. With this, our *very easy* level can reach up to 3.3, *easy* up to 2.3, *medium* between 1.4 and 0.7, *hard* down to 0.4, and *very hard* down to 0.3. Therefore, compared with Sepulveda et al [34], we apply a larger and asymmetrical error margin, which is 0.3 for the harder adjustments and 0.4 for the easier adjustments. This is also graphically confirmed in the figure in Table 4, where most settings fall on the harder side. It has to be mentioned here that this classification should be confirmed or refined in more extensive follow-up studies.

Many publications can be found in the area of automatic and dynamic difficulty adjustment of game levels, as reviewed by Zohaib and Hideyuki [35]. It would be interesting to apply our ranges to one of the proposed algorithms and test whether they could be useful for an automatic adjustment of exercise games for people with disabilities. Furthermore, to the best of our knowledge, there are no publications on the adjustment of the level of play for people with motor disabilities; most approaches consider "accessibility," for example, the studies by Bierre et al [36], Cairns et al [37], and Carr et al [38], but this is not the same. Accessibility deals with different disabilities and adapts interfaces. Making a game "easy" does not necessarily guarantee that people with disabilities can play it. Game level adjustment goes beyond accessibility, as an accessible game still needs to adapt to the players' abilities like any other game to challenge the player; only the rules should not be the same as those for abled people.

Limitations

As stated before, on some occasions, the Kinect has difficulty capturing the smallest students, and specific problems were detected in handling the main character of the game, which led to some frustration. We are currently developing a new version of the game based on Kinect One, which has much better detection possibilities.

Furthermore, it is necessary to perform tests with larger population groups and analyze the changes that would appear at a longer intervention time. For future studies, it is important to assess whether benefits are maintained in the long term and analyze motivation. Currently, we are conducting a long-term study on the same game but using an improved web interface that visualizes the range in which the users are playing. In this way, readjustments can be made according to an objective measure and, if necessary, after each session.

Conclusions

The use of video games is considered a viable intervention to carry out in physical therapy sessions in the school environment. We observed that when the parameters were not well adjusted, the play time was short, which led to less changes in motor function (proved with the BBT and JTHFT evaluations).

The adjustment of the game seems to be related to the motor benefits found, so it would be appropriate to have access to the patients' game performance data easily and continuously to be able to modify the parameters in time and to work within the adjusted range. Therefore, we consider it a good option to use the criteria established in this study to achieve an adequate adjustment, seeking that the child performs most of the game in the range between 70% and 100% of the goal and time. However, exhaustive tests must be performed now to prove these values.

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Conflicts of Interest

None declared.

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Abbreviations

BBT: Box and Block Test
CEIP: Centro de Educación Infantil y Primaria
CP: cerebral palsy
GMFCS: Gross Motor Function Classification
ICF: International Classification of Functioning, Disability, and Health
JTHFT: Jebsen Taylor Hand Function Test
MACS: Manual Ability Classification System
OBPP: obstetric brachial plexus palsy
UPM: Universidad Politécnica de Madrid
Vf: final evaluation
Vi: initial evaluation
Vp: previous evaluation
VR: virtual reality

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Original Paper

Negami: An Augmented Reality App for the Treatment of Spatial Neglect After Stroke

Britta Stammler[1]; Kathrin Flammer[2]; Thomas Schuster[3]; Marian Lambert[3]; Hans-Otto Karnath[1]

[1]Center of Neurology, Division of Neuropsychology, University of Tübingen, Tübingen, Germany
[2]Flammer & Gläser UXplain GbR, Karlsruhe, Germany
[3]XPACE GmbH, Pforzheim, Germany

Corresponding Author:
Hans-Otto Karnath
Center of Neurology
Division of Neuropsychology
University of Tübingen
Hoppe-Seyler-Strasse 3
Tübingen, 72076
Germany
Phone: 49 7071 29 80467
Email: Karnath@uni-tuebingen.de

Abstract

Background: A widely applied and effective rehabilitation method for patients experiencing spatial neglect after a stroke is "visual exploration training." Patients improve their ipsilesional bias of attention and orientation by training exploration movements and search strategies toward the contralesional side of space. In this context, gamification can have a positive influence on motivation for treatment and thus on the success of treatment. In contrast to virtual reality applications, treatment enhancements through augmented reality (AR) have not yet been investigated, although they offer some advantages over virtual reality.

Objective: This study aimed to develop an AR-based app (Negami) for the treatment of spatial neglect that combines visual exploration training with active, contralesionally oriented rotation of the eyes, head, and trunk.

Methods: The app inserts a virtual element (origami bird) into the real space surrounding the patient, which the patient explores with the camera of a tablet. Subjective reports from healthy elderly participants (n=10) and patients with spatial neglect after stroke (n=10) who trained with the new Negami app were analyzed. Usability, side effects, and game experience were assessed by various questionnaires.

Results: Training at the highest defined difficulty level was perceived as differently challenging but not as frustrating by the group of healthy elderly participants. The app was rated with high usability, hardly any side effects, high motivation, and entertainment. The group of patients with spatial neglect after stroke consistently evaluated the app positively on the dimensions of motivation, satisfaction, and fun.

Conclusions: The Negami app represents a promising extension by adding AR to traditional exploration training for spatial neglect. Through participants' natural interaction with the physical surrounding environment during playful tasks, side effects as symptoms of cybersickness are minimized and patients' motivation appeared to markedly increase. The use of AR in cognitive rehabilitation programs and the treatment of spatial neglect seems promising and should receive further investigation.

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KEYWORDS

spatial neglect; gamification; augmented reality; visual exploration training; stroke rehabilitation; serious games; rehabilitation; stroke

Introduction

Spatial neglect is the dominant disorder after a brain lesion of the human right hemisphere [1,2]. The most common cause of spatial neglect is a large stroke in the right middle cerebral artery area that affects a perisylvian network consisting of the superior/middle temporal cortex and the parietal and ventrolateral frontal cortexes [3]. Affected patients behave as though the left side of their surrounding space no longer exists. The patient's eyes and head are sustainedly oriented to the side of the brain lesion (ie, mostly to the right side) [4,5]. When searching for objects, the patient's visual and tactile exploration is shifted to the right side. Accordingly, objects or people located on the left side are ignored and not found. Many therapeutic approaches to spatial neglect thus entail exercises (eg, search training on large projection screens) and activities (eg, reading and copying tasks, picture descriptions) that require increased and active turning of the patients toward the neglected contralesional side [6-9]. In this training, termed "visual exploration training" or "visual scanning training," exploration movements are improved, and compensatory search strategies are practiced, leading to improvements in neglect behavior in important everyday situations.

A critical component of neurorehabilitation and its success is related to patients' motivation to train [10]. Improving the latter is one of the main aspects of recent rehabilitation efforts known as "gamification" [11,12]. Gamification describes the application of game design elements in a nongame context to motivate desired behavior. Treatment motivation in stroke rehabilitation can additionally be increased by gamified feedback (ie, giving feedback about the performance in the corresponding task by awarding points) [13].

The principle of gamification is further emphasized when combined with virtual reality (VR) methods. The principle of active exploration training in spatial neglect has already been extended by several VR approaches. Nonimmersive VR procedures, in which a virtual environment is displayed on a monitor with which the patient interacts without being immersed in it, have been successfully used in group studies for therapeutic purposes [14-16]. On the other hand, immersive VR procedures, in which the patient becomes part of a virtual 3D environment surrounding them by means of VR goggles, have also been developed, gearing toward active exploration scenarios. Recent proof-of-concept studies have shown that healthy participants and patients who have had a stroke perceive this technique as highly motivating and enjoyable [17-19]. Moreover, immersive VR applications have already been tested with individual patients with spatial neglect for treatment purposes [20,21].

Another promising way to increase training motivation in poststroke rehabilitation is through augmented reality (AR). AR describes the computer-generated addition of virtual elements to reality. The visual, real world is augmented by virtual images and figures via a video camera of an electronic device such as a tablet. The virtual addition takes place in real time in the sense of a live transmission and thus combines the real and the virtual [22]. Bakker and colleagues [23] developed the first game combining AR elements with visual scanning training in the context of neglect rehabilitation. It consisted of participants searching for virtual images projected onto a wall in the environment of a museum. Design decisions were made based on expert opinion as well as the opinion of patients with spatial neglect. Features to increase extrinsic motivation were rated as the most important design decision.

In this development and feasibility study, the application of an AR technique for the treatment of spatial neglect is further developed. It is based on the observation that visual exploration training seems to be particularly effective when combined with an active rotation of the trunk contralesionally [24]. An attractive extension of this treatment principle is the innovative app named Negami. This app is based on the principle that patients are playfully motivated to orient themselves to their neglected side of the real room by (1) following and (2) searching for a virtual element (in this case an origami bird), actively exploring space by turning their gaze, head, and trunk. In developing the game, special consideration was given to the age group to ensure high usability. Our goal was to develop a task that would motivate the patients and that they would enjoy. By eliciting the subjective views of both healthy elderly participants (aged 57 to 89 years) and patients with spatial neglect after stroke regarding our AR-assisted exploratory therapy app, we also aimed to uncover barriers to its use and make recommendations to improve the future development of therapies with AR.

Methods

Participants

Ten elderly neurologically healthy individuals with a mean age of 66 (SD 11.9) years, including 5 (50%) females, participated in this study. In addition, we included 10 patients, including 2 (20%) females, who were experiencing spatial neglect and left-sided hemiparesis after a stroke in the neurological right hemisphere —5 (50%) with infarction and 5 (50%) with hemorrhages. They had a mean age of 61.3 (SD 15.2) years and a poststroke interval of 138.4 (SD 192.1) days when they were tested for spatial neglect. More details of the patients are provided in Multimedia Appendix 1.

The inclusion criterion for the patients was the presence of spatial neglect after a stroke. In addition to clinical behavioral observations, diagnostic criteria had to be met in at least 2 of the following 4 neglect tests: the Letter Cancellation Test [25], the Bells Test [26], a Copying Task [27], and a Line Bisection Task [28]. All 4 neglect tests were performed on a Samsung S7+ tablet with screen dimensions of 285 × 185 mm. The severity of spatial neglect in the cancellation tasks was determined by calculating the center of gravity of the target stimuli marked in the search fields, known as the Center of Cancellation (CoC). A CoC value ≥0.08 indicated left-sided spatial neglect [3,29]. The Copying Task consisted of a complex scene consisting of 4 objects (fence, car, house, and tree), wherein points were assigned based on missing details or whole objects. One point was given for a missing detail and 2 for a whole object. The maximum number of points was therefore 8. A score higher than 1 (ie, >12.5% omissions) indicated neglect [27]. In the Line Bisection Task [28], patients were presented with 4 different line lengths eight times each (ie, 32 lines in total). The cut-off value for spatial neglect was an end point weightings bias (EWB) value ≥0.07 [30].

In the group of patients, the mean CoC on the Letter Cancellation Test was 0.42 (SD 0.28), the mean CoC on the Bells Cancellation Task was 0.38 (SD 0.29), the score on the copying test was 4.4 (SD 1.51), and the EWB score on the Line Bisection Task was 0.33 (SD 2.5).

Ethics Approval

All participants gave their informed consent to participate in the study, which was conducted following the ethical standards of the 1964 Declaration of Helsinki. This study was also approved by the ethics committee of the University Clinic of Tübingen (373/2021B02).

The Negami App

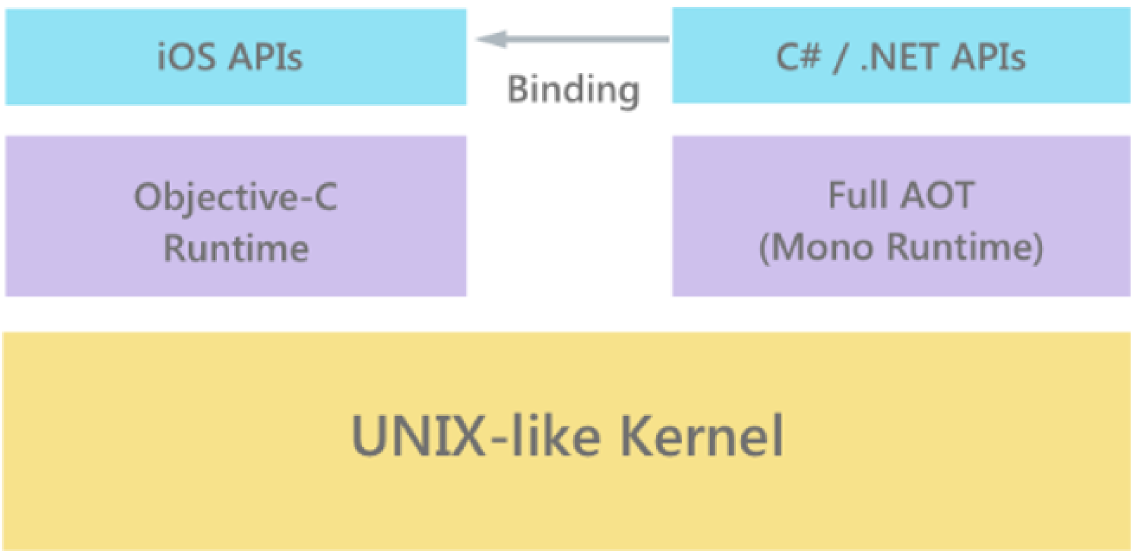
Overview

Negami [31] is a mobile app that enables the treatment of spatial neglect using gamified AR. It is optimized for use on tablets but also works on smartphones. In this study, a 3rd generation Apple iPad Pro 12.9” was used to run the app and conduct the therapy sessions. Negami provides 2 modes (Task A and Task B), which are detailed in the subsequent section. In both tasks, the live video stream from the devices’ back cameras is displayed on the screen. Additionally, a virtual element (origami bird) is added (augmented) as a 3D object that must be followed (Task A) or searched for (Task B) by moving the tablet in 3D space. An overlaying crosshair user interface (UI) element provides visual feedback and guidance for the patient.

Technical Background

The Negami app can be achieved via the Negami website. The app was implemented in C# programming language using the open-source cross-platform framework Xamarin (Microsoft Corp) [32]. It allows the creation of native Android, iOS, and Windows apps by sharing UI and code across platforms. The Xamarin platform consists of Xamarin.iOS and Xamarin.Android projects, which are implementations of the Mono framework for iOS and Android, respectively. Mono is a cross-platform open-source .NET compatible software framework. Additionally, Xamarin includes the Xamarin.Forms library for the creation of cross-platform user interfaces using XAML (Extensible Application Markup Language). A UI created in Xamarin.Forms is automatically mapped to native controls on each platform during the build process. Xamarin was chosen for the development of the Negami app because it provides native runtime performance, which is important for game-based apps, as well as an abstraction layer over many platform-specific application programming interfaces (APIs), thus increasing development speed. Additionally, Xamarin offers a set of bindings for full access to all device-specific APIs (Figure 1). Apps built with Xamarin are compiled into native packages for each platform. For the Android platform, the written code is compiled down to Intermediate Language (IL), which is then just-in-time compiled to native assembly on app launch. On iOS, the app is fully ahead-of-time compiled into native ARM (Advanced Reduced Instruction Set Computer Machine) assembly code (Figure 1 [33]).

Figure 1. Architecture of an application developed using Xamarin.iOS (left) and Xamarin.Android (right) [33]. AOT: ahead of time; API: application programming interface.



Utilizing Xamarin, the implementation of the Negami app’s entire business logic and user interface could be shared across platforms. The development followed the Model-View-View-Model design pattern and applied other best practices such as the use of an inversion of control container for dependency injection, commands, and event aggregators. Additionally, the app’s functionality was verified using both unit tests and manual testing. To facilitate the data collection process, a data synchronization feature was implemented that regularly syncs the local SQLite database (which enables the app’s offline usage) containing metadata about each patient and app settings with a remote Microsoft SQL (Structured Query Language) database utilizing the Dotmim.Sync library. As the actual data for each completed exercise session were too large to be stored efficiently in a database, a file-based synchronization was implemented using the Azure Blob Storage (Microsoft Corp) service.

Unlike the business logic and UI elements, the AR aspects of the app had to be implemented in a platform-specific way because Xamarin provides no abstraction layer for these APIs. The implementation was only completed for the iOS platform. For this, the Apple ARKit platform [34] was used (through native bindings provided by Xamarin.iOS) to implement all AR-related logic, such as world tracking, placing and rendering of the objects in 3D space, and retrieving the current screen position of the bird. For Android, the Google ARCore library was utilized in the future to implement the same logic.

Design

Since the target group consists mainly of elderly people, the design of the app was tailored to their needs to facilitate the most positive user experience. The app was intended to reduce the distance and strangeness that this user group often feels from digital devices. We did not want it to feel like a monotonous, mandatory clinical treatment. Instead, we wanted patients to playfully find the motivation to work on their recovery.

A further aim was to ensure that patients—after discharge from inpatient treatment—can safely use the app to practice on their own or with family members to make further progress. This is achieved through short distances in operation and simple instructions and assistance. The same applies to large control buttons that are easy to reach even with shaky or stiff fingers. We also took into account that patients with spatial neglect ignore information on the contralesional side. For example, this was considered when placing and labeling the exercise buttons. Simple letters like “A” and “B” presented on the right tablet side were used instead of complex icons or text. Moreover, we took into consideration that patients with spatial neglect are often hemiparetic. Instead of holding the tablet from the right and left with both hands, hemiparetic patients can hold it with the unaffected hand from the bottom/center. However, if the tablet is too heavy for the patient to hold in this single-handed position, a loop with Velcro can be attached to the patient’s wrist, which, in turn, is attached to the middle of the back of the tablet to help the patient carry the weight.

In addition to the patients, there is another user group: the therapists. This group of users has different requirements for the app than the patients. Since therapists are often responsible for several patients concurrently, they need to treat patients as efficiently as possible. For this purpose, the app offers the therapist the possibility to easily adjust the corresponding performance level of each patient to their current treatment status. The development of each patient's skills is easily visible to the therapist. Further, the app offers the possibility to create a plan for independent therapy at home. The patient's progress thus is recorded and can be viewed by the therapist at any time, allowing them to make the exercises more difficult or easier depending on the patient's level of ability.

Tasks Provided by the Negami App

During the typical use of Negami, the participant sits in a chair or a wheelchair. If possible, the tablet is held with both the left and right hands. If the participant is hemiparetic, the tablet can be held from below with one hand positioned in the middle. Using arm movements in combination with trunk rotations, the tablet can then be moved to the left or right through real space (Figure 2). The participants perform 2 different tasks in succession.

Figure 2. Patient performing tasks of the Negami app. A virtual element (origami bird) was added (augmented) to the video stream of the surroundings produced by the camera of a tablet.

The patient's first task (Task A: "follow the bird") is to follow the virtual origami bird through real space. The patient's straight-ahead eye/head/body orientation is set as 0. Beginning at set point 0, the bird flies with random sinusoidal movements toward one side of space (in neglect patients toward the contralesional, neglected side). While doing so, the patient sees an orange circle in the center of the screen (Figure 3). The bird should be held in this circle while performing the task. As soon as the patient fails to successfully follow the bird and keep it in the circle during its flight, they are provided with an additional orientation aid. A blue compass needle appears showing the patient in which direction the bird is located (see Figure 3). The task is successfully completed as soon as the bird has finished its trajectory and the bird has been positioned centrally in the orange circle. During the performance, the patient receives auditory feedback. Every time the patient manages to get the bird into the orange circle, a short, bright tone is presented. If the patient manages to keep the bird continuously in the orange circle, the tone is presented every 2 seconds. When the task has been successfully completed, the patient receives feedback auditorily again through a different tone and visually through the change of the color of the circle to green.

At the end of a successful trial, the options "change angle" and "lead to point 0" are provided on the screen. If the patient/therapist wants to repeat the task, they can select "lead to point 0," and if the difficulty of the task must be varied, the patient/therapist can select "change angle." The patient/therapist has 3 different difficulty levels to choose from: easy, medium, or difficult (Table 1). The difficulty levels are saved as templates.

Figure 3. Task A: "follow the bird." The patient has the task to follow the flying origami bird and to keep the bird within the orange/blue circle (A). If the task is successfully solved the circle turns green (B).

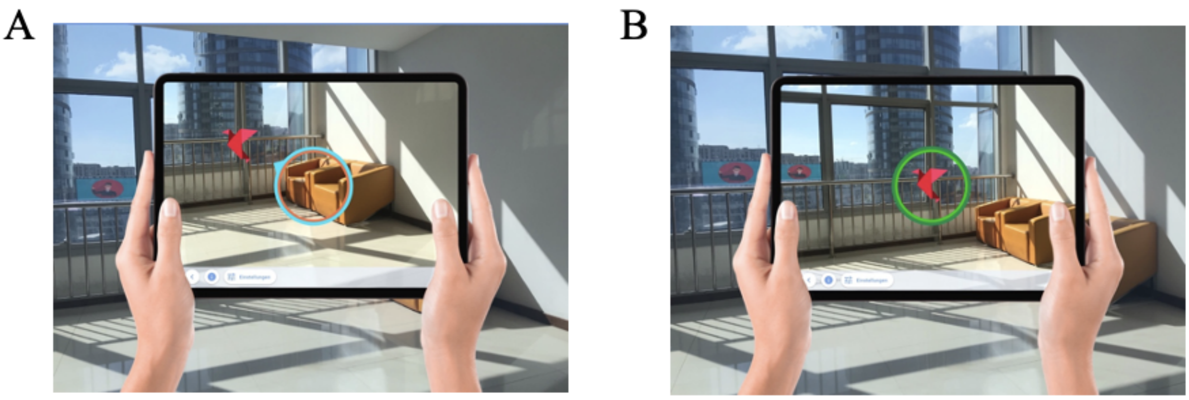


Table 1. Difficulty levels provided with Task A ("follow the bird")[a].

Level	Maximum distance of the bird's path	Speed of bird movement	Amplitude of bird movement
Easy	up to ±35°	2.3°/sec[b]	6.8°
Medium	up to ±55°	4.1°/sec	8.0°
Difficult	up to ±85°	8.1°/sec	11.3°

[a]Angular degrees are participants' space coordinates, starting from their straight-ahead eye/head/body orientation, which is set as 0.

[b]sec: second.

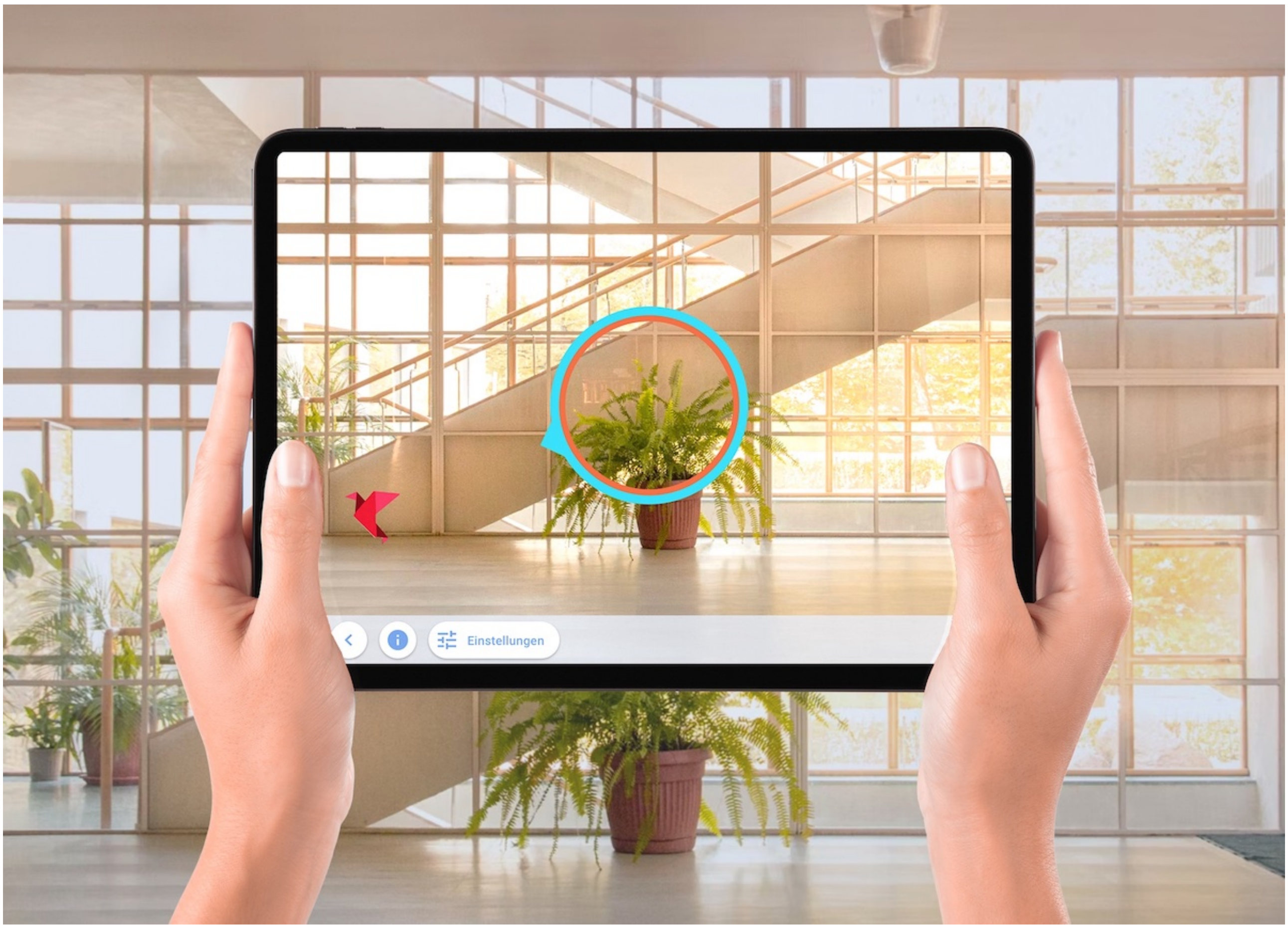
In the second task of the Negami app (Task B: "find the bird"), the therapist hides the virtual origami bird in the room surrounding the patient. For this purpose, the patient's straight-ahead eye/head/body orientation again is set as 0. Starting from this location, the therapist hides the bird somewhere on the left/right side of the patient without the patient seeing it. The best way to do this is for the therapist to step behind the patient and hold the tablet above the patient's head in such a way that they cannot see where exactly the tablet is pointing. The area within the bird that can be hidden by the therapist is predefined by the app depending on the chosen difficulty level of the task (Table 2). Once the therapist has positioned the bird in space by clicking on the center of the screen, they return the tablet to the patient's hand. The patient is then instructed to find the bird, and once found, to position it centrally into the orange circle. No time limit is given. Should the patient show difficulties in finding the bird, it is possible to provide the patient with orientation assistance by turning on the blue compass needle (Figure 4). The task is successfully solved when the patient finds the bird and places it in the center of the circle. As with Task A, the circle then turns green (Figure 3), and the patient hears a bright tone signaling the successfully solved task. After successful completion of the task, options "change angle" and "lead to point 0" are provided (see Figure 3) so that the task can be repeated or changed in difficulty.

Table 2. Difficulty levels provided with Task B (“find the bird”)[a].

Level	Extension of the area (along the horizontal dimension of the surroundings) within which the bird can be hidden
Easy	0° to −40° (or 0° to +40°)
Medium	−40° to −75° (or +40° to +75°)
Difficult	−75° to −90° (or +75° to +90°)

[a]Angular degrees are the participants’ space coordinates, starting from their straight-ahead eye/head/body orientation, which is set as 0. Negative values indicate positions to the participant’s left, while positive values indicate positions to the participant’s right.

Figure 4. Task B: “find the bird." The patient has to search for the bird that has been hidden by the therapist somewhere in the surrounding room (in this image, at the corner located at the foot of the stairs) and has to transfer it into the orange/blue circle.



Procedure

All neurological patients received training with Negami in their room in the ward of the respective rehabilitation facility. The healthy participants also received the training indoors for comparability. The healthy participants had 1 training session with Negami that lasted 20 to 25 minutes. They completed Task A in the first half and Task B in the second half, each at the highest difficulty level. If patients were not able to use both hands to hold the tablet due to hemiparesis, they were instructed to hold the tablet with the unimpaired hand only by grasping the tablet in the middle from the top or bottom. A video example of a patient working with Negami is shown in Multimedia Appendix 2. To assess feasibility, usability, and game experience, the System Usability Scale (SUS) [35], Simulator Sickness Questionnaire (SSQ) [36], and Perception of Game Training Questionnaire (PGTQ) [37] were administered to the participants directly after the training session.

To assess usability, the participants answered the 10 questions of the SUS through a 5-point Likert scale ranging from 1 (fully disagree) to 5 (fully agree). The mean score was calculated for each participant across all questions. To capture the presence of side effects of simulation technologies, the SSQ was applied. For this purpose, the presence of a series of symptoms grouped under “cybersickness” was tested by a 4-point Likert scale ranging from 0 to 3 (not at all, slightly, moderately, and strongly). The following 15 symptoms were recorded in total: general discomfort, fatigue, headache, eyestrain, difficulty focusing, increased salivation, sweating, nausea, difficulty concentrating, fullness of the head, blurred vision, dizziness, vertigo, stomach awareness, and burping. Again, the mean score was calculated across all items for each patient. Finally, the patients were asked via the PGTQ, which uses a 7-point Likert scale ranging from 1 (fully disagree) to 7 (fully agree), about how motivating, frustrating, challenging, and enjoyable they found the training with Negami to be. Since each of the 4 questions covers a different aspect of the perception of Negami, no mean value was calculated.

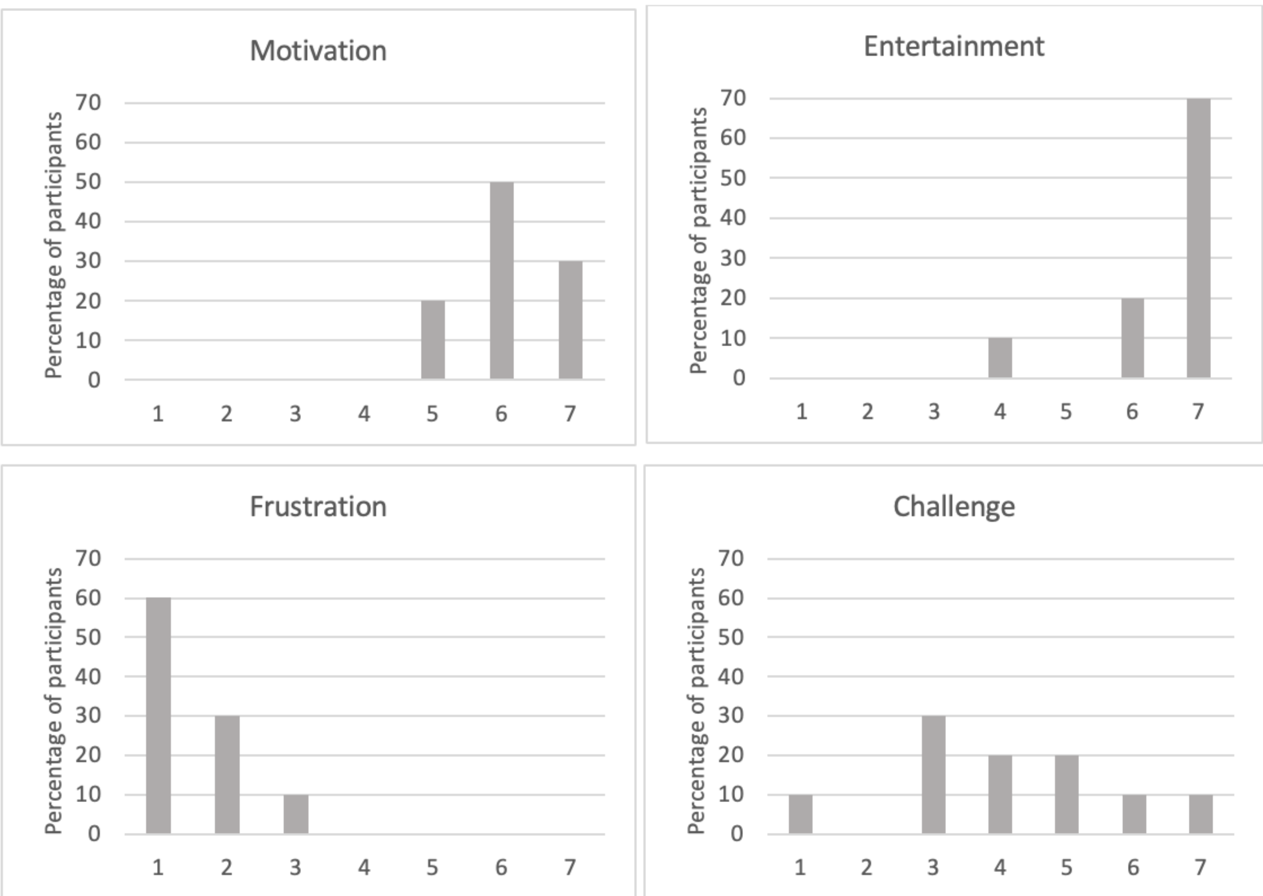
The patients with spatial neglect received a 2-week application with 5 training sessions per week. Each session lasted 20 to 25 minutes. As the healthy participants, they completed Task A in the first half and Task B in the second half. The tasks were always initiated for the patients with the easiest difficulty level. The criterion for success in advancing to the next difficulty level was that the task was successfully completed 3 times in a row. A return to a lower difficulty level was indicated when the task was not solved 2 times in a row. Upon completion of the treatment, subjective reports about the use of the Negami app were collected from the patients by using the following three questions: (1) How satisfied were you with the treatment? (2) How motivating did you find the treatment? (3) How much did you enjoy the treatment? The answer options varied from 1 to 6, with 1 being the best result. The patients were further asked whether they would recommend the treatment to others (yes/no) and in an open response format, whether they had any suggestions for improvement.

Results

Healthy Participants

The results of the healthy elderly participants from the SUS on usability resulted in a mean value of 4.3 (SD 0.6), indicating that the usability of the Negami app was rated on average as high to very high. Moreover, there were hardly any side effects detected, as assessed by the SSQ and indicated by a mean score of 0.8 (SD 1.32). More specifically, only 1 patient (10%) reported mild symptoms of fatigue, headache, difficulty focusing, and blurred vision. In addition, 2 (20%) other participants reported mild problems with strained eyes and focusing. None reported moderate or strong side effects. Finally, the PGTQ captured the dimensions of motivation, frustration, challenge, and entertainment during training with Negami. The healthy participants' evaluations on these dimensions are shown in Figure 5. The participants found Negami to be motivating (mean 6.1, SD 0.7) and highly entertaining (mean 6.5, SD 0.9). As indicated by a mean score of 1.5 (SD 0.7), the training was not perceived as frustrating. However, some participants found the training challenging, while others did not (mean 4.1, SD 1.7).

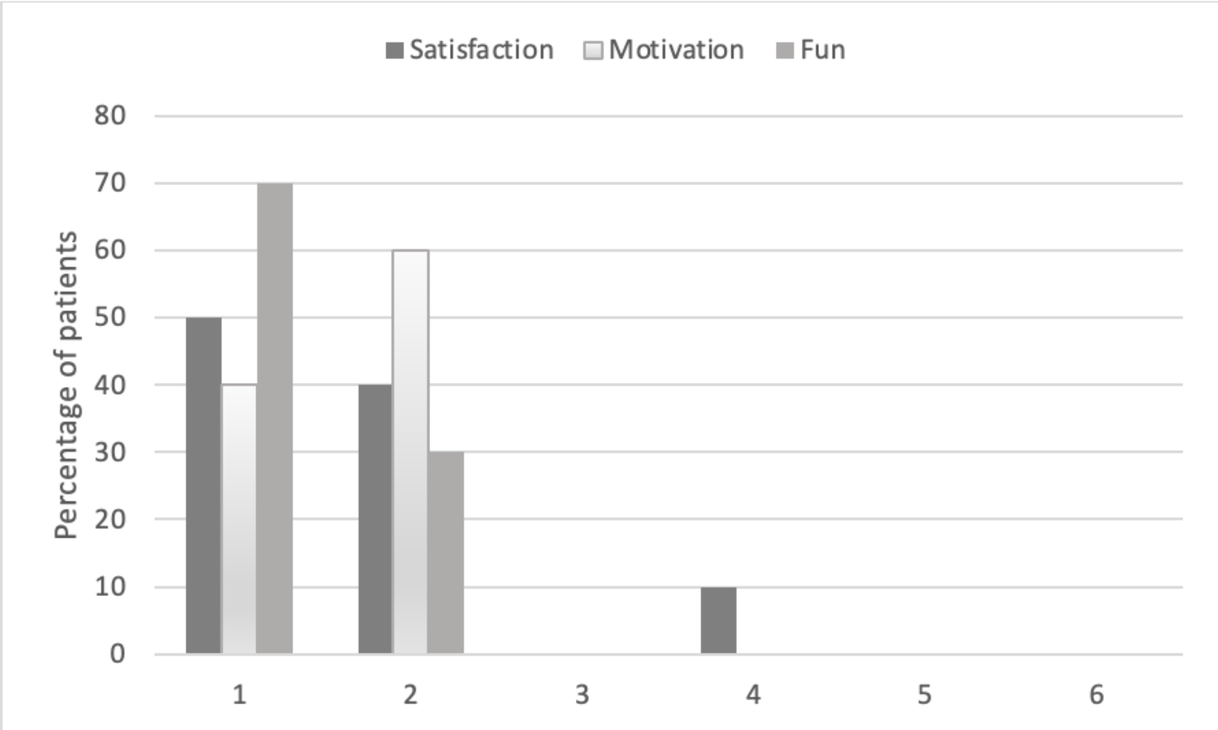
Figure 5. Percentage of healthy, older adults (n=10) evaluating training with the Negami app on the dimensions “motivation,” “frustration,” “challenge,” and “entertainment,” on a 7-point scale (1 = "I fully disagree"; 7 = "I fully agree").



Neglect Patients

An analysis of the reports by the patients regarding the use of the app revealed that all 10 patients recommended treatment with Negami. The patients' evaluation of the app treatment on the dimensions of fun, satisfaction, and motivation are shown in Figure 6. The results demonstrate that all patients evaluated the app treatment on all 3 dimensions with the best 2 scores. Only 1 (10%) of the patients chose a score of 4 on the dimension of satisfaction. Consistent with these very positive ratings by the patients with spatial neglect, the Spearman rank correlation coefficients between the dimensions of satisfaction, motivation, and fun and the severity of spatial neglect (expressed as the mean value of the CoC from the 2 cancellation tasks) were not significant (satisfaction: r=.21, motivation: r=.57, fun: r=.42; all P≥.086). Regarding suggestions for improvement in the open response format, 3 (30%) of the 10 patients with hemiparetic neglect reported that they had trouble holding the tablet due to the weight. They had to hold the tablet with 1 hand instead of both. One (10%) patient noted that older patients might be digitally overwhelmed with the treatment. All other patients had no suggestions for improvement.

Figure 6. Percentage of stroke patients (n=10) with spatial neglect evaluating training with the Negami app on the dimensions "satisfaction," "motivation," and "fun," on a 6-point scale (1 is the best score; 6 is the lowest score).



Discussion

Principal Findings

This study aimed to develop and assess the usability, side effects, and game experience of a new rehabilitation app (Negami) for patients with spatial neglect. By using AR, the app was designed to playfully encourage patients to actively explore space by turning their gaze, head, and trunk. Our investigation showed that Negami was perceived as motivating and entertaining by the healthy elderly controls. Training at the highest defined difficulty level was perceived as differently challenging but not as frustrating. The survey further revealed high usability and no to very low side effects such as headache, strained eyes, or blurred vision. Additionally, the second group evaluated in this study (ie, the patients experiencing spatial neglect after a stroke) consistently evaluated the app positively on the dimensions of motivation, satisfaction, and fun. Furthermore, we observed that the app and the tablet could also be used by patients with hemiparesis (by holding the tablet with the unimpaired hand only, grasping the tablet in the middle from the top or bottom). However, 3 (30%) of the 10 patients with hemiparesis complained about the heaviness of the tablet, so the use of even lighter devices seems beneficial.

Gamification and the Negami App

These positive results give us reason to believe that the new app could become a very useful tool in the treatment of patients with spatial neglect. Ogourtsova and colleagues [38] have shown that patient expectation of performance is the most important factor for acceptance of the use of VR technologies in rehabilitation. Therefore, when defining the 3 different difficulty levels of training with Negami, our focus was on ensuring that the easiest task could be solved relatively quickly even for patients with more severe neurological impairment. This could also be the reason why Negami was so well received by the tested patients who had a stroke. The use of different difficulty levels, as well as auditory and visual feedback on performance during training, are elements that supported the gamification of the Negami app. Gamification for the purpose of rehabilitation has been shown to have positive effects on the patients' engagement and motivation for their treatment [39]. Another reason for the positive feedback from both patients and healthy participants could be due to our app design in that we paid special attention to the age group, as 75% of patients who have had a stroke are aged over 65 years [40] and are typically not "digital natives" [41]. In implementing short distances in operation, simple instructions, and assistance, we aimed to ensure that this age group feels comfortable in dealing with an electronic device such as a tablet when using the Negami app.

AR Versus VR Techniques and Telerehabilitation

A third aspect that might have contributed to the positive ratings by the 2 groups tested could be the choice of the AR over VR technique. It is a frequent observation that the use of VR may evoke symptoms that are summarized under the term "cybersickness" [42]. These include symptoms such as drowsiness, headache, balance and coordination problems, nausea, and blurred vision. We observed that such symptoms were absent during the training with Negami. The reason for this could be that the risk of sensory mismatch concerning visual, vestibular, and proprioceptive information, which is considered one of the causes of cybersickness [43], is reduced to a maximum—if not completely avoided—when working with AR. The AR-based Negami app prompts people to move in the real world by actually moving their heads and bodies. The use of the tablet merely adds a virtual object to the real world. In this respect, manipulation is kept to a minimum.

Negami can also offer an advantage over VR games in terms of cost. The development of a VR system is often associated with high costs due to the need for dedicated hardware [42]. Since Negami is available online (see the Negami website), it can be easily downloaded to any available tablet or smartphone. This provides wide availability and ensures that additional costs are avoided. The use of already existing technical hardware also offers immense opportunities regarding remote/telerehabilitation. This is important because, in one-third of patients experiencing spatial neglect in the acute phase of the stroke, the disorder becomes chronic [44]. During their inpatient stay, patients are well cared for in terms of their recovery, but what happens after discharge from inpatient rehabilitation? An answer to that could be remote/telerehabilitation. Easy-to-understand instructions for the tasks in Negami can allow patients to practice independently from home. With online data storage, the therapist has external access to patients' treatment data and can monitor them remotely.

Limitations

One limitation of this study is the small sample size. We only could include 10 elderly neurologically healthy individuals and 10 patients experiencing spatial neglect and left-sided hemiparesis after a stroke in the right brain hemisphere. Therefore, testing the Negami app with a larger number of participants in a future study will be useful. It would also be desirable to evaluate the use of the app on the part of the therapists in the future. It should be further mentioned that Negami thus far can only be used on Apple devices. However, it is being further developed with the aim of being able to use on Android devices as well. The further development of all smart devices with different operating systems would also ensure the use of lighter devices, as 3 (30%) of the patients complained about the weight of the tablet. At this point, it should also be mentioned that very severely affected patients, who are not yet able to hold a tablet in the acute phase after a stroke, may not benefit from Negami initially, and other therapeutic approaches should be considered first for them.

Conclusion

AR represents a promising extension to the traditional "visual exploration training" for spatial neglect. The natural interaction with the environment during playful tasks appears to markedly increase patient motivation. An advantage of AR, as implemented in Negami, over immersive VR-based treatments may be that it minimizes the risk of sensory mismatch concerning visual, vestibular, and proprioceptive information, which is considered one of the causes of cybersickness.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic and clinical data of all 10 patients with right brain damage and spatial neglect.
[DOCX File , 19 KB - games_v11i1e40651_app1.docx]

Multimedia Appendix 2
Patient performing Task B on Negami.
[MP4 File (MP4 Video), 21397 KB - games_v11i1e40651_app2.mp4]

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Abbreviations

API: application programming interface
AR: augmented reality
ARM: Advanced Reduced Instruction Set Computer Machine
CoC: Center of Cancellation PGTQ: Perception of Game Training Questionnaire
EWB: end point weightings bias
IL: Intermediate Language
SQL: Structured Query Language
SSQ: Simulator Sickness Questionnaire
SUS: System Usability Scale
UI: user interface
VR: virtual reality
XAML: Extensible Application Markup Language

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Original Paper

Appropriate Image Selection With Virtual Reality in Vestibular Rehabilitation: Cross-sectional Study

Kerem Ersin[1*], MSc; Emre Gürlek[1*], BSc; Hakan Güler[1*], BSc; Çiğdem Kalaycık Ertugay[2*], Assoc Dr; Mustafa Bülent Şerbetçioğlu[3*], Prof Dr

[1]Graduate School of Health Sciences, Istanbul Medipol University, Istanbul, Turkey

[2]Department of Audiology, Istanbul Education Research Hospital, Istanbul, Turkey

[3]Faculty of Health Sciences, Istanbul Medipol University, Istanbul, Turkey

[*]all authors contributed equally

Corresponding Author:
Emre Gürlek, BSc
Graduate School of Health Sciences
Istanbul Medipol University
Göztepe Mahallesi Atatürk Caddesi No. 40 Beykoz
Istanbul, 34820
Turkey
Phone: 90 507 934 71 16
Fax: 90 212 521 23
Email: emregurlek1622@gmail.com

Abstract

Background: While vestibular rehabilitation with virtual reality (VR) is becoming more popular every day, the disadvantages of this method are not yet clear.

Objective: The aim of this study is to examine the effect of the image to be used in vestibular rehabilitation with VR on the systems that provide body posture.

Methods: The study was carried out with 36 participants (18 women and 18 men) aged 18 to 30 years. To assess balance control components separately, a sensory organization test was administered to the participants in the presence of stressful and relaxing environment images with VR technology. The State-Trait Anxiety Inventory survey was also used to measure the stress values in the created environments.

Results: The State-Trait Anxiety Inventory survey revealed that while stressful videos significantly increased stress, relaxing videos reduced stress. Among measurements obtained in the presence of VR, significant decreases were observed mostly in the visual system data. A significant increase in vestibular system data (*P*=.01) was observed with a decrease in visual system data (*P*<.001) when the relaxing image was presented. Additionally, there was a significant difference in the somatosensory (*P*=.001), composite (*P*=.002), and visual system (*P*<.001) data in the presence of stressful videos.

Conclusions: Although the use of a VR system for vestibular rehabilitation is relatively new, no extant studies have examined how the image type used in VR can affect the integration of visual system data. Therefore, this study is unique in terms of showing the effects of the stress created by the change in the type of the image used in VR. When VR technology is used for therapeutic vestibular rehabilitation for patients whose balance disorder is due to the vestibular system, stress-free videos should be used. However, the use of stressful videos in VR technology will be beneficial in the rehabilitation of those with balance disorders due to the somatosensory system.

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KEYWORDS

balance; computerized dynamic posturography; stress; vestibular rehabilitation; vestibular system; virtual reality

Introduction

Maintaining posture uses a complex mechanism involving the brain's processing of multiple sensory inputs from the visual, proprioceptive, and vestibular systems by the central nervous system [1]. Computed dynamic posturography (CDP), which is used to examine the effects of these multisensor inputs separately, is a kind of test that can be used to evaluate the mechanisms that ensure the protection of the individual's posture by using different test positions similar to those we often experience in our daily lives [2]. The sensory organization test (SOT), one of the CDP test protocols, is a test that can evaluate a person's ability to use inputs from the vestibular, somatosensory, and visual systems to maintain balance in different stimulus situations and to monitor the compensatory condition in case of balance deterioration [3].

Virtual reality (VR) can be defined as a computer-generated simulation of a 3D image or environment with which the user can interact. Recently, the scope of VR use has expanded greatly, and it is being used in many areas, especially in rehabilitation programs, where it is increasing the effectiveness of vestibular rehabilitation. Studies have shown that a VR protocol may be a safe option to improve postural control and quality of life in individuals with vestibular disorders [4-6].

The classical stress response is a negative feedback system mediated by the hypothalamic-pituitary-adrenaline axis [7]. Studies have found that balance is affected in people who are under stress [8-10]. According to Saman et al [11], stress may affect central vestibular function either directly through the effects of cortisol and corticosteroids on ion channels and neurotransmission in the brain or indirectly through stress-related neuroactive substances. Gliddon et al [12] observed a significant increase in postoperative salivary cortisol levels in guinea pigs undergoing unilateral vestibular deafferentation.

One of the most widely used clinical tests for the measurement of anxiety is the State-Trait Anxiety Inventory (STAI) survey (Multimedia Appendices 1 and 2). The survey test, which evaluates stress immediately after an individual has undergone a test in a research or clinical setting, was administered, and the Turkish validity form, the reliability of which had been ascertained before, was filled in. There are questions in the inventory that increase and decrease the anxiety score [13,14].

Additionally, in the study by Seinfeld et al [15], increases in stress indicators (heart rate and skin responses) were observed in stress environments created by a VR system [16]. However, in some other published studies, the effect of stress was not considered in vestibular rehabilitation using a VR system. For this reason, the aim of this study is to examine the effect of the image to be used in vestibular rehabilitation with VR on the vision-proprioception-vestibular systems that provide body posture.

Methods

Participants and Recruitment

We calculated the sample size using power analysis. In the study, we set an α (type I error) of 5%, Cohen medium standardized effect size of 0.5, and power of 80% (with β [type II error] set to 20%). Power analysis revealed that a minimum of 28 patients were required. A total of 36 patients, 18 men (aged 23.33, SD 2.54 years) and 18 women (aged 21.66, SD 2.22 years) between the ages of 18 and 30 years (sample mean age 22.50, SD 2.50 years), were included in the final analysis. While individuals who were psychologically healthy and had no problems with balance in daily life in the preceding 1-year period were included in the study, those with eye problems, a fear of heights, dizziness in daily life, physical discomfort, or regular use of alcohol or drugs were excluded from the study.

Experimental Design

The study was conducted in the audiology clinic at the Istanbul Training and Research Hospital between February 23 and May 10, 2021. A NeuroCom device (Natus Medical Inc) was used to administer the SOT from among the CDP test repertoire.

The SOT measures how well the patient maintains equilibrium under 6 sensory conditions. Each condition is scored between 1 and 100, with an increased score indicating better stability. Each of the 6 conditions is repeated 3 times, and the duration of each test is 20 seconds. After 6 conditions (ie, 18 tests) the composite equilibrium score is then determined [16].

For the first 3 conditions, the force plates are fixed, and for the other 3 conditions, they move in anterior and posterior directions. In the first condition (baseline), the person is placed on the system such that all sensory information involved in postural control is available. In the second condition, the participant is tested with eyes closed (the visual information system is eliminated). In the third condition, the person's eyes are open, but the visual environment moves to present incorrect visual sequences. In the fourth to sixth conditions, the force plates are moved so that they act as what is referred to as a "sway referenced surface," making proprioceptive information inaccurate; hence, the subjects use visual and vestibular (or only vestibular) information to maintain their balance, in addition to having to overcome the inaccurate proprioception signals by relying on other systems and compensatory mechanisms. In the fourth condition, information from the visual and vestibular systems is evaluated. In the fifth condition, the eyes are closed. In this condition, information from the vestibular system is evaluated. In the sixth condition, inappropriate visual arrays are presented; thus, information from the vestibular system is evaluated [16].

Comparison of scores from the first 2 trials produces a "somatosensory score"; comparison of the score for test 4 with that from test 1 yields the "visual score"; comparison of scores from trial 5 to trial 1 reflects the "vestibular score." Comparing the sum of scores from the third and the sixth trials with the sum of scores from the second and fifth trials yields the "visual preference score" [17].

The SOT, one of the CDP tests, was administered to the participants in 3 different conditions generated using VR: in the control condition, in a stressful environment, and in a relaxing environment (Figure 1). An HTC VIVE VR system was used to generate the different environments. In the control condition, normalization values were determined by administering the SOT to the participants without wearing VR glasses (Figure 1).

To generate a stressful environment in the VR simulation, participants were raised to a height of 40 meters in a simulation of an elevator. Then, in the simulation, the elevator door opened, and they walked onto a platform that appeared in front of them. The end of the platform was mapped to the test area of the CDP device. When they arrived at this position, the SOT was administered to the participants while they saw VR images from a simulated height of 40 meters (Figure 1).

In the relaxing environment, while participants were waiting for the test on the CDP device, a meditation application was opened in VR. The SOT was administered while the participants were in the relaxing scenery (Figure 1).

Considering that the participants could adapt to the test, the tests were applied to each participant starting from a different condition. This aimed at preventing possible adaptation. A participant who completed one condition rested for at least 1 hour, after which another condition was applied.

After the tests, the participants took the STAI survey. Certain questions in the survey could increase or decrease the anxiety score. For each question, a score between 1 (or –1) and 4 (or –4) is assigned in accordance with the positive or negative characteristics of the question. The highest score is 80 and the lowest score is 20. The higher the total anxiety score, the higher the anxiety level of the person taking the survey [13].

Figure 1. Three different visually generated test environments.

Ethics Approval

The study was approved by the Non-Invasive Clinical Research Ethics Committee of Istanbul Medipol University (923/2020). All individuals participating in the study received explanations of the aims of the study, how long it would last, and practices and expectations. Participants then signed the consent form.

Statistical Analysis

The minimum subject size was estimated using G*Power (version 3.1; Heinrich-Heine-Universität Düsseldorf). The data analysis of our study was performed using SPSS (version 22.0; SPSS Inc). Descriptive statistics included mean and SD values. Normality of the distribution and homogeneity of the data were analyzed with the Kolmogorov-Smirnov test. A triple comparison of the groups (control condition [CC], stressful condition [SC], and relaxing condition [RC]) was carried out using the Friedman test. CC-RC, CC-SC, and RC-SC comparisons were made using the Wilcoxon signed-rank test. The statistical significance level was set to a *P* value of ≤.05 when analyzing the results of the Wilcoxon signed-rank test. In the Friedman test, statistical significance level was set to a *P* value of ≤.017.

Results

Triple Comparisons

Significant differences were observed in the visual system ($P<.001$) and somatosensory system ($P=.001$) data in the triple comparison of SOT data obtained in different stress environments (Figure 2). While no significant difference was observed in the vestibular system ($P=.03$) data, a significant difference was observed in the composite ($P=.002$) values (Figure 3). While a significant difference was observed in stress values ($P<.001$), there was no significant difference in the preference values (Figure 4).

Figure 2. The sensory organization test and visual and somatosensory system data.

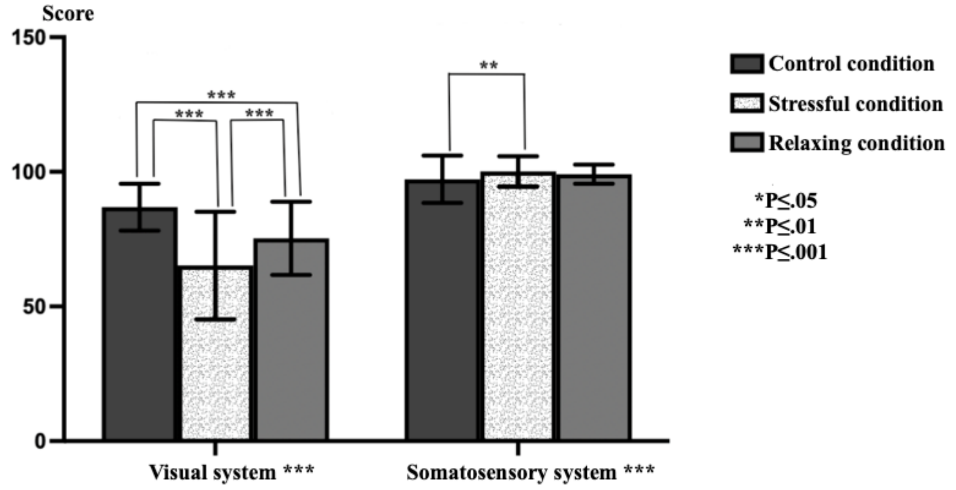


Figure 3. The sensory organization test for the vestibular system and composite data.

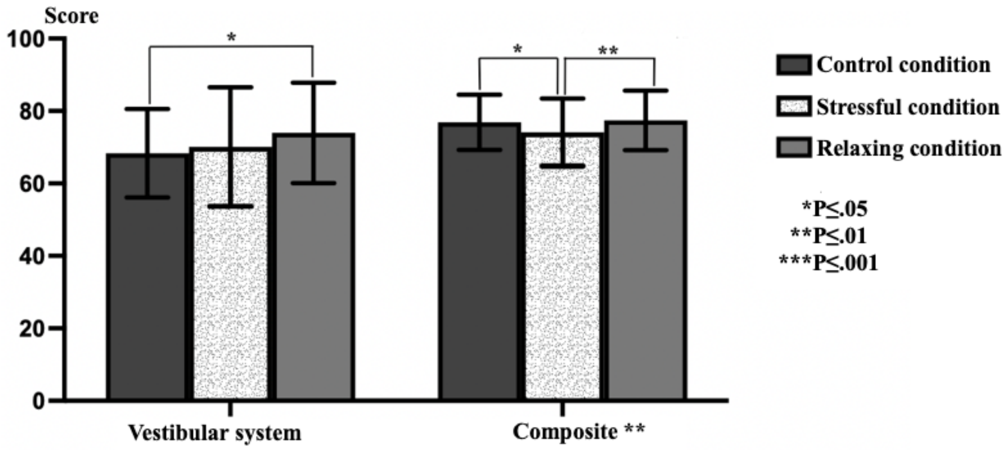
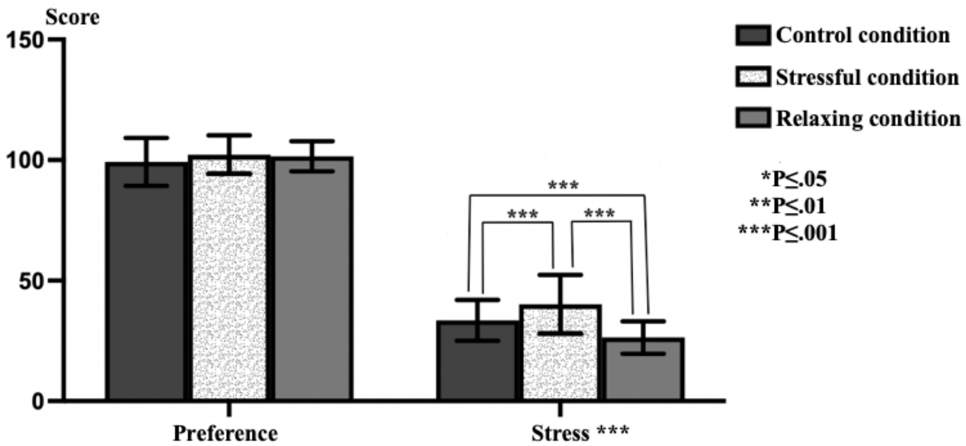


Figure 4. The sensory organization test, preference scores, and survey stress data.



Dual Comparisons

Significant differences were observed in visual system data in pairwise comparisons between the cases (CC-RC and CC-SC, *P*<.001; RC-SC, *P*=.001). A significant difference was observed when comparing the CC and SC environments (*P*=.002) in the somatosensory system data. A significant difference was observed when comparing the CC and RC environments (*P*=.01) in the vestibular system data (Table 1). No significant difference was observed in the comparisons made with preference data. A significant difference was observed when comparing the CC and SC environments (*P*=. 02) and the SC and RC environments (*P*=.005) in the composite data. When only the stress data were evaluated, a significant difference was observed when comparing the CC and SC environments (*P*<.001), CC and RC environments (*P*<.001), and SC and RC environments (*P*<.001; Table 2).

Table 1. Dual and triple comparisons of visual, vestibular, and somatosensory system data in 3 different cases.

	Control condition (CC), mean (SD)	Stressed condition (SC), mean (SD)	Relaxed condition (RC), mean (SD)	*P* value (CC-SC-RC)	*P* value (CC-SC)	*P* value (CC-RC)	*P* value (SC-RC)
Visual system	86.88 (8.70)	65.22 (19.98)	75.30 (13.61)	<.001	<.001	<.001	.001
Vestibular system	68.36 (12.20)	70.11 (16.46)	73.97 (13.87)	.03	.43	.01	.12
Somatosensory system	97.22 (8.79)	100.16 (5.64)	99.11 (3.52)	.001	.002	.21	.10

Table 2. Dual and triple comparisons of preference, composite, and stress data in 3 different cases.

	Control condition (CC), mean (SD)	Stressed condition (SC), mean (SD)	Relaxed condition (RC), mean (SD)	*P* value (CC-SC-RC)	*P* value (CC-SC)	*P* value (CC-RC)	*P* value (SC-RC)
Preference	99.19 (9.95)	102.25 (8.03)	101.55 (6.27)	.50	.12	.30	.97
Composite	76.91 (7.62)	74.11 (9.31)	77.44 (8.21)	.002	.02	.52	.005
Stress	33.50 (8.48)	40.16 (12.18)	26.38 (6.72)	<.001	<.001	<.001	<.001

Discussion

Principal Findings

The aim of the study was to investigate the effect of stress on the systems that provide data for maintaining posture. The SOT was administered to the study participants in different stress environments generated with VR. The changes in visual, vestibular, and somatosensory systems were examined with the SOT. Our results indicate that stress, especially presented visually, has a significant effect on the systems that protect posture.

Wuehr et al [18] took people to a height of 40 meters with a VR-based elevator simulation and observed specific changes in subjective fear levels, muscle activity, and balance control. In our study, like that of Wuehr et al [18], the SOT was administered by raising people to a height of 40 meters in an elevator simulation with a VR system as an instant stress source. When we examined the change in stress in the participants using the STAI survey before and after the test, we found that the participants were affected by stress in the presence of a stressful video. In the presence of a relaxing video, we found that the stress level was significantly lower than in the control group. Thus, we proved that our image selection is effective for assessing stress factors.

VR, which we use as an instant stress generation tool, has been used frequently in clinical studies with the development of technology in recent years [19]. In addition, its use in vestibular rehabilitation is increasing [20]. It has not been specifically reported in the literature whether VR has an adverse effect in VR-based vestibular rehabilitation or whether it has an adverse effect on the systems that provide data for maintaining posture [21]. Micarelli et al [22,23] reported that symptoms of nausea, oculomotor stress, and disorientation decreased over time in people participating in a vestibular rehabilitation program with VR. Both studies saw a significant reduction in nausea, oculomotor stress, and disorientation in the first to fourth week of the rehabilitation program with VR [22,23]. However, the instantaneous effect of VR and the effect of the video type used on treatment were not investigated in these studies. In our study, when we looked at the instantaneous effect of VR on the systems that maintain posture by comparing the CC and RC environments and considering the results of the SOT, we found that VR application does not directly cause stress, but rather makes the person feel more comfortable than normal. However, we also observed that VR had a negative effect on the visual system while in this condition. Although there was no negative effect on the somatosensory system, we observed a significant increase in the values of the vestibular system. With the decrease in values for the visual system and the increase in those for the vestibular system, there was no significant decrease in the composite value, which is the general balance score. We believe that VR-based vestibular rehabilitation will be a successful process based on these findings. To avoid potential side effects from staying in a virtual environment for a long time during this process, special attention should be paid to the effect on the visual system, cyber sickness, dizziness under visual stimuli, nausea, and imbalance [24,25].

In Öztürk’s [25] study, individuals were evaluated with cervical vestibular-evoked myogenic potentials and video head impulse tests in the presence of visual illusions. The amplitudes of the vestibular-evoked myogenic potentials increased in cases where visual illusions were presented, and gains in some semicircular canals increased significantly. This showed that the vestibular system works more efficiently when there is a decrease in the consistency of the data obtained from the visual system [25]. In this study, the increase in vestibular system data is compatible with the visual stimulus provided by wearing the VR device.

In a study by Smyth et al [26] , healthy individuals with the highest cortisol response to psychosocial stress—that is, those who were most affected—had less-impaired postural sway when exposed to visual movement [26]. This is consistent with the findings of our study, in which the somatosensory system performed better when the VR image containing the stress stimulus was used, because in healthy people, minor oscillations are modulated by the ankle, which is part of the somatosensory system.

Psychological effects are common in patients experiencing vertigo or dizziness. In particular, the fear of falling and the resulting stress and anxiety seriously impair the quality of life of these individuals [27]. Eagger et al [28] found that patients with vestibular symptoms had higher social stress and trait anxiety scores than those without vestibular symptoms. The balance-stress neuroanatomical link has been defined as follows: the nucleus tractus solitarius has been shown to have extensive connections with the vestibular nuclei, both directly and through indirect projections through the parabrachial nucleus, which provides major inputs to the limbic system, including the enlarged central amygdaloid nucleus, infralimbic cortex, and hypothalamus [29]. Because of this connection between the vestibular system and the limbic system, the stress factor should be taken into account when planning treatment for individuals with vestibular symptoms. Choosing less stressful images during the vestibular rehabilitation phase, especially near the end of the study, will aid in the recovery of vestibular systems.

Studies have shown that stress has an effect on the systems that maintain posture [7,9,11]. In line with the findings of the literature review, this study found that stress has a significant effect on these systems and that the stress effect provided by VR is primarily due to the effect on the visual system. When comparing the RC and SC environments, there was a significant decrease in visual system data and composite scores, accompanied by a significant increase in stress values. When we compared the visual system values of the CC and SC environments, we found a significant decrease as a result of stress, as well as a significant change in stress. Similarly, a significant increase in somatosensory values was observed with stress. This result shows the importance of the image used in vestibular rehabilitation. Confidence in the somatosensory system increased significantly when the participants watched a stressful video, while confidence in the vestibular system increased significantly when a relaxing video was shown. Thus, data on which group would be more effective for use in vestibular rehabilitation with VR, and the appropriate images to be used, should be highlighted.

Limitations

The SOT is not normally administered while wearing VR glasses. However, to investigate the effects of VR on balance while wearing these glasses, the SOT was used with relaxing images. To investigate the effect of image selection, a stress-inducing image, rather than a relaxing image, was used.

Conclusions

Our study investigated the effects of stress on the systems that protect posture and how much each of the systems is affected by stress, and the effect on individuals of using VR technology to provoke stress. Our results show that the visually created stressful environment had a significant effect on balance. In individuals with balance disorder, it would be more beneficial to use stressful images if the problem relates to the somatosensory system and to use less stressful images if it is related to the vestibular system. To obtain more successful and quicker results in the treatment processes for individuals with balance problems, it is necessary to focus on the stress condition and its effect on patients. In addition, the decrease in visual system data as a result of the stress we induced visually and the effect of rehabilitation with VR in people whose visual system contributes to their balance disorder should be the subject of further studies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Stait-Trait Anxiety Inventory.
[PDF File (Adobe PDF File), 43 KB - games_v11i1e40806_app1.pdf]

Multimedia Appendix 2
Stait-Trait Anxiety Inventory (Turkish).
[PDF File (Adobe PDF File), 71 KB - games_v11i1e40806_app2.pdf]

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Abbreviations

CC: control condition
CDP: computed dynamic posturography
RC: relaxing condition
SC: stressful condition
SOT: sensory organization test
STAI: State-Trait Anxiety Inventory
VR: virtual reality

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Original Paper

Cognitive Training With Head-Mounted Display Virtual Reality in Neurorehabilitation: Pilot Randomized Controlled Trial

Julian Specht[1*], BSc; Barbara Stegmann[1*], BSc; Hanna Gross[2*], BSc; Karsten Krakow[2,3*], Prof Dr

[1]SRH University of Applied Sciences Heidelberg, Department of Applied Psychology, Heidelberg, Germany

[2]Asklepios Neurologische Klinik Falkenstein, Department of Neurorehabilitation, Königstein im Taunus, Germany

[3]Rehaklinik Zihlschlacht, Department of Neurorehabilitation, Zihlschlacht, Switzerland

[*]all authors contributed equally

Corresponding Author:
Julian Specht, BSc
SRH University of Applied Sciences Heidelberg
Department of Applied Psychology
Ludwig-Guttmann-Straße 6
Heidelberg, 69123
Germany
Phone: 49 01737808422
Email: julian.specht@livingbrain.de

Abstract

Background: Neurological rehabilitation is technologically evolving rapidly, resulting in new treatments for patients. Stroke, one of the most prevalent conditions in neurorehabilitation, has been a particular focus in recent years. However, patients often need help with physical and cognitive constraints, whereby the cognitive domain in neurorehabilitation does not technologically exploit existing potential. Usually, cognitive rehabilitation is performed with pen and paper or on a computer, which leads to limitations in preparation for activities of daily living. Technologies such as virtual reality (VR) can bridge this gap.

Objective: This pilot study investigated the use of immersive VR in cognitive rehabilitation for patients undergoing inpatient neurorehabilitation. The goal was to determine the difference in rehabilitation effectiveness between a VR serious game that combines everyday activities with cognitive paradigms and conventional computerized cognitive training. We hypothesized the superiority of the VR serious game regarding cognitive abilities and patient-reported outcomes as well as transfer to daily life.

Methods: We recruited 42 patients with acute brain affection from a German neurorehabilitation clinic in inpatient care with a Mini Mental Status Test score >20 to participate in this randomized controlled trial. Participants were randomly assigned to 2 groups, with 1 receiving the experimental VR treatment (n=21). VR training consisted of daily life scenarios, for example, in a kitchen, focusing on treating executive functions such as planning and problem-solving. The control group (n=21) received conventional computerized cognitive training. Each participant received a minimum of 18 treatment sessions in their respective group. Patients were tested for cognitive status, subjective health, and quality of life before and after the intervention (Alters-Konzentrations-Test, Wechsler Memory Scale—Revised, Trail Making Test A and B, Tower of London—German version, Short Form 36, European Quality of Life 5 Dimensions visual analog scale, and Fragebogen zur Erfassung der Performance in VR).

Results: Repeated-measures ANOVA revealed several significant main effects in the cognitive tests: Tower of London—German version (*P*=.046), Trail Making Test A (*P*=.01), and Wechsler Memory Scale—Revised (*P*=.006). However, post hoc tests revealed that the VR group showed significant improvement in the planning, executive control, and problem-solving domains (*P*=.046, Bonferroni *P*=.02). In contrast, no significant improvement in the control group between t_0 and t_1 was detected (all *P*>.05). Furthermore, a nonsignificant trend was observed in visual speed in the VR group (*P*=.09, Bonferroni *P*=.02).

Conclusions: The results of this pilot randomized controlled trial showed that immersive VR training in cognitive rehabilitation had greater effectiveness than the standard of care in treating patients experiencing stroke in some cognitive domains . These findings support the further use and study of VR training incorporating activities of daily living in other neurological disorders involving cognitive dysfunction.

Trial Registration: Federal Registry of Clinical Trials of Germany (DRKS) DRKS00023605; https://drks.de/search/de/trial/DRKS00023605

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KEYWORDS
cognitive rehabilitation; virtual reality; neurorehabilitation; psychology; stroke

Introduction

Background

The primary goal of neurorehabilitation is to restore or preserve critical function, thereby enabling patients to participate in daily life. Neurological diseases can lead to severe disabilities. This requires the patient to make great effort in rehabilitation. For example, stroke is one of the leading causes of disability. It is estimated that 33% to 42% of stroke survivors require assistance in managing activities of daily living (ADL). Reduced ability to manage ADL is often long term, with 20% of patients being unable to manage ADL independently 5 years after a stroke [1,2]. Even patients with only mild stroke have unmet rehabilitation needs and require support in managing ADL [3,4]. This also raises the question of whether there should be more ADL-focused therapies in principle, because the study by Rejnö et al [1] showed that there is a continuous decrease in ADL independence over time after a stroke; the proportion of patients who can independently manage ADL 3 months after a stroke decreases by about 3% per year, so that 5 years after the stroke, only just over 80% of the group of independent patients can independently manage ADL [1].

Furthermore, stroke is associated with a substantial economic burden, creating a cost of €60 billion (US $67.2 billion) in the European Union [5]. Wilkins et al [6] highlighted that these costs are far greater when including indirect costs from the subsequent burden on society by lost employment and expenses related to the need for multidisciplinary, extensive rehabilitation. This points to the great need for more effective rehabilitation interventions that support patients in regaining their ability to participate and manage everyday life independently.

ADL, such as making coffee or preparing lunch, require multiple motor and cognitive processes to achieve their functional goals. Seemingly trivial activities demand several temporally overlapping cognitive functions such as planning, problem-solving, recall, and execution [7]. Toth et al [8] demonstrated in collaboration with 36 occupational therapists that the 20 most critical instrumental ADL were closely related to different cognitive functions in older adults. Cognitive domains that have been frequently discovered in this context are memory, executive functions (EF), attention, visuospatial abilities, and language. They also found that, for instance, in grocery shopping, making and keeping medical appointments and medication management EF were the most demanded cognitive domains, whereas paying bills, making a phone call, and making and keeping medical appointments were identified to require language the most [8]. In addition, there exists a correlation between ADL performance, multimorbidity, and quality of life [9]. Therefore, it would be beneficial if neurorehabilitation methods emphasized preparation for everyday life to reduce morbidity. One component of this process is improving the cognitive skills required to handle ADL. With the findings of Toth et al [8], it would be beneficial if rehabilitation explicitly addresses patients' requirements in everyday life and provides training, especially on the more complex instrumental ADL and its cognitive functional domains.

However, computerized cognitive training (CCT), or pen-and-paper training, is the standard practice in German rehabilitation facilities. It involves training in isolated domains, including attention, working memory, EF, and language. They are economical and efficient tools for delivering therapies. Still, its use is recommended only with restrictions by national guidelines for treating EF in various diseases, for example, in the stroke guidelines [10].

Furthermore, researchers discovered insufficient evidence of computer-based training in a second-order meta-analysis in neurorehabilitation [11]. The authors concluded that the processes initiated by CCT are often limited to near-transfer effects. The effects remained within the scope of the trained task regardless of the far-transfer measure, study population, or cognitive training application used. However, a far-transfer effect is crucial for later-stage rehabilitation and return to daily life. This report aligns with the above-referenced stroke guidelines, advising caution using computer-based training owing to the limited evidence on its effectiveness. Although Gajewski et al [12] demonstrated in their clinical trial that some far-transfer effect occurs when conducting combined PC and paper-and-pencil training, a transfer effect on ADL was not detectable.

Instead, customized virtual reality (VR) training is suitable for multidomain ADL training [13,14]. VR is defined as images and sounds created by a computer that seem almost indistinguishable from the real world and users can interact with via sensors [15]. Although it can be experienced nowadays with purpose-made head-mounted displays (HMDs) placed on the head in front of the eyes for a fully immersive experience, the interaction with the virtual world is mainly carried out with 2 hand controllers. VR enables a combination of principles from occupational therapy, neuropsychology, and ADL, resulting in an ecologically valid training setting for many individuals with neurological impairments who want to regain their ability to participate in daily activities. Although insights exist concerning the acceptance of immersive HMD-VR in patients with stroke [16] or older adults [17], knowledge about the processes of cognitive rehabilitation facilitated by immersive VR needs to be expanded.

One concept that is becoming more widespread in neurorehabilitation is serious games (SG) [18]. SGs are defined as games developed not only for entertainment but also for serious learning purposes and can be considered a nonpharmacological, gamified approach to treat and evaluate [19] a patient's executive dysfunction in an ecologically valid way [20]. SGs and VR have already been combined, as Faria et al [21] demonstrated. They trained EF in immersive VR with a virtual city, Reh@City, including attention, memory, visuospatial abilities and other EF, in performing ADL and found that this approach boosts cognitive rehabilitation and leads to better results in contrast to conventional cognitive rehabilitation methods [21]. A systematic review of the assessment and treatment of EF with VR in clinical populations and healthy participants concluded that VR is a promising tool [22]; however, more research is necessary, as the authors cited only a few trials on this topic. Training systems focused on ADL have the potential for better transfer to the real world after rehabilitation. Still, more evidence on the interrelation between SGs, ADL, EF training, and immersive VR [22] is necessary.

Investigating VR-based cognitive rehabilitation involves research of a multitude of groups. The number of publications in scientific journals has increased almost exponentially since 2004 [23]. The 3 most frequently studied diseases in VR-based cognitive rehabilitation are stroke, dementia, and mild cognitive impairment. Jahn et al [13] noted in their systematic review of publications about VR and cognitive rehabilitation that there is promising evidence for the functionality of this approach. However, current research findings still struggle with several issues, including group sizes being too small (N=6-34 participants, with 89% of reviewed trials having N<20 participants per intervention arm), the lack of randomization (eg, no randomization at all), or suboptimal statistical analyses (no group-by-time interaction analysis reported).

Maggio et al [14] found in their review of VR for cognitive rehabilitation that VR training in neurorehabilitation has measurable effects on executive functioning, visuospatial abilities, speech, attention, and memory skills. In particular, executive functioning and depression at discharge from stroke rehabilitation are strong predictors of functioning at the time of discharge and the following 12 months, as Shea-Shumsky et al [24] found in their study that executive functioning was a strong predictor of ADL capacity to a more significant extent than mental status. It is a strong signal that problems with EF are involved in issues regarding functionality in everyday life and that viable training is helpful and necessary [24].

Objectives

In this paper, we present the results of a pilot clinical randomized controlled trial in patients undergoing neurological treatment after acute brain injury. The trial compared two treatments: (1) a novel immersive VR intervention to treat cognitive dysfunction, specifically EF, presenting ADL in the form of an SG, and (2) conventional computerized cognitive rehabilitation training in inpatient care at a German rehabilitation hospital. VR intervention includes training in a virtual kitchen or garden, simultaneously targeting various cognitive domains, including planning, attention, and problem-solving. Furthermore, interaction with the virtual environment was enabled using HMD-VR to fully immerse users. The trial was conducted to investigate whether training with a VR-SG produces measurable effects in different cognitive domains in patients after acute brain injury and whether the potential effects outperform, are similar to, or are inferior to traditional training methods, specifically CCT.

We hypothesized that VR training will significantly improve cognitive performance and outcomes related to quality of life and general health compared with our control condition throughout the 4-week treatment. Therefore, this study addressed the following objectives:

- The primary objective was to assess the impact of an ADL-based VR-SG on patients’ cognitive abilities after acute brain injury throughout a 4-week treatment period and compare it with a conventional CCT treatment.
- The secondary objective was to assess the impact of an ADL-based VR-SG on self-reported outcomes, quality of life, state of health, and affect and compare it with conventional CCT treatment.
- The tertiary objective was to assess the impact of an ADL-based VR-SG on the actual transfer of learned abilities in VR to daily life and reality compared with conventional CCT treatment.
- The exploratory objective was to investigate the extent to which an ADL-based VR-SG is suitable for cognitive rehabilitation from phase C onward.

No changes to these objectives were made after trial commencement.

Methods

Participants

Participants were screened and recruited for enrollment at the Asklepios Neurologische Klinik Falkenstein clinic in Königstein im Taunus, Germany. The patients were transferred to the rehabilitation clinic directly from the emergency hospital (rehabilitation phase A) or had already undergone early rehabilitation (rehabilitation phase B). The differentiation to which unit a patient was admitted was based on the Barthel index: it was first developed by Mahoney and Barthel in 1965 [25] and Colin et al [26] and Shah et al [27] modified it over the years. The original 10-item form consists of 10 scales describing ADL, including feeding, bathing, grooming, dressing, bowel and bladder control, toilet use, transfers (bed to chair and back), mobility, and stair climbing. The rating describes the independence of patients to perform the named ADL on a scale from 0 to 10, with a maximum of 15 points for the transfers and mobility scale. The maximum score was calculated by summing up the results of all the scales. A maximum score of 100 indicates that patients have no difficulty managing the described ADL, whereas a score between 30 and 70 indicates the patient’s ability to conduct rehabilitation phase C in Germany. All patients were admitted to the rehabilitation phase C unit and had subacute stroke syndromes. The trial was planned using a parallel design.

The admission interview at the rehabilitation clinic and records of newly admitted patients undergoing rehabilitation were used to recruit the sample. A phase C status qualified patients to participate in the clinical trial, and a transition to phase D during study participation was possible. None of the patients started earlier or later than phase C. All participants were required to be legally competent and of age and had to undergo inpatient neurological rehabilitation treatment at the neurorehabilitation clinic because of acute brain affection (eg, cerebral infarction, intracerebral hemorrhage, subarachnoid hemorrhage, subdural or epidural intracranial hemorrhage, traumatic brain injury, brain tumor, meningitis or encephalitis, and hypoxic encephalopathy), had to have full functionality for at least one arm, had known adequate or corrected eyesight in the central field of vision, and had to give written consent to participate. Patients were also screened for cognitive performance using the Mini Mental Status Test (MMST) [28]. The score obtained had to be >20 out of 30 points. The cut-off value was chosen because some cognitive impairment was expected in this sample, and scores of 27 to 30 (no cognitive impairment) would not properly represent the sample of patients undergoing neurorehabilitation. Patients were excluded if they had present or prior psychiatric comorbidities or disorders and a known overreaction to visual stimulation leading to seizures. Once patients eligible for the study were identified, they were targeted by trained study personnel and informed of the opportunity to participate. In this course, the content and objectives of the study are explained.

Materials: Training Tools

For the trial, 2 different treatment methods were applied. The control group received CCT used in routine care at the rehabilitation center at least 3 times a week for 30 minutes each session, in this case, Freshminder. Freshminder is a cognitive training program with multiple training paradigms, focusing on attention, planning, and memory (Figure 1). Training was conducted on a PC with a keyboard and mouse. Users must interact with the application by clicking objects or deciding by pressing a key on the keyboard. In this study, the following tasks were considered: pearlfish (vigilance and working memory), picture series (memory), step sequence (action planning), task switching (flexibility), and double play (divided attention). For example, in the pearlfish task, participants had to click on fish carrying pearls. Participants had to discriminate which fish were holding the pearls and identify the fish at the correct time so that the pearl fell appropriately into the box at the bottom of the sea. This exercise trained selective attention, visual perception, and visuomotor skills. All exercises were adapted to the patient's performance by changing the difficulty and level at the beginning of each task. This was adapted by the therapist in charge. Patients received information about their performance during the training tasks. They could choose from a subset of exercises with the therapist, ensuring that all exercises were performed at a well-balanced frequency.

Figure 1. Computerized cognitive training exercises, representing the exercises of Freshminder; upper images: Doppelspiel (double play) and Perlenfische (pearlfish), bottom images: Schrittfolge (step sequence) and Aufgabenwechsel (tasks switching).

The VR group received treatment with an early version of Teora mind, conceptualized and developed by the medical device manufacturer Living Brain, a cognitive training in immersive VR. Teora mind is a certified medical device of risk class IIa according to Medical Device Regulation (EU) 2017/745. The certification procedure was executed by Notified Body TÜV Süd in 2021. The SG integrates ADL and cognitive training methods in a playful way to improve cognition and transfer into daily life and consists of realistic scenarios for training specific abilities.

The participants were trained in a virtual garden and kitchen scenario. Patients were asked to make coffee for multiple people in the kitchen. Therefore, they had to actively implement all the necessary steps for serving coffee, including filling the coffee machine with beans and water, changing the coffee filter, choosing a mug, and considering whether the coffee had to be served with milk and sugar (Figure 2). Other exercises included sorting groceries according to their categories, for example, beverages, fruits and vegetables, and durable food for stock, or sorting out the refrigerator according to specifications, such as spoiled food. A time pressure component was added with increasing difficulty. All activities were implemented in real time and through patient interactions with the virtual environment.

Figure 2. Virtual reality training scenarios, upper images: virtual garden scenario, showing action planning board (left) and greenhouse with user harvesting cucumbers (right); bottom images: virtual kitchen scenario, showing user refilling coffee machine with coffee beans (left) and start screen when entering the kitchen (right).

In the garden scenario, patients were asked to plant seeds to grow strawberries, tomatoes, and cucumbers. In the growth phase, users had to ensure that there was always sufficient water in the bed and that popping weeds did not destroy the seedlings, which required watering the bed with a watering can. After successfully growing fruits and vegetables, users can produce juices from the harvested food. Participants had to plan their activity by first sorting picture cards describing each action step on a board in what they thought was the correct order. Next, they were required to confirm their orders. Finally, the system reported whether the order was correct or incorrect and indicated the steps that were arranged incorrectly. The exercise could begin only after the right order was achieved. The complexity varied depending on the difficulty level; at the highest level, planning was omitted and the activity had to be started immediately.

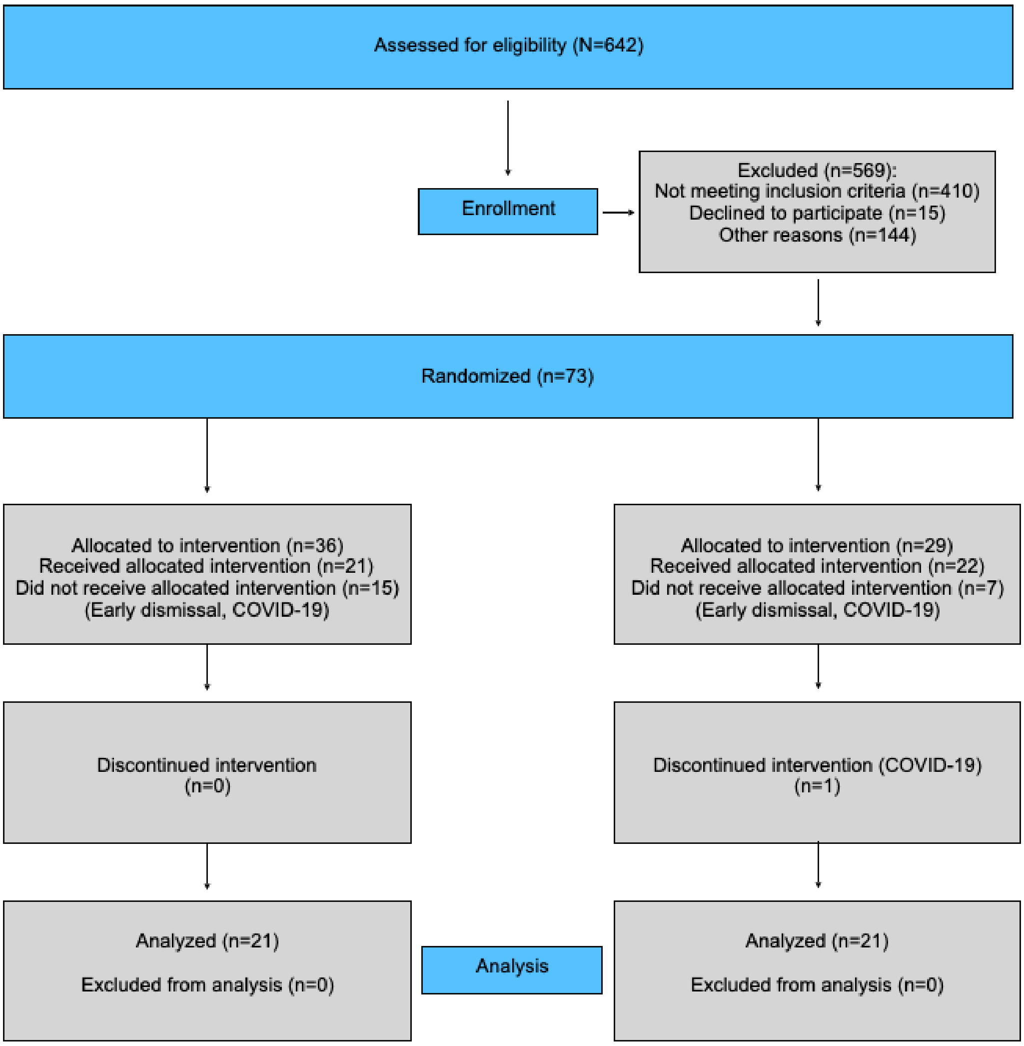
The main cognitive domains targeted by this VR training are EF, in particular action planning, problem-solving, selective attention, and working memory. The specific pieces of training themselves do not primarily focus on a single cognitive domain but rather on training the ADL, which typically comprises multiple cognitive domains simultaneously. Similar to the CCT intervention, the difficulty could be adapted to individual performance by changing to 20 different degrees of difficulty, which was adjusted by the therapist in charge. Patients received information on how they performed their training tasks in the VR application. In this trial, an early version, specifically designed for this clinical trial, was used. At that time, the medical device had not been introduced to the market. It was updated 2 times during the trial for minor bugs.

VR devices of the type Oculus Quest (manufacturer: Meta) were used for the trial conduction. The device is a stand-alone HMD, and additional technical devices for experiencing immersive VR are not required. In addition to the VR device, the study nurses and therapists in charge received a tablet (Samsung Galaxy Tab A) for monitoring ongoing VR activities; all VR procedures were mirrored on the tablet in real time. This allowed patient-therapist interaction despite the high grade of immersion, particularly in the first training sessions of benefit. Interaction in immersive VR was enabled by the hand controller used by the patients. The blue hands visually represented them and were congruent with the actual movement of the upper extremities. The controllers included multiple buttons, of which only 2 were necessary to use the VR software. Moving the head makes it possible to gain a complete overview of the virtual world. Through a visible white beam, users can assess what they are currently pointing at in a virtual environment. This allowed for the selection of objects. To introduce the patients to the technology and virtual environment, they went through a dedicated tutorial at the beginning of each treatment. High resolution pictures of the training are available in Multimedia Appendices 1-4.

Procedure

In the first 2 sessions, which lasted approximately 60 minutes each, comprehensive testing (Alters-Konzentrations-Test [AKT], Wechsler Memory Scale—Revised [WMS-R], Trail Making Test [TMT] A and B, Tower of London—German version [TL-D], Short Form 36 [SF-36], visual analog scale [VAS; EQ-5D VAS], and Fragebogen zur Erfassung der Performance in VR [FEPVR]) was conducted (t_0). The testing consisted of psychological tests conducted by a psychologist and self-assessed questionnaires. After completing the testing, individuals were randomly assigned to 1 of the 2 training groups by drawing from an urn, which was performed by the study nurse. Only the responsible investigator had access to the list of individuals in each group. Because of the nature of the study, it was impossible to ensure the blindness of the investigator responsible for the intervention and participants. The process of participant randomization is described in the flowchart prepared according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines (Figure 3), and we used an analog randomization process by drawing notes from an urn. The whole CONSORT checklist is available in Multimedia Appendix 5. Simple randomization was performed by the study nurse. The treatment was scheduled for 18 to 25 sessions with a duration of 30 minutes for the individual, based on the date of admission and the participant's immediate health and neurological condition. The sessions were conducted at least 3 to 5 days per week. Both groups received their allocated treatments from day 3 to day 20. A maximum of 25 treatment sessions were allowed.

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



The study nurse instructed the intervention group on the device's functions and use before the first VR training session. This included the general operation of the device from the outside with the attached buttons (on-off button and volume control), especially the handling of the hand controllers. After receiving the instructions, participants went through a VR tutorial, consisting of training in basic functionality, a memory game, and a recycling game, in which they were familiarized with general handling in the first training session. This tutorial demonstrated the interaction with the VR environment, virtual objects, and the handling of the entire experience. The tutorial was developed and tested with stroke patients, leading to high acceptance in a group of patients with stroke and healthy older adults, indicating that it is suitable for introducing this critical user group to immersive VR [16]. In addition, the familiarization phase helps reduce possible effects due to unawareness about the technology and negative attitudes toward it [29]. During all training sessions, the study nurse was able to track the process on a tablet and was thus able to provide accurate, customized assistance if needed.

The control group was also instructed on the operation of the used computer if needed, and an introduction to the program, explaining the different tasks, before the first training session was conducted by the study nurse in charge. During all training sessions, the study nurse was close to the participant and was thus able to provide accurate, customized assistance if needed.

The patients remained statically seated in the same place throughout all training sessions to minimize the potential risks of injury. Locomotion was performed using only a controller in a virtual environment. The study nurse documented the task results during the training sessions (ie, the time needed to finish a task and other observations), in a separate, pseudonymized document. The patients could choose from the exercises themselves, with the therapist ensuring that all exercises were performed at a well-balanced frequency. All participants could stop the treatment at any time, for example, if they felt unwell during training.

Immediately after the seventh training session, participants in both groups were asked to complete the Positive and Negative Affect Schedule (PANAS) questionnaire and rate their current subjective health status using the EQ-5D VAS. After the final treatment session, the test battery was repeated (t_1). Furthermore, a survey regarding the overall VR experience was conducted using open-ended questions, and the patient was asked for suggestions for improvement and satisfaction with the application.

Dependent Measures

Overview

Each participant was comprehensively tested at 2 points: before treatment (t_0) and immediately after the last session (t_1). The focus was on investigating the impact of the 2 cognitive training methods on diverse cognitive abilities. We tested the patients regarding working memory, selective attention, planning, attention, task organization, cognitive flexibility, and problem-solving. We also examined their quality of life, affect, and health status. In addition, a new measurement tool was tested to evaluate subjective performance in a situation similar to VR training to determine the extent to which the VR training was transferred to reality. The test battery included the following tests.

AKT Measure

The AKT [30] is a psychometric procedure that measures concentration ability and vigilance. The test was developed and standardized specifically for older people and is therefore adapted to their needs in terms of comprehensibility, task difficulty, and resilience requirements. Participants had to differentiate a figure at the top of the test sheet from a series of similar figures and cross it out. In this trial, we used the German version.

TMT A and B Measure

The TMT [31] is a cognitive test for measuring EF, particularly visuomotor abilities, which are essential for executing ADL properly [24]. In TMT A, patients had to connect numbers in ascending order; in TMT B, they had to connect numbers and letters in ascending and alternating order. The test has been standardized for patients with cognitive disorders undergoing neurological rehabilitation and is often used for neurorehabilitation screening and diagnostics.

TL-D Measure

The TL-D is a transformation task that captures convergent problem-solving thinking and planning processes [32]. The objective of the task is to transfer 3 different-colored balls from an initial state to a specified target state in a minimum number of moves. The test consists of 20 tasks of varying severity and has been standardized in a sample of patients with neurological diseases; we used the German version of the test.

WMS-R: Number Span Forward and Backward

The WMS-R measures different memory functions [33]. In this study, a subset number span was used. First, the therapist reads a series of numbers of increasing length out loud. Depending on the task, the patient was then asked to recall the numbers in the correct order, either forward or backward. The WMS-R has been tested and standardized in patients with neurological and psychiatric disorders.

SF-36 Measure

The SF-36 questionnaire assesses patients' health-related quality of life and consists of 36 items [34]. It measures 8 dimensions of subjective health: physical functioning, physical role functioning, physical pain, general health perception, vitality, social functioning, emotional role functioning, and psychological well-being. The SF-36 has been standardized in various patient populations; we used the German version of the instrument in this trial.

EQ-5D VAS Measure

Scientists use EQ-5D instruments developed by EuroQol for many different diseases. The EQ-5D VAS is a VAS in the standard layout of a vertical 20-cm scale with a range of values from 0 to 100, asking respondents to rate their current health status on the scale. The higher the rating, the better the indicated health status. The tool has been used in more than 117 countries and standardized for multiple patient groups.

FEPVR Tool

The VR performance instrument is a measurement tool to assess how well everyday activities can be performed and what effects training in VR has on daily performance. The test consisted of questionnaires, individual actions that were actively performed, and observation forms for therapists to rate patient activities. These activities included, among others, actively sorting laundry, planting strawberries, self-assessment of the ability to plan an action, and quantitative and qualitative feedback on the training experience. Our research group developed this tool specifically for this trial; however, it has yet to be validated in a large clinical sample. Therefore, the use was experimental. Book et al [35] and Graessel et al [36] developed and published a similar testing tool.

PANAS Trial

For this trial, we used the German version of the PANAS [37]. This questionnaire measured positive and negative affective states and traits. The patient rated the intensity of a sensation or feeling on a 5-point scale from “not at all” to “extremely.” Twenty items were presented.

Power and Statistical Analysis

Statistical analyses were performed using SPSS 29 (IBM Corp), with statistical significance set at $P<.05$. We performed repeated-measures ANOVA and post hoc tests to detect inner-subject and between-group changes between t_0 and t_1.

Comparing the VR and control groups in terms of cognitive performance and health-related measures involved group mean comparisons from 2 independent samples. Power calculations (power analysis tool GPower [Heinrich-Heine-Universität Düsseldorf, release 3.1.9.6 for Mac OS X]) revealed that our sample size of n=21 per group was sufficient to detect a standardized estimated population mean difference of f=0.25, which is considered a medium effect size, with a power of $1 - \beta = .88 - \alpha = .05$. This shows that our small sample size did not constrain the detection of between-group effects at a conventional power goal of 0.8 with a medium effect size of f=0.25.

Ethics Approval

Approval for this pilot trial was obtained from the local Ethics Committee of the Regional Medical Association Hessen, Germany, under approval 2020-1768-fMP. The VR training Teora mind is a certified medical device (class IIa) in line with the European Medical Device Regulation and therefore obtained approval to conduct this trial from the state authority Bundesinstitut für Arzneimittel und Medizinprodukte under the file number 94208-5660-12543. All regulatory approvals were obtained before the recruitment of the first patient.

Results

Baseline Characteristics

The recruitment process started on November 1, 2020, and the last patient completed the treatment on March 31, 2022. We initially planned to include 52 patients but decided to close the study when we reached 42 patients finishing all treatment sessions because this sample size was large enough to calculate repeated-measures ANOVA. Further extension of the trial was not possible due to administrative reasons. A total of 21 patients received the novel VR treatment, whereas the other 21 received control CCT. Furthermore, 33% (14/42) of the patients were female. Patients in the control group were, on average, aged 67.3 (SD 4.6) years at trial participation, while the VR group had a mean age of 68.3 (SD 14.5) years at trial participation; no statistical difference between both groups regarding age was found (P=.69). Detailed information on the brain damage of the included participants is found in Table 1. For more detailed information on the demographic characteristics, mean performance, and SD for all sample measures in this clinical trial, please refer to Tables 2 and 3.

Of the 642 patients receiving treatment at the center at the time of trial conduction, 73 patients were primarily included for participation, of which 42 (14 female patients) completed all treatment sessions. However, 31 patients were not able to complete the minimum treatment number for the following reasons: COVID-19 (n=4), early dismissal (n=12), psychiatric comorbidities not detected earlier (n=3), and treatment discontinuation due to a high incidence of COVID-19 cases at the trial center (n=12).

Of the 42 included patients, 17 (28%) had a right-sided pathology, 22 (52%) had left-sided pathology, and 3 (7%) had damage occurring in both brain hemispheres.

Table 1. Types of brain damage.

Brain region	Patients, n
Cerebral infarction	33
Brain hemorrhage	3
Subarachnoid hemorrhage	2
Basal ganglia hemorrhage	4

Table 2. Demographic characteristics of control and VR[a] group.

Variable	Control group (n=21)	VR patients (n=21)	*P* value
Age (years), mean (SD; range)	67.3 (4.6; 59-74)	68.3 (14.5; 36-93)	.69
MMST[b], mean (SD; range)	26.95 (2.04; 24-30)	27.05 (2.11; 24-30)	.97
Sex, n (%)			.67
Female	8 (38)	6 (29)	
Male	13 (62)	15 (71)	

[a]VR: virtual reality.

[b]MMST: Mini Mental State Test.

Table 3. Mean performance and SD in the control and VRa group for all measures used in the trial at baseline.

Measure	Control group, mean (SD; range)	VR patients, mean (SD; range)
TMT[a] A	93.7 (47.83; 36-205)	80.95 (47.84; 39-200)
TMT B	326.9 (216.7; 91-853)	29 2.2 (244.3; 96-1056)
TL-D[b]	54.9 (31; 3-99)	42.62 (32.1; 1-99)
EQ-5D VAS[c]	45.5 (21.02; 0-80)	49.05 (17.22; 0-75)
AKT_T_PR[d]	43.04 (21.4; 0-74.4)	41.07 (21.8; 0-97)
WMS-R[e] forward	39.6 (29.23; 0-98)	41.9 (34.99; 0-98)
WMS-R backward	28.2 (29.82; 0-98)	36.7 (32.96; 2-97)
SF-36[f] energy	42.83 (20.47; 0-80)	42.38 (20.77; 5-80)
SF-36 emotional well-being	55.15 (22.65; 0-88)	64.24 (23.94; 16-100)
SF-36 social functioning	36.87 (26.74; 0-100)	50.6 (31.99; 0-100)
SF-36 pain	51.75 (34.57; 0-100)	63.88 (34.6; 0-100)
SF-36 general health	47.5 (14.18; 25-75)	46.85 (13.82; 10-70)
SF-36 physical function	29.75 (30.45; 0-100)	20.77 (20.08; 0-66.6)
SF-36 role limitation in physical health	22.37 (36.22; 0-100)	13.49 (30.44; 0-100)
SF-36 role limitation emotional problems	35.09 (45.1; 0-100)	31.66 (43.9; 0-100)

[a]TMT: Trail Making Test.
[b]TL-D: Tower of London—German version.
[c]VAS: visual analog scale.
[d]AKT_T_PR: Alters-Konzentrations-Test time percentile rank.
[e]WMS-R: Wechsler Memory Scale—Revised.
[f]SF-36: Short Form 36.

Nausea and Motion Sickness

Of the 21 patients in the VR group, none reported problems with motion sickness or associated nausea, and no treatment had to be stopped due to motion sickness or nausea. This is congruent with the results of our feasibility trial with patients with stroke and healthy older adults, where we demonstrated that applying specific principles in VR development, such as having complete control of all motions in VR, reduces the risk of experiencing motion sickness and is feasible for use in special needs groups such as patients with stroke [16]. Patients in the control group using CCT reported no negative side effects. The patients conducted, on average, 18.7 (SD 0.99) successful treatment sessions.

Treatment Satisfaction

Patients were asked as part of the FEPVR tool to rate the treatment satisfaction on a Likert scale ranging from 1 (*very dissatisfied*) to 7 (*very satisfied*). Both groups reported a tendency toward high acceptance and satisfaction with both treatments (M=5.7). The treatment also created the impression that it helped against the present condition in both groups (VR: M=5.5, CCT: M=5.7), rated from 1 (*I completely disagree*) to 7 (*I fully agree*).

Adverse Events

While the trial was conducted, no severe adverse event or adverse event was linked to the intervention in either group; nevertheless, we had to report adverse events as the clinical trial was conducted amid the COVID-19 pandemic in 2020 and 2021. Owing to the general incidence of infections in Germany, 4 patients included in the trial were infected with SARS-CoV-2 and were isolated and excluded from the study.

Survey Completion

Of the patients who completed the study, 97% (41/42) of the participants completed all the questionnaires and tests, with only occasional missing items or tests. This might be explained by the fact that all surveys were conducted in the presence of a therapist or neuropsychologist working and trained in the clinic.

Cognitive Tests

To evaluate the impact of both treatments on cognitive status, subjective health, and quality of life, we used *SPSS Statistics* (version 29, IBM) and calculated repeated-measures ANOVA. For the comparisons between the 2 groups between the pre- and posttest, repeated-measures ANOVA and Bonferroni post hoc test indicated that TL-D scores significantly differed in the VR group after the intervention (P=.046). Table 4 presents the results of all other conducted tests. As a nonsignificant trend emerged in the TMT A (main effect: P=.01; time by group interaction: P=.09) and WMS-R (main effect: P=.006; time by group interaction: P=.18) results, a post hoc test was also performed. No further post hoc tests were performed for the other variables.

Table 4. Clinical parameters of the virtual reality (VR) and computerized cognitive training groups before and after the intervention.

Measure and time point	Control group[a] (n=21)	VR group[b] (n=21)
TMT[c] A scores, mean (SD; range)[d]		
Pretreatment	93.7 (47.83; 36-205)	80.95 (47.84; 39-200)
Posttreatment	89.95 (55.2; 26-257)	61 (22.87; 32-135)
TMT B scores, mean (SD; range)[e]		
Pretreatment	326.9 (216.7; 91-853)	292.24 (244.26; 96-1056)
Posttreatment	283.75 (198.86; 64-877)	268.29 (217.6; 99-855)
WMS-R[f], mean (SD; range)[g]		
Pretreatment	39.6 (29.23; 0-98)	41.9 (34.99; 0-98)
Posttreatment	44.75 (31.24; 0-88)	55.95 (30.29; 0-98)
TL-D[h] scores, mean (SD; range)[i]		
Pretreatment	54.9 (31; 3-99)	42.62 (32.1; 1-99)
Posttreatment	52.2 (33.7; 2-99)	73.1 (32.5; 7-99)
EQ-5D VAS[j] scores, mean (SD; range)[k]		
Pretreatment	45.5 (21.55; 0-80)	49.05 (17.22; 0-75)
Posttreatment	46.84 (25.01; 0-80)	62.86 (21.3; 10-95)
AKT[l] scores, mean (SD; range)[m]		
Pretreatment	87.47 (62.98; 32-281)	89.23 (69.57; 28-357)
Posttreatment	93.15 (67.83; 33-351)	87.86 (69.56; 35-350)
SF-36[n] energy domain, mean (SD; range)[o]		
Pretreatment	42.83 (20.47; 0-80)	42.38 (20.77; 5-80)
Posttreatment	51.32 (20.27; 15-90)	47.86 (21.3; 10-85)
SF-36 emotional well-being domain, mean (SD; range)		
Pretreatment	55.15 (22.65; 0-88)	64.24 (23.94; 16-100)
Posttreatment	64.63 (17.55; 32-100)	66.1 (22.36; 24-100)
SF-36 social functioning domain, mean (SD; range)		
Pretreatment	36.87 (26.74; 0-100)	50.6 (31.99; 0-100)
Posttreatment	48.13 (28.76; 0-100)	54.17 (34.08; 0-100)
SF-36 pain domain, mean (SD; range)		
Pretreatment	51.75 (34.57; 0-100)	63.88 (34.6; 0-100)
Posttreatment	59.38 (30.27; 20-100)	60.48 (33.3; 0-100)
SF-36 general health domain, mean (SD; range)		
Pretreatment	47.5 (14.2; 25-75)	46.85 (13.82; 10-70)
Posttreatment	48.25 (16.8; 10-90)	48.57 (16.52; 20-90)
SF-36 physical functioning domain, mean (SD; range)		
Pretreatment	29.75 (30.46; 0-100)	20.77 (20.07; 0-66.7)
Posttreatment	27.89 (21.99; 0-65)	36.43 (29.33; 0-95)
SF-36 role limitation physical health domain, mean (SD; range)		
Pretreatment	22.37 (36.22; 0-100)	13.49 (30.44; 0-100)
Posttreatment	21.25 (35.61; 0-100)	15 (31.83; 0-100)
SF-36 role limitation emotional problems, mean (SD; range)		

Measure and time point	Control group[a] (n=21)	VR group[b] (n=21)
Pretreatment	35.09 (45.1; 0-100)	31.66 (43.9; 0-100)
Posttreatment	45.33 (49.68; 0-100)	42.86 (48.47; 0-100)

[a]Control group using computerized cognitive training.

[b]VR group using immersive VR cognitive training.

[c]TMT: Trail Making Test.

[d]Repeated-measures ANOVA: no significant interaction detected (P=.09).

[e]Repeated-measures ANOVA: no significant interaction detected (P=.68).

[f]WMS-R: Wechsler Memory Scale—Revised.

[g]Repeated measures analysis of variance: no significant interaction detected (P=.18).

[h]TL-D: Tower of London.

[i]Repeated-measures ANOVA: time, $F_{1,39}$=4.255; P=.046 (significant); time × group, $F_{1,39}$=6.07; P=.02 (significant). A Bonferroni post hoc test was significant between the VR group at pretest and the VR group at posttest (P_{bonf}=.02; η^2=0.135).

[j]VAS: visual analog scale.

[k]Repeated-measures ANOVA: no significant interaction detected (P=.16).

[l]AKT: Alters-Konzentrations-Test.

[m]Repeated-measures ANOVA: no significant interaction detected (P=.52).

[n]SF-36: Short Form 36.

[o]Repeated-measures ANOVA: no significant interaction detected (P_{pain}=.28; P_{energy}=.69; P_{emo_wb}=.31; P_{soc_func}=.59; P_{gen_health}=.87; P_{phys_func}=.06; $P_{role\_lim\_phys}$=.88; $P_{role\_lim\_emo}$=.69).

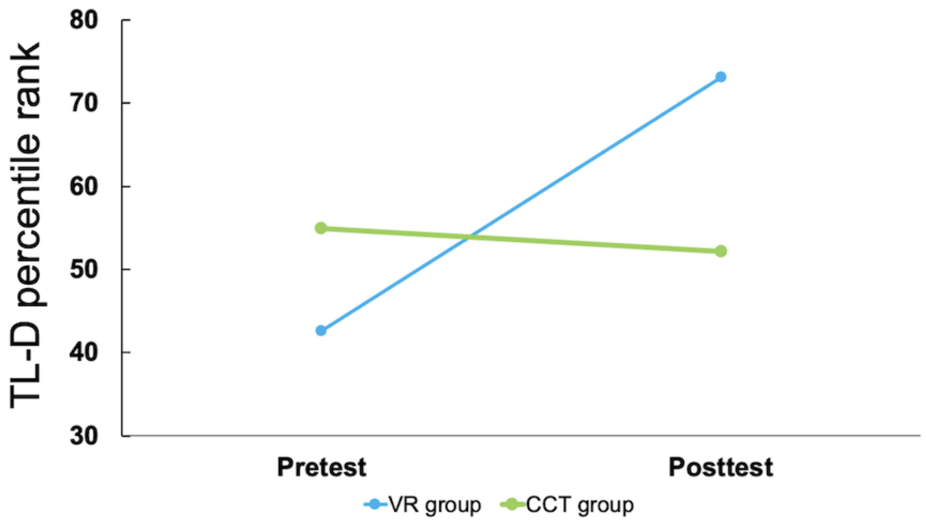
PANAS Trial

Patients were asked to describe their affects on the allocated treatment after 7 sessions of trial participation. Affect was measured with the German version of PANAS, and patients were asked to rate their affect immediately after treatment. An ANOVA was performed, resulting in $F_{1,36}$=0.879 (P=.63) for the positive affect scale and $F_{1,36}$=0.954 (P=.57) for the negative affect scale. The test results showed no difference between the intervention and control groups regarding positive and negative affect toward the kind of treatment received by both groups during the trial. Both groups reported high positive affect, with the VR group at mean 29.809 (SD 7.98) and the control group at mean 25.6 (SD 8.23), showing a slightly higher positive affect in favor of the VR group. Negative affect results were rated mean 15.95 (SD 8.59) in the VR group and mean 15.66 (SD 6.18) in the control group, showing similar negative affect ratings in both groups.

Summary

The critical effects for both groups are presented in Table 4, showing mean changes between t_0 and t_1 and the results of repeated-measures ANOVA for group effects. Figure 4 shows the mean changes for TL-D results in both groups.

Figure 4. Results of repeated measures analysis of variance Tower of London—German version (TL-D). CCT: computerized cognitive training; VR: virtual reality.



Discussion

Overview

To our knowledge, this is one of the few trials comparing immersive VR cognitive training, incorporating ADL and SG and focusing on the ability to perform ADL, with a multitude of cognitive domains and not single domains only, with CCT. In this randomized controlled trial, we aimed to determine the impact of both cognitive training in immersive VR and CCT on cognition and the ability to perform ADL in patients in inpatient neurological rehabilitation with an MMST score >20 in rehabilitation phases C and D, combining immersive VR with paradigms of neuropsychology and occupational therapy. In the patient group receiving VR therapy, we found a statistically significant improvement in executive functioning within the 4-week treatment interval. Some nonsignificant trends were detected for attention and processing speed, working memory, and subjective health. No significant changes were observed in the control group.

In recent years, VR systems found their way to neurological rehabilitation. However, being used most often for motor rehabilitation, only a few systems have been developed and evaluated concerning their impact on cognition in patients with acute brain affection. Furthermore, some developed trainings have only been used for research purposes but have yet to undergo more extensive testing or application in clinical practice. In addition, several cognitive trainings in VR were developed to target a specific cognitive domain, for example, memory [38] and attention [39].

Principal Findings

We compared the VR group with a control group using CCT, which represents care as usual in German rehabilitation facilities. Both groups were able to engage in their assigned interventions successfully. Despite our initial concerns regarding the number of sessions to be conducted in VR, no significant side effects were reported. All patients participated in all sessions required to complete the trial. Some initial hurdles had to be overcome, for example, mainly introducing older adult patients to an entirely new technology or ensuring continuous disinfection of all equipment, as the trial took place at a time when the COVID-19 pandemic situation in Germany was very tense. However, after the first treatment session, those problems were solved without further external intervention. Overall, the acceptance and usability of both technologies were observably high, which, in terms of the VR experience, is congruent with the results of our feasibility study using an earlier version of the software used in this trial [16].

The demographics between the 2 groups were similar: not significantly different in age and pathology but with a larger proportion of male participants in the trial. The trial's sample size was too small to make far-reaching statements, but clear tendencies provided the first indication of training effects that opened up room for further research in a larger trial.

We detected the effects of immersive VR on different cognitive functions in patients with acute brain affection receiving treatment during inpatient neurological rehabilitation. Comparing both groups by calculating repeated-measures ANOVA, we detected improvements in some cognitive domains in the VR group but no significant improvement in any cognitive function in the control group. By conducting the TL-D, specifically assessing problem-solving and planning, we found significant improvements from pre- to postintervention phase in the VR group, and the Bonferroni post hoc test also verified these significant improvements with a medium-sized effect of η^2=0.135. Oliveira et al [40] conducted a trial to investigate the impact of VR on ADL in stroke rehabilitation. They found that VR training resulted in better tests measuring EF, global cognition, attention, and memory training. This partly overlaps with the results of this study. We also observed improvements in attention, processing speed, and subjective health status in the VR group. However, these did not become significant in the repeated-measures ANOVA, while the scores for the named variables persisted at the t_0-level after the treatment in the control group. No significant improvements and differences between groups were detected in concentration and memory in both groups.

The improvements in subjective health state are of interest for further research, as Domínguez-Tellez et al [41] ascertained in their systematic review that VR interventions for upper limb rehabilitation were a part of improving quality of life. They hypothesized that an improvement in the actual pathology leads to better abilities for carrying out ADL, and an improvement in quality of life goes hand in hand with a higher grade of participation. The higher levels of subjective health state in the VR group (mean 62.86, SD 21.03) compared with the control group (mean 46.84, SD 25.01) after the intervention, with an improvement on the EQ-5D VAS-scale of 13.81 points in the VR group and 1.34 points in the control group between t_0 and t_1, although not significantly different, showed a tendency toward the impact of VR treatment when considering the significant improvement in TL-D scores in the VR group and the resulting implications for participation in daily life. More thorough research is necessary to better understand the interrelationship between these constructs and the results of the SF-36 subscales.

Looking at the results the VR group achieved in planning and problem-solving (TL-D), we would have expected to notice a significant difference in TMT results as well, as both tests are positively correlated [42]. TMT specifically measures cognitive flexibility, alternating attention, sequencing, visual search, and motor speed, which overlap with the measured domains of TL-D, predominantly measuring planning and problem-solving. The missing significant improvement in the abilities measured by TMT in this trial raises the question of how specifically the VR training stimulates particular cognitive skills. We still see a tendency for improvement in these cognitive abilities, as the VR group achieved more improvement between t_0 and t_1 than the control group, as measured by TMT A. We found a nonsignificant trend in the repeated-measures ANOVA (P=.09). As we expected a correlation between TL-D and TMT results, we calculated a Bonferroni post hoc test, which resulted in a significant improvement in the VR group (Bonferroni P=.02). This is only a trend, which cannot be used to draw far-reaching conclusions. Nevertheless, it is interesting, as this might correlate with the significant improvement in TL-D measures in the same group. Nevertheless, it would be interesting to investigate in a larger trial if an optimized version of the training software leads to more diversified and measurable effects.

In addition, other studies cited in this paper have reported further improvements in multiple cognitive subdomains. In our study, significant improvements were found only in the EF. One explanation for the difference in results is that both groups received only 1 therapy to treat cognitive dysfunction rather than simply augmenting the existing treatment. A 2017 Cochrane Review found that in many studies, VR therapy was added to traditional treatment, resulting in a higher total amount of therapy [43]. Therefore, it cannot be said with certainty whether VR therapy alone is causal for the improvement in these studies or whether the overall increased measure of treatment compared with the control group is the determining factor. The fact that each group in our study received only 1 cognitive rehabilitation treatment means that the effects can be more precisely attributed to a single treatment method.

When developing the software used in collaboration with occupational therapists, neuropsychologists, neurologists, and patients, we were particularly faced with the lack of proximity to daily life of current CCT, which led us to the question of how we could depict everyday life and its challenges in a way that is easy to understand, therapeutically beneficial, and motivating, so that patients could adhere to training over a more extended period. The results showed the VR training used in this trial. The following components have played a significant role in its development and could provide a directional indicator for further development of new training methods for cognitive rehabilitation.

The results of this trial helped us formulate hypotheses on why VR-based training might lead to better results in cognitive rehabilitation than PC-based interventions:

Ecological Validity

In rehabilitation, particularly when focusing on returning to daily life, it is vital to have ecologically valid training simulations, for which VR is well suited [40,44]. In our application, we presented a garden and kitchen scenario to simulate activities and situations in which subjects found themselves after rehabilitation. In reality, as it is either dangerous or unavailable, it is often not viable to let patients train in real-life settings. VR enables stimulation with settings as close as possible to reality, potentially facilitating a more effortless transfer from training to reality.

The results of this trial indicate that high ecological validity is beneficial for training cognition. Patients in the VR group achieved significantly higher scores in planning and problem-solving than their counterparts in the control group. In addition, they reported better scores in terms of speed and health status than the conventionally treated patients. This is congruent with the results of Faria et al [21], who examined the benefits of immersive ADL simulation in neurological rehabilitation [21].

Gamification and Immersion

Gamification adds games or game-like elements to encourage participation or engagement. Engagement is a crucial component of rehabilitation; in patients with stroke, it increases the rate of rehabilitation and rehabilitation outcomes of survivors of stroke [45]. The VR experience relies to a great extent on the grade of immersion. Immersion describes the effect of a virtual environment that causes the user's awareness of being exposed to illusory stimuli to fade into the background to such an extent that the virtual world is perceived as real. High-grade immersion can be created using HMD-VR. The user wears device-like goggles on the head over the eyes, effectively masking the actual environment.

Combining these 2 aspects and adding up the feature of receiving immediate feedback from the virtual environment on performance leads to increased motivation and, subsequently, patients stuck with the treatment longer [43]. Yoshida et al [46] discussed motivation in patients with subacute stroke and discovered that it is mainly influenced by extrinsic reward factors (eg, positive feedback provided by therapists). However, if basic psychological needs are met, for example, autonomy or competence, which play a critical role in stroke rehabilitation, the motivation pattern switches from extrinsic to intrinsic [46]. Long after an acute event, improvements in rehabilitation can still be achieved, and patients' self-perception regarding the improvements is paramount.

On the Right Dosage

Participants in this trial received a treatment dosage of 18.7 sessions over 4 to 6 weeks, each lasting 30 minutes (9.35 hours per participant). Other trials reported an average intervention duration of 13.3 hours [39,40,47-50], ranging from 4 to 24 hours, with a session duration of 30 to 60 minutes, 3 to 5 times a week. Our dosing was sufficient to achieve a measurable effect in some domains and was also oriented toward the care reality in German rehabilitation hospitals. To attain more significant outcomes in multiple domains, it would be interesting to see if other training tasks in immersive VR create an effect on cognition and if a varying number of treatment sessions beyond inpatient care leads to different results than those reported here. On the basis of the results of this trial, we conclude that 18 to 19 sessions over 30 minutes are sufficient to achieve a measurable treatment effect. Still, we cannot determine whether fewer sessions would create similar effects if more treatment automatically leads to more significant outcomes and if those effects vary between patient groups. More extensive trials with blinding, subgroups, and longer treatment duration are necessary to answer this question.

Transfer to Daily Life and How to Measure it

One end point of this trial, which we were not able to meet, was to identify whether the treatments in both groups induced transfer effects on daily life by examining if patients in either group were in a better state to perform instrumental ADL, such as preparing food or handling the washing machine, after the intervention. While designing this trial, we noted that standardized neuropsychological testing batteries are well suited to test particular cognitive domains and performance therein, but that daily life is more complex—it can not be reduced to 1 or 2 cognitive processes at the same time—and that functional capabilities of managing everyday life as the end goal of rehabilitation are not sufficiently represented by those testing batteries when focusing on cognitive rehabilitation [40]. Therefore, we developed a testing tool, FEPVR. It was used for the first time in this trial, and we faced some issues with properly capturing the ADL. We plan to publish the battery and its manual in a revised version, including experiences from use in this trial so that further development and testing by other research groups is possible.

Limitations

Although this study provides valuable insights into the impact of immersive VR on cognitive rehabilitation, several questions remain unanswered. Specifically, we identified the following limitations that should be considered: future research in this field should be conducted with larger sample groups. This randomized controlled pilot study builds a profound understanding of the potential immersive VR can have in neurological rehabilitation for cognitive impairment in patients with MMST scores >20, affected by stroke, to the largest extent. Conclusions cannot be drawn for patients below this cut-off score. We also need more information on the manifestation of training effects, for example, if the measured results are still the same 6 to 12 months after the intervention and if an actual transfer effect to ADL occurs. Therefore, long-term studies with follow-up over multiple years are necessary.

The applied VR environment was limited to only 2 training scenarios inspired by ADL. More training scenarios replicating other ADL should be developed and tested in future studies.

Even though there are findings about the application of VR in rehabilitation of other patient groups, for example, multiple sclerosis, psychiatric disorders, and pain management [51], the application used here has chiefly been tested in the rehabilitation of patients with acute brain affection. Therefore, the evaluation needs to consider patients from the abovementioned groups to draw further conclusions in other patient groups.

Conclusions and Outlook

Our group of psychologists, software developers, 3D artists, neurologists, and occupational therapists has developed a new form of immersive VR-based cognitive rehabilitation training. After proving the feasibility and acceptability in stroke patients with stroke, we demonstrated the initial therapeutic effects of a novel immersive VR training on EF in patients undergoing inpatient neurological rehabilitation. Data were collected over 18 months, including multiple recruitment pauses due to the COVID-19 pandemic between 2020 and 2022. The supervision of patients was necessary for conducting treatment, but it was administered by trained therapy assistants, freeing time for neuropsychologists and occupational therapists. None of the patients in the VR group had previously been exposed to VR, but that did not diminish their excitement about receiving the experimental treatment and getting the most out of it.

It was reported earlier that combining cognitive training with physical activity leads to even better results; for example, a group of older adults with mild cognitive impairment showed more significant improvements in multiple cognitive domains when receiving combined therapy than physical or cognitive training alone [52]. Investigating whether the treatment effects of VR-based cognitive training can be increased by additional full-body physical training would be an interesting research topic for future trials. We also intend to depict everyday life in VR even more with new training scenarios, a higher level of gamification, and using techniques to personalize the treatment itself to a greater extent.

Our goal is to ensure that treatments in neurorehabilitation are improved and that all parties involved profit from new developments. The excellent acceptance, low side effects, and initial therapeutic effects of immersive VR treatment presented here offer new therapeutic options, for example, applying SG in routine therapy [53]. The results of this pilot trial show that a short but intense period of treatment leads to measurable improvement in EF, a manifold construct consisting of behavioral and higher-order cognitive skills necessary for independent functioning and carrying out everyday life, such as shopping, managing money, and preparing meals [3,8]. It would be interesting to determine if these results can be extended if patients continue treatment at home and increase the overall number of treatment sessions.

Temehy et al [4] explored the needs of patients with stroke after discharge from rehabilitation; they discovered that patients often not only need physical rehabilitation but also psychological services, comprising cognitive rehabilitation. Shipley et al [54] cite a patient who says, “it should have been a formal process to gain access to a psychologist, and it would have been beneficial from an earlier time point, such as from the acute hospital.” Access to qualified and trained neuropsychologists in Germany is difficult, as the *Gemeinsamer Bundesausschuss* (Federal Joint Committee) states that only 1100 neuropsychologists in outpatient care are available. The 2019 German Society for Neuropsychology list contains even fewer specialists with only 350 practitioners in outpatient settings [55]. This shortcoming highlights the need for complementary treatment approaches. This is in line with what the COVID-19 pandemic has uncovered: the need for digitized rehabilitation tools, bringing the general problem of accessibility of rehabilitation services to center, for example, for people living in rural areas or simply an insufficient number of neuropsychologists or occupational therapists in Germany, which prevents the actual implementation of necessary aftercare in neurological rehabilitation with a regular high number of treatment sessions for manifesting rehabilitation progress. Further development of video game–based rehabilitation approaches with digitized platforms to bring care home should be the focus of other groups active in this field, which is also emphasized by Ong et al [56] and Salisbury et al [57], who stated that VR is a promising technology to foster home care and shorten hospitalization. As prices for HMD-VR devices continuously decrease and the acceptance of digitized treatments in Germany increases, it augments the chance that access to VR-assisted rehabilitation will become more accessible and a standard in a wide range of treatment settings.

Acknowledgments

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Data Availability

The data sets generated during this study are available from the corresponding author only upon reasonable request.

Conflicts of Interest

This work was partially funded by the medical device manufacturer Living Brain GmbH, Heidelberg, Germany, who developed the used virtual reality software. The coauthors of this publication, BS and JS, are cofounders of Living Brain. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Greenhouse screenshot 1.
[PNG File , 691 KB - games_v11i1e45816_app1.png]

Multimedia Appendix 2
Greenhouse screenshot 2.
[PNG File , 3493 KB - games_v11i1e45816_app2.png]

Multimedia Appendix 3
Kitchen 1.
[PNG File , 489 KB - games_v11i1e45816_app3.png]

Multimedia Appendix 4
Small kitchen lobby.
[PNG File , 948 KB - games_v11i1e45816_app4.png]

Multimedia Appendix 5
CONSORT-EHEALTH checklist (V. 1.6.1).
[PDF File (Adobe PDF File), 1375 KB - games_v11i1e45816_app5.pdf]

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Abbreviations

ADL: activities of daily living
AKT: Alters-Konzentrations-Test
CCT: computerized cognitive training
CONSORT: Consolidated Standards of Reporting Trials
EF: executive functions
FEPVR: Fragebogen zur Erfassung der Performance in VR
HMD: head-mounted display
MMST: Mini Mental Status Test
PANAS: Positive and Negative Affect Schedule
SF-36: Short Form 36
SG: serious game
TL-D: Tower of London—German version
TMT: Trail Making Test
VAS: visual analog scale
VR: virtual reality
WMS-R: Wechsler Memory Scale—Revised

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Original Paper

Design Preferences for a Serious Game–Based Cognitive Assessment of Older Adults in Prison: Thematic Analysis

Rhys Mantell[1], MPH; Adrienne Withall[1,2,3], PhD; Kylie Radford[2,3,4], PhD; Michael Kasumovic[5,6], PhD; Lauren Monds[7], PhD; Ye In Jane Hwang[1,2], PhD

[1]School of Population Health, University of New South Wales, Sydney, Australia
[2]Ageing Futures Institute, University of New South Wales, Sydney, Australia
[3]School of Psychology, University of New South Wales, Sydney, Australia
[4]Neuroscience Research Australia, Sydney, Australia
[5]School of Biological, Earth & Environmental Sciences, University of New South Wales, Sydney, Australia
[6]Arludo, Sydney, Australia
[7]Addiction Medicine, Central Clinical School, The University of Sydney, Sydney, Australia

Corresponding Author:
Rhys Mantell, MPH
School of Population Health
University of New South Wales
Samuels Building, F25, Samuel Terry Avenue, Kensington
Sydney, 2052
Australia
Phone: 61 0427161651
Email: r.mantell@unsw.edu.au

Abstract

Background: Serious games have the potential to transform the field of cognitive assessment. The use of serious game–based cognitive assessments in prison environments is particularly exciting. This is because interventions are urgently needed to address the rapid increase in the number of currently incarcerated older adults globally and because of the heightened risks of dementia and cognitive decline present in this population. Game-based assessments are assumed to be fun, engaging, and suitable alternatives to traditional cognitive testing, but these assumptions remain mostly untested in older adults. This is especially true for older adults in prison, whose preferences and needs are seldom heard and may deviate from those previously captured in studies on cognition and serious games.

Objective: This study aimed to understand the design preferences of older adults in prison for a game-based cognitive assessment.

Methods: This study used reflexive thematic analysis, underpinned by critical realism, and applied the technique of abduction. Overall, 4 focus groups with a total of 20 participants were conducted with older adults (aged ≥50 years; aged ≥45 years for Aboriginal and Torres Strait Islander people) across 3 distinct prison environments in Australia.

Results: Self-determination theory was used as a theoretical foundation to interpret the results. Overall, 3 themes were generated: *Goldilocks*—getting gameplay difficulty *just right* through optimal challenge (the first theme emphasizes the participants' collective desire for an individualized optimal level of difficulty in serious gameplay), *Avoiding Childish Graphics*—gimmicky gameplay can be condescending (the second theme raises the importance of avoiding immature and childlike gameplay features, as some older end users in prison felt that these can be condescending), and *A Balanced Diet*—meaningful choice and variety keeps game-based assessments fun (the third theme highlights the strong user preference for meaningful choice and variety in any serious game–based cognitive assessment to maximize in-game autonomy).

Conclusions: The collection of these themes provides novel insights into key game design preferences of marginalized older adults.

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KEYWORDS

serious game; gamification; cognitive assessment; prison; older adults; older prisoners; game design; self-determination theory

Introduction

Assessing Cognition Through Serious Games

Gamification stands as one of the most promising solutions to enhance the user experience of traditionally monotonous tasks [1]. The process of gamification includes applying game design elements such as challenges, scoring, graphics, and narratives to nongame environments (eg, psychometric testing) to increase engagement and motivation [2]. When gamified tasks are embedded into an immersive user experience, they are typically referred to as *serious* games. Serious games present users with unique and exciting environments to complete objectives that go beyond entertainment [3]. An emerging area of research is the study of serious games for cognitive assessment. Although there are well-evidenced benefits of using traditional cognitive assessment tools (proven psychometric validity, high sensitivity to neurological disease, etc) [4-6], they are often seen as boring and repetitive by users [7]. This can reduce task engagement [2] and affect the reliability of the performance data collected [1,8]. People also report test anxiety and self-stigma regarding low literacy or education levels when performing traditional cognitive tests [9-12]. In addition, there is evidence that some widely used neuropsychological tests are not culturally safe [13-15].

Serious games have the potential to transform the field of cognitive assessment. Game-based assessments appear to be suitable alternatives to traditional tasks given their potential to improve motivation and enjoyment and support individuals to produce their best effort, without making them feel overly bored, anxious, or distracted [1,16]. Recent studies have indicated that the experience of playing digital cognitive games was perceived as less stressful, more interesting, and more enjoyable when compared with standard cognitive tasks [2,3]. Serious games can also offer a brief, cost-effective, and scalable substitute for more traditional assessment methods [8,17]. In addition, serious games might support more ecologically valid assessment through realistic context and gameplay by engaging cognitive processes in a way that is more similar to a real-life situation [18].

Although the user benefits of enhanced motivation, engagement, and enjoyment are promising, they are not automatically derived through gamification. In recent years, some gamified cognitive assessments have assumed that, because something is presented as a game, it is fun. In a systematic review (conducted in 2021) of game-based cognitive assessments [1], less than half of the games included in the study evaluated any aspect of gameplay or user preference. Furthermore, although many studies have reported the positive effects of serious games on enjoyment [8], additional findings suggest that some games do not increase engagement, with Birk et al [19] concluding that their gamification actually reduced task engagement when compared with a traditional task. These findings suggest that serious games that assume user enjoyment and engagement overlook the complexity of end-user preferences. Poorly designed and executed serious games can be expensive and ineffectual and are unlikely to result in a more enjoyable and motivating experience than traditional tasks [1,16,19,20]. If games are to be used as cognitive assessment tools, they must first be designed with the end user's enjoyment and motivation in mind. Furthermore, ensuring that a game-based assessment is culturally safe to play is critical [21]. This means acknowledging the context in which a serious game will be played by a user and ensuring a relevant level of sensitivity to the distinct backgrounds, beliefs, and experiences of target users [21]. These are essential steps in justifying the use of a serious game, especially in the context of cognitive assessment.

The Cognitive Health of Older Adults in Prison

There has been a rapid increase in the number of people aging in prisons across the world in the last decade [22]. One area of particular concern for older adults in prison is age-related cognitive decline. There is evidence indicating that cognitive deficits are considerably underdetected in prison environments [23], and when they are detected, they are often managed informally or inadequately [24,25]. Studies on cognitive impairment in Australia, France, and the United Kingdom reported high levels of potential cognitive decline, with impairment rates of 15.3% (Australia) [26], 19% (France) [27], and 13% (the United Kingdom) [28] found in samples of people aged ≥50 years (≥45 years for Australian Aboriginal and Torres Strait Islander people) in prison.

Cognitive impairments lead to poor outcomes for older adults in the criminal justice system [23,29] and those transitioning out of prison [30]. Unidentified cognitive impairment can hamper a person's ability to navigate the prison system and reduce their capacity to access (and routinely engage with) health and aged care services during incarceration and after being released from prison [31]. People with cognitive impairment are also prone to manipulation and coercion in prison, including physical and sexual trauma, peer pressure, and victimization [32]. People with cognitive impairments in prison can also have their symptoms perceived by staff and peers as purposefully obstructive or combative, resulting in punishment [33,34]. In addition, after being released from prison, people who have substantial cognitive impairments are less likely to adapt to *life on the outside* without appropriate support [24,25], resulting in increased risks of recidivism, homelessness, and hospitalization [30].

Although prison staff view early screening and diagnosis of dementia as a priority area for prison dementia care reforms [23,29,35], there still exists very limited cognitive assessment of older adults in prison, often because it is resource intensive. The use of a serious game for cognitive screening in prison appears to be a potential solution to the growing need for an effective and affordable cognitive assessment to support older adults in prison presenting with or at risk of cognitive deficits.

Conceptualizing Motivation to Play Games in Prison Using Self-determination Theory

If gamification promises to enhance user motivation to undertake cognitive assessment, but gamification does not always fulfill this promise, then a way to understand what increases (or decreases) a person's motivation is necessary. A prominent theory used to understand a person's motivation is self-determination theory (SDT). In SDT, the basic needs that ought to be satisfied to produce motivation, enjoyment, and overall well-being are competence (ie, experiencing mastery over challenges), autonomy (ie, doing something owing to an individual's own volition), and relatedness (ie, experiencing meaningful social relations). In addition to helping researchers understand motivation generally, SDT has also been applied specifically to understand the motivation to play digital games [36-38]. The theory has been useful in explaining how game features relate to basic psychological needs and thus how game design and development decisions can increase (or decrease) user motivation and enjoyment [39]. Games have been shown to directly enhance motivation through features and gameplay [38].

In the video game context, competence refers to being challenged at the optimal level. For instance, a player will experience low competence if the challenges are very great (eg, game controls are difficult to use or enemies are very numerous) [37]. Autonomy may include the feeling of free choice to play a desired game and make choices within the game (eg, choosing which level to complete). Autonomy may also be satisfied when a user can design their own playable character and feel empowered to do things that they cannot do in real life. Relatedness can be achieved by playing with others, either in person or via the web [36]. Relatedness or a sense of belonging or connection can be satisfied by achieving team goals (eg, defeating the enemy together) or through healthy competition (eg, racing each other in Mario Kart).

SDT is a helpful framework to understand the motivation to play a serious game–based cognitive assessment in prison. Specifically, it provides a theoretical foundation to understand a specific user group's fundamental psychological needs [40-42] and map these needs to tailored game design preferences [37,38]. In doing so, it ensures that a game is designed appropriately with the end user's enjoyment, motivation, and well-being in mind [39]. Using SDT to query game design preferences and acceptability is an important exercise capable of expanding knowledge about desired user preferences for a serious game in prison.

Objectives of This Study

A critical first and ongoing step in developing suitable game-based assessment is to collaborate with the target population for whom the intervention is intended [43-45]. This point is especially important for older adults in prison whose preferences, values, and needs may deviate from those previously captured in studies on cognition and game design [46,47]. It is essential to capture and embed end-user input into game design and development to produce a game that is relevant to and compatible with the lives of older adults who are in prison.

Thus, the purpose of this qualitative thematic analysis was to understand the design preferences for a cognitive game-based assessment for older adults in prison, in the context of the prison environment and future transition back to community. Using the theoretical framework provided by SDT, the user design preferences for and user acceptability of a serious game–based assessment can be hopefully understood in a way that is useful for game designers to develop a cognitive assessment that is motivating, culturally suitable, nonthreatening, and enjoyable.

Methods

Philosophical Approach

This qualitative study was informed by a critical realist philosophy [48-51]. Critical realism broadly assumes that there are things that have a real, objective existence *out there* (ie, an independent world exists beyond our own constructions). However, critical realism appreciates that knowledge is fallible; our understanding of the world is based on and filtered through our own personalized interpretations [52]. Thus, critical realism makes an important distinction between epistemological and ontological assumptions. That is, ontology (ie, what is real and the nature of reality) is not reducible to epistemology (ie, our knowledge of reality) [48]. In other words, the critical realist approach combines realist ontology with constructivist epistemology [52]. After assuming this position, we can make ontological distinctions between our unique experiences and observations of events, the actual events themselves (which can be different from our experience of them), and the underlying mechanisms or structures that produce events [53]. Once we perceive reality in this way, we are open to exploring and explaining social events through reference to these mechanisms and structures and their effects.

Using the philosophical position of critical realism for this study has 2 major benefits. First, the deeply individual and subjective game preferences of older adults in prison can be interpreted empirically. Such an exercise can (and should) have direct input into game design considerations regarding the features, preferences, and esthetics of the game development process. Second, a more theoretical and critical analysis of participants' observations and how the underlying mechanisms and structures may explain game preferences (and motivation for game-based cognitive assessments) can be undertaken. This second type of analysis is necessary to explore latent themes that may influence the success of a serious game–based intervention in the context of this complex population [54,55]. Considering both empirical observations and underlying mechanisms, simultaneously, and how they interact is critical to adequately design, develop, and deliver a game-based cognitive assessment for this marginalized population.

Sampling and Recruitment

Purposive sampling was used to produce representation across age, sex, and security level. Correctional staff identified and recruited potential participants after guidance from researchers to identify any older adults in prison, that is, aged ≥50 years (or ≥45 years for Aboriginal and Torres Strait Islander people). Aboriginal and Torres Strait Islander people are the Indigenous people of Australia, and relatively young ages are typically used in health, aged care, and policy settings to define *older adults* in this population, owing to population-level disparities in morbidity and mortality. Suitable participants were known to corrective staff through their day-to-day operations. Staff oversampled those who were potentially eligible for the study and shared the study information (study flyers and consent forms) with them. Consent forms were signed by participants in front of the prison staff. Potential participants were allowed to ask any clarifying questions to staff. After the consent forms were signed, these were sent back to the research team for confirmation of informed consent.

We are sympathetic with the criticism by Braun and Clarke [56] about saturation as a useful concept in reflexive thematic analysis underpinned by constructionist epistemology. As such, we do not discuss our sample in terms of saturation. However, given our commitments to critical realist ontology, it is important to confirm the sufficiency of our sample in terms of information power [57] to support validity claims [52]. Thus, according to the criteria stipulated by Malterud et al [57], our sample size of 20 participants across 4 focus groups (FGs) was deemed sufficiently powerful given the (1) applied aim of the study, (2) sample specificity, (3) use of established theory (eg, SDT), (4) high quality of dialogue, and (5) comprehensive analysis strategy. As is standard, participants received AUD $15 (US $10.05) for lost work time. Funds were deposited into the inmates' *buy-up* account.

Ethics Approval

Human research ethics approval was obtained from Corrective Services New South Wales Ethics Committee (D20/1014950), the University of New South Wales Human Research Ethics Committee (HC210546), Justice Health and Forensic Mental Health Network Human Research Ethics Committee (2021/ETH11114), and The Aboriginal Health and Medical Research Council (1873/21) before the commencement of the study.

Procedure

FG Approach and Schedule

We conducted 4 FGs, all of which were between 60 and 120 minutes long. All FGs were completed using internet-based audio-visual technology owing to the COVID-19 protocols. Sessions were led by the second author (AW), a neuropsychologist, and supported by RM and JH. FG questions were semistructured, and all 4 sessions followed a similar interview schedule. We were interested in game interventions but also more broadly in understanding people's interaction with prison and past health services and their personal experiences with these services. After the objective of our study was discussed with participants, we showed a serious game demonstration (Graze Invaders; designed by AW, LM, and MK). This was used to provide a grounded example of what a serious game–based cognitive assessment might look like, in turn, setting some parameters for targeted design while still enabling participants to be open and creative [58] (refer to the study by Povey et al [21] for similar approach). After the general discussion about health and the demonstration, we asked targeted questions about what people thought about the serious game and then asked them to provide their general preferences for games and scrutinize the suitability (eg, logistically) of a game-based cognitive assessment in prison.

Example questions include the following:

1. Do you remember ever being asked questions about your memory or thinking while you have been in prison?
2. Have you ever had a memory or thinking test before coming to prison, maybe from a psychologist?
3. Before entering prison, did you ever use a computer or tablet?
4. Did you ever use a computer/phone/tablet to play games?
5. What kinds of extra things make you enjoy games more?
6. Do you think there would be any issues with you and other older adults in prisoner using this sort of brain game technology?
7. Is there anything else about using a serious game in prison you might like us to consider?

Data Analysis

This study used reflexive thematic analysis in which the active role of the researcher in producing knowledge is emphasized, with themes conceptualized as meaning-based patterns, rather than summaries of data [59]. Reflexive thematic analysis is compatible with our overarching philosophy of critical realism [60], which can be used to accurately explore the participant's empirical world while engaging with underlying mechanisms and theories that can inform game design and development in the context of prison [44,61]. An abductive analytical approach was adopted to conduct this process. Abduction—also known as theoretical redescription—is a technique whereby empirical data are redescribed using theoretical concepts (in this case, SDT and game design research) [54,62]. Abduction has been defined as a process of "inference or thought operation, implying that a particular phenomenon or event is interpreted from a set of general ideas or concepts" [51]. Abduction raises the level of theoretical engagement beyond detailed description of the empirical entities but with an acknowledgment that the chosen theory is fallible [51]. This enables us to investigate participant observations in the context of latent, theoretical, and underlying mechanisms [51,53], which may be influencing game design preferences and motivations, while also ensuring that user observations and insights are still central to theme generation [56].

The analytical process followed the phases presented by Braun and Clarke [56,59,63]. Specifically, the first author transcribed and reread the interview transcripts and then coded and collated the interesting features of the data. Next, codes were added or updated deductively; that is, we explicitly analyzed our data through the lens of existing theory (namely, SDT). When we were satisfied with our coding, we used an abductive approach to combine and recontextualize existing codes. After coding and collating was completed, themes were drafted. These theory laden themes were analyzed to query any important underlying mechanisms, which may have been influencing the empirical observations. Finally, themes were organized and named in ways to appropriately portray the overall story of analysis. Using the process of abduction, all themes embody both the experiences of end users and relevant theories redescribing these observations in a context relevant to developing game design features [45].

Validity

While generating themes, the rigor and quality of the analysis can be enhanced by considering the types of validity (descriptive, interpretive, and theoretical) by Maxwell [52] and broad indicators of validity such as empirical adequacy, ontological plausibility, and explanatory power [64]. Interviews were transcribed verbatim and then reread to check the accuracy of the transcription by the first author (RM), who also conducted the primary analysis. This addressed the questions regarding descriptive validity. The predetermined group design differences (women vs men; Aboriginal vs non-Aboriginal; and aged 50-64 years vs aged ≥65 years) in the FGs were used to establish consistency and key differences [49] in participant accounts from varied perspectives. The FG questions were partially informed by existing theoretical accounts on serious game design (eg, questions about game design features and typical duration of a game-based assessment); however, given the nature of FG sessions, general and open-ended questions were also asked, which enabled participants to discuss general ideas together and form intragroup consensus organically. The second author (AW) and senior author (JH) acted as *critical friends* [65] to the first author (RM), who provided critical dialogue and challenged the first author's assumptions and explanations of phenomena at all stages of analysis (ie, initial coding, developing themes, and reviewing and naming themes). The use of the *critical friend* approach to thematic analysis underpinned by critical realism was conducted successfully by Goddard et al [44]. Finally, the applied basis for the research objectives (ie, to establish design preferences for an effective game-based assessment) produced clear practical utility [44,64] (this is discussed further in the *Limitations* section).

Results

Overview

Overall, 4 FGs with a total of 20 people were conducted with older adults (aged ≥50 years; aged ≥45 years for Aboriginal and Torres Strait Islander People) across 3 distinct prisons in New South Wales, Australia. Participants' characteristics are presented in Table 1.

Overall, 3 distinct themes were generated. The first theme emphasizes the participants' collective desire for an individually optimal level of difficulty in serious gameplay. The second theme raises the importance of avoiding immature and childlike gameplay features, as they can feel condescending to some older end users. The third theme highlights the strong user preference for meaningful choice and variety in any serious game–based cognitive assessment. According to SDT, the first theme relates to satisfying competence needs, whereas the second theme empathizes the need to avoid competence violations. The final theme is related to satisfying autonomy needs through meaningful choice.

Table 1. Participant characteristics.

Group; security classification and participants	Age (years)	Time served	Identified as Aboriginal	Sex
FG[a] 1; maximum security				
P1	52	<1 year	No	Female
P2	54	<1 year	No	Female
P3	49	<1 year	Yes	Female
P4	51	<1 year	Yes	Female
P5	53	<1 year	No	Female
P6	54	<1 year	No	Female
FG2; maximum security				
P1	49	>1 year	Yes	Male
P2	57	>5 years	Yes	Male
P3	61	>5 years	Yes	Male
P4	63	>10 years	Yes	Male
FG3; maximum security				
P1	66	>20 years	No	Male
P2	47	>1 year	Yes	Male
P3	52	>1 year	No	Male
P4	64	>5 years	No	Male
P5	60	>1 year	No	Male
FG4; minimum/maximum security				
P1	72	>1 year	No	Male
P2	76	>5 years	No	Male
P3	82	>1 year	No	Male
P4	90	>5 years	No	Male
P5	69	>5 years	No	Male

[a]FG: focus group.

Goldilocks—Getting Gameplay Difficulty Just Right Through Optimal Challenge

There was considerable diversity in background, time served, education level, experience with computers and technology, and health status across the FG participants. This contributed to a variety of different expectations and preferences for what a serious game ought to be and the level of complexity that should be incorporated into gameplay.

One of the older men from FG4 felt that a simplified approach would be the most suitable:

> *I was in rehab 40 years ago...A couple of the blokes complained that it was a complicated program for simple people. And it should have been a simple program for complicated people. So, keep it simple stupid.* [Participant 3; FG4]

In contrast, one of the women from FG1, who had plenty of previous experience with games, was interested in a challenging game-based assessment:

> *I'm a games freak! So, yeah, I play...Obviously [it's good if] it gets harder, like to challenge us as you go, as you progress. Yeah, that would be good.* [Participant 2; FG1]

This desire for a challenge through gameplay emerged several times across FG1, FG2, and FG3:

> *You need a challenge to keep people interested.* [Participant 5; FG3]

However, FG4, which consisted of a group of older men (aged ≥65 years) residing in a Frail and Aged Unit, was keen to reiterate that whatever serious game was designed, it was best if it was "probably not too complicated" (participant 1; FG4).

One of the men in FG4 also added the following:

> *If you're happy doing it, I don't think it matters.* [Participant 3; FG4]

This highlighted that if the level of complexity in gameplay was appropriate, participants would be motivated to play it.

This desire for an optimal difficulty level [37,38] reflected a broad consensus across all groups that if the game provided a suitable challenge, it would be far more enjoyable.

When discussing a game he enjoyed, a participant from FG2 reflected the following:

> *Because you need skills to do it, it is pretty good.* [Participant 2; FG2]

What constitutes a challenge is likely to be different for each end user. For instance, the need for a technical and skill-based challenge by participant 2 in FG2 was not the preference of another member of FG2:

> *The other ones are too hard...I stay with Solitaire.* [Participant 4; FG2]

With this desire for different levels of difficulty, participants agreed about the need for challenge flexibility to ensure that game difficulty was suitable for each player:

> *As long as it challenges you, I'd probably stay with it.* [Participant 5; FG3]

> *...And if you can speed it up and slow it down, that gives people with no memory a better go at it. I can't remember things very well, so that adjustment of the speed level is pretty good. That's the only reason that I'd play that game.* [Participant 4; FG3]

According to SDT, participant observations and consensus about the need for optimal challenge reflect the need to satisfy the basic psychological need for competence [37,38]. In the context of games, optimal challenges can lead to a sense of efficacy and thus competence [39]. If a game is very easy, it becomes boring and reduces the likelihood of attentive engagement [66]:

> *If you lose interest early, it is doomed.* [Participant 5; FG3]

In contrast, if it is very hard, it can become frustrating and discouraging, thus also reducing the likelihood of motivation, engagement, and enjoyment:

> *My brain doesn't work that quick.* [Participant 4; FG2]

Optimal challenge is mediated by an individual's threshold for difficulty [39,66]. Difficulty creates the challenge that is essential for satisfaction of competence needs. However, the right level of difficulty will be vastly different across individuals, especially in the diverse prison context:

> *Maybe you can design the project that you're doing to different levels of how people want to react to these things.* [Participant 1; FG3]

Given the participants' need for optimal challenge, alongside the diversity in what challenge means for each person, a serious game–based assessment that can effectively differentiate game complexity appears to be important in the prison context to ensure that the challenge level is *just right* to address competence needs.

Avoiding Childish Graphics—Gimmicky Gameplay Can Be Condescending

Participants from FG2 and FG3 agreed that if a game did not have modern graphics or if it appeared childish, it was not playable and was even condescending:

> *No disrespect for who designed that game [the demo shown to participants] but that's a game for a 9-to-10-year-old...no offense but I couldn't play that...* [Participant 1; FG3]

> *I'm 60 years old and I use the phone and the graphics on the phone are better than that. You can't expect people to go back, to be honest.* [Participant 1; FG3]

It was clear that their expectations were for a game to feel more mature:

> *Your graphics are really bad [laughing]. Nintendo 64 was better than those graphics.* [Participant 1; FG2]

> *[The game needs to be] more realistic.* [Participant 5; FG3]

> *[And] more adult.* [Participant 1; FG3]

In contrast, the women from FG1 had a far more positive response to the serious game demonstration, with only 5% (1/20) of the participants finding the game to be problematic:

> *It's giving me anxiety.* [Participant 3; FG1]

> *[This game demo is good] because memory tests aren't usually fun.* [Participant 5; FG1]

> *I like it.* [Participant 4; FG1]

> *It's cute.* [Participant 2; FG1]

When queried about their general game preferences, the women in FG1 reacted positively to the ability to choose a character, even a character of the opposite sex. A participant suggested the following:

> *That's half the fun in it!!* [Participant 4; FG1]

The older men from the *aged ≥65 years* group were mostly indifferent to the game demonstration and did not comment about the graphics. They seemed to be more interested in functional issues connected to the game, such as whether it had audio and what the game was testing.

Although the openness to different game types varied across the groups, the strength of the aversion to *childish* games from several participants in FG2 and FG3 is important to be emphasized. Any game experience that makes a substantial portion of the target users feel condescended needs to be avoided:

> *I'd rather throw it out the window then just occupy my time with it. It has to be more than just the premise of being a game. In that regard, that's condescending. I don't consider myself unintelligent so, as someone said earlier, speak to me as an adult. Not as a ten-year-old kid. I understand there's people who have learning problems and all the rest of it, but do I have to be spoken to in the same manner as them?* [Participant 1; FG3]

Games that felt childish and immature appeared to violate competence needs in FG2 and FG3 for some participants [37-39]. Although these negative responses were not evident in FG1 and FG4, the need to avoid competence violations is of high importance for any game-based assessment. This is especially true for a cognitive assessment game in the prison context, where people already report feeling overlooked and unheard [40-42].

Furthermore, if people are worried about their cognitive health before completing the game-based assessment, any risk of competence violations must be minimized, otherwise feelings of self-stigma or shame may be exacerbated [9-11]. A participant reflected the following:

> *Just a thought. When you're planning for this...this is where psychs get it wrong...Say what you mean, mean what you say. We're grown men. Don't dabble around. Get to your point. Get your yes or no. Factor that in when you're planning this stuff. Don't treat humans like children. Nothing worse. It's patronising and condescending. Makes you feel stupider than you know you already are.* [Participant 2; FG3]

Thus, the need to ensure that game-based assessments in prison environments do not feel overly childlike or immature appears to have vital importance:

> *As far as games and all that, we had the Atari and Mario Brothers and all that. We played it with the kids. It's not just us playing. That was my involvement with games. But yeah, like the boys have said chess, backgammon, tiddlywinks, monopoly, we played all that. But I mean, games need to be more geared towards brain power, rather than just simplistic things like building blocks on top of other blocks like Tetris. But yeah, I got no problems with them.* [Participant 1; FG3]

Games that explicitly focus on *brain power*—such as quizzes, crosswords, and numeracy challenges—seem to be more aligned with the preferences and expectations of many participants in FG2 and FG3. In addition, there was no clear aversion to these types of *mature* games in FG1 and FG4, suggesting that they may be more appropriate for a wide range of older adults in prison.

A Balanced Diet—Meaningful Choice and Variety Keeps Game-Based Assessments Fun

Given the subjective nature of game enjoyment, a variety of different, and at times, contrary, game preferences were highlighted.

For example, when people were asked if they liked gaming features such as earning badges for performance achievements, there was a spectrum of opinions:

> *No, I don't want badges. I don't wanna know that.* [Participant 4; FG2]

This contrasted with views such as the following:

> *Oh, I love winning. I'm a really good winner! Yeah. That'd be cool.* [Participant 3; FG1]

Game variety appeared to be a key preference for participants:

> *It doesn't matter who you are, you can see on the screen, ok, I don't know how to do that, but I'd like to know, so I'll go and play that one...or, ok...I know how to do that, so I'll go play that other one.* [Participant 1; FG2]
>
> *Yeah, you got to have a variety.* [Participant 4; FG2]

Participants were also quick to acknowledge and discuss the purpose of the game, that is, to test different types of cognitive functioning (reaction time, memory, executive ability, etc). By acknowledging the primary purpose of the game, participants saw the opportunity to create a variety of gamified tasks addressing different design appetites within the groups and within themselves:

> *Yeah, you could have mind games, where you gotta think about what you're doing. And reactive games, where you gotta react to something and all that sort of thing...you could have literacy sort of games where you gotta think about what's being written and other games where you're using your reaction time and you're thinking about what's going on but you're not reading it.* [Participant 1; FG2]

When brainstorming about game design preferences, a participant from FG2 even suggested the technique of game customization to avoid amotivation and maximize meaningful choice:

> *Ohh, I just come up with a thing you can do for what you need. If you got someone who is getting dementia and they are retired, and you knew what their trade was, with the trade they'd done for work, you could ask them things like...let's say they done carpentry...Say, "what kind of tools would I need to build this kind of table and the process that I need to go through to start [to] build that table?" And you could see what their memory is from what they used to do. If you use to do something, your memory should recall, and you ask them something about that.* [Participant 2; FG2]

Another member of FG2 expanded upon this customization idea:

> *Going back to the building side of things, you could have a Mah-jong sort of game with building materials. Even engineering, you could do it with cars, make it like you gotta build a car or something.* [Participant 1; FG2]

Throughout the brainstorming conducted across a number of FGs, especially FG2, the game design technique of minigames emerged as a viable solution to address the need for variety and meaningful choice across the serious game.

When asked about the potential to use minigames, a participant positively reflected the following:

> *Like little minigames where, between what's going on around them, they're coming down like a map of different quests type thing? You're progressing through, or something, and play a little mini*

> *game...then move on and play another mini game? Yeah, that sounds good. To break the attention up. Yeah, yeah, that that would work.* [Participant 3; FG2]

This preference for different minigames reinforces the appetite for meaningful choice, a critical element of autonomy in the context of game design [37-39]. According to SDT, autonomy in digital games involves interesting options and volitional engagement [67]. Although choice and variety are critical design elements in most games, the strong desire for these elements by participants is important to be highlighted in the context of prison—an environment where autonomy is often thwarted [41].

Discussion

Principal Findings

This study aimed to qualitatively examine the design preferences for a serious game–based cognitive assessment among older adults in prison. Using an abductive approach underpinned by critical realism, we generated 3 distinct themes. They were (1) Goldilocks—getting gameplay difficulty *just right* through optimal challenge, (2) avoiding childish graphics—gimmicky gameplay can be condescending, and (3) a balanced diet—meaningful choice and variety keeps game-based assessments fun. These themes provide novel insights into the game design preferences of older adults in prison, whose voices have been seldom heard in the development of serious games so far. In addition, the production of these themes in the context of SDT and game design research should, we hope, provide a useful and actionable base for serious game designers to develop appropriate cognitive games that are acceptable and motivating for older adults within the unique prison context.

Within theme 1, it was clear that the competence needs for an individually optimal level of difficulty was a priority across all FGs. Regarding game design, this can be addressed by developers through dynamic game balancing [66,68]. Dynamic game balancing is a popular game design technique that overcomes variability in individual difficulty thresholds through real-time adjustment of game parameters, so that task difficulty adapts and eventually aligns with a player's ability [66]. This ensures that competence can be satisfied for a variety of users through optimal challenge [69]. The goal is to keep the user interested from beginning to the end. Dynamic game balancing is associated with high levels of user satisfaction [70] and feelings of competence, which predicates high levels of motivation and enjoyment [69]. The use of dynamic game balancing for serious game–based cognitive assessments is an emerging area, and potential complexities such as maintaining psychometric validity are yet to be fully considered [66]. Nonetheless, the technique appears to be theoretically capable of addressing the competence needs for optimal challenge highlighted by participants.

Theme 2 reflected the need to avoid competence violations by minimizing childlike game features, which made some participants feel condescended. In the context of SDT, game features offering opportunities for mastery that provide optimal challenges can satisfy competence needs by helping a player feel a sense of accomplishment and control [38]. However, the opposite can also be true. When people are tasked with playing a game that they believe is not suitable for them or does not align with their self-perceived level of capability, it can become boring, frustrating, and even insulting. This is an especially important consideration in the context of prison, where the need for competence is often thwarted, and people often distrust the prison system and report feeling disrespected by health and corrective professionals [71]. A noteworthy minority of our study participants highlighted that childish graphics made them feel condescended, and some members of our FGs appeared to be frustrated by the idea of playing a childish game for the purpose of cognitive assessment. We suggest that this frustration stems, at least in part, from a misalignment between some participants' self-perceived level of capability and the perceived inability of a game that looks and feels childish to meet this capability. We further suggest that this frustration, a common and natural response to perceiving a game as incompatible with one's intellectual capacity, can be exacerbated by the competence-thwarting prison environment, in which control is already difficult to achieve [72]. Thus, avoiding games that feel similar to *kids' games* and designing features that are more *adult* and *realistic*, which are *geared toward brain power* appear to be important to avoid competence violations and, more broadly, guard against overly negative responses to serious game–based assessments in prison.

Theme 3 highlighted the strong user preference for choice and variety, both of which satisfy the need for autonomy and can enhance intrinsic motivation [37,38,67]. Although the positive effects of choice can be complex and depend on a variety of factors (eg, cultural background), multiple studies have shown that choice has a beneficial effect on motivational outcomes such as effort and task performance [41,73]. Autonomy satisfaction has also been associated with better quality of life in prison [41]. However, both autonomy [74,75] and choice [76] are often difficult to attain in prison [41]. Therefore, ensuring that games are autonomy-focused through *meaningful choice* when they are restricted in real life may be particularly beneficial for this group. Minigames are an effective game technique to maximize choice and variety [38,39] and, as highlighted by participants, align well with the objectives of cognitive assessment. Thus, designing minigames with emphasis on user control appears to be a suitable way to maximize in-game autonomy for people from marginalized groups who may struggle to achieve autonomy in other aspects of their lives.

Limitations

This study has some important limitations. First, this study purposefully sampled end users from 3 different prisons in New South Wales, Australia. Although attempts were made to select a distinct variety of older adults in prison and in turn understand empirical observations in terms of prominent theories or underlying structures, the themes generated are not necessarily generalizable to other locations or user groups. Second, all FGs were monitored by a correctional officer owing to security protocols. This power imbalance may have affected the responses given by participants, particularly those who are highly reliant on staff, such as those in the Frail and Aged Unit. However, no evidence of this was observed during the FGs. Third, the method of analysis used in this study and our interpretation of data are underpinned by the philosophy of critical realism. It is entirely possible that a researcher informed by a different philosophical approach would interpret the empirical observations differently and thus make different truth claims. Similarly, results are reported using the technique of abduction. We have made attempts to be clear and transparent about our theory-focused interpretations and recontextualization of the data when producing our results. However, it is critical to acknowledge that our interpretations are inevitably based on our own beliefs and objectives. In addition, our chosen theories are fallible. To overcome this, we attempted to reduce biases and improve validity (refer to the *Validity* section); however, these attempts are not perfect. Moreover, they are not intended to remove the researcher completely from the qualitative process. With this in mind, it should be noted that the authors of this paper are focused on building a serious game for cognitive assessment that is suitable for use by diverse older adults in prison. We want the game to be successful and have likely interpreted participant observations and preferences to ask *how to make a serious game work* rather than *whether serious games work?* This does not mean we are certain that a game will be valid, feasible, or acceptable in prison. However, we certainly hope it will be, and this desire to design and develop a suitable serious game has informed this study.

Practical and Research Implications

A serious game–based assessment provides a novel challenge for game designers and developers. This is because the intended application of a serious game assessment is likely to be a relatively short (eg, 10-20 minutes) user experience, which is only *played* by users sporadically. The implication is that traditional game design focusing on intrinsically motivating features such as narrative and social connectedness may not be feasible or desirable. For instance, a complex and value-based storyline, with unique characters and quests, is likely very complex for an assessment that someone is going to undertake irregularly for 10 to 20 minutes. This tension has not been given much attention in the serious game literature from a user design perspective. Most of the previous studies on user preferences of cognitive game design has highlighted the importance of embedding intrinsically motivating game features without considering the complexity of embedding these features into a very short and sporadically played game-based assessment [77]. These traditional features may be desirable in long-form games focused on cognitive training or rehabilitation but are less suitable for the narrow and short objectives of a cognitive assessment. In contrast, other attempts to make game-based cognitive assessments have gamified traditional tasks in very basic ways. Although this may be more suitable to ensure psychometric validity, this process risks not being particularly engaging or fun. For instance, some previous attempts to digitize cognitive tasks or introduce simple gamification have been unsuccessful, with users reporting that, similar to traditional tasks, the experiences were tedious and boring [3,20,78,79].

Our study was guided in part by the need to address this tension. We were open with our participants about the typical length of serious games and the intended purpose of a gamified cognitive assessment (ie, to detect cognitive decline or dementia). This enabled users to provide practical design insights that reflect the unique parameters of serious game–based cognitive assessment. As such, the themes generated are consistent with the reality of serious game–based design and conform to the nuances of gamifying short and sporadic assessments while still highlighting game design features that are immersive, motivating, and enjoyable to our distinct user group. In this way, optimizing the challenge by balancing the difficulty level, avoiding childish features, and maximizing meaningful choice through minigames are unique user-generated design preferences suited to addressing user needs within a short and potentially infrequent serious game–based assessment in the prison setting.

Conflicts of Interest

MK is the chief executive officer of Arludo.

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Abbreviations

FG: focus group
SDT: self-determination theory

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Original Paper

Computerized Block Games for Automated Cognitive Assessment: Development and Evaluation Study

Xiangyi Cheng[1], PhD; Grover C Gilmore[2], PhD; Alan J Lerner[3], MD; Kiju Lee[4,5], PhD

[1]Dr Carl D and H Jane Clay Department of Mechanical Engineering, TJ Smull College of Engineering, Ohio Northern University, Ada, OH, United States

[2]Department of Psychological Sciences, Case Western Reserve University, Cleveland, OH, United States

[3]Department of Neurology, Case Western Reserve University, Cleveland, OH, United States

[4]Department of Engineering Technology and Industrial Distribution, Texas A&M University, College Station, TX, United States

[5]J Mike Walker '66 Department of Mechanical Engineering, Texas A&M University, College Station, TX, United States

Corresponding Author:
Kiju Lee, PhD
Department of Engineering Technology and Industrial Distribution
Texas A&M University
Fermier Hall, 3367 TAMU
466 Ross St
College Station, TX, 77843
United States
Phone: 1 979 458 6479
Email: kiju.lee@tamu.edu

Abstract

Background: Cognitive assessment using tangible objects can measure fine motor and hand-eye coordination skills along with other cognitive domains. Administering such tests is often expensive, labor-intensive, and error prone owing to manual recording and potential subjectivity. Automating the administration and scoring processes can address these difficulties while reducing time and cost. e-Cube is a new vision-based, computerized cognitive assessment tool that integrates computational measures of play complexity and item generators to enable automated and adaptive testing. The e-Cube games use a set of cubes, and the system tracks the movements and locations of these cubes as manipulated by the player.

Objective: The primary objectives of the study were to validate the play complexity measures that form the basis of developing the adaptive assessment system and evaluate the preliminary utility and usability of the e-Cube system as an automated cognitive assessment tool.

Methods: This study used 6 e-Cube games, namely, Assembly, Shape-Matching, Sequence-Memory, Spatial-Memory, Path-Tracking, and Maze, each targeting different cognitive domains. In total, 2 versions of the games, the fixed version with predetermined sets of items and the adaptive version using the autonomous item generators, were prepared for comparative evaluation. Enrolled participants (N=80; aged 18-60 years) were divided into 2 groups: 48% (38/80) of the participants in the *fixed group* and 52% (42/80) in the *adaptive group*. Each was administered the 6 e-Cube games; 3 subtests of the Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV; Block Design, Digit Span, and Matrix Reasoning); and the System Usability Scale (SUS). Statistical analyses at the 95% significance level were applied.

Results: The play complexity values were correlated with the performance indicators (ie, correctness and completion time). The adaptive e-Cube games were correlated with the WAIS-IV subtests (*r*=0.49, 95% CI 0.21-0.70; *P*<.001 for Assembly and Block Design; *r*=0.34, 95% CI 0.03-0.59; *P*=.03 for Shape-Matching and Matrix Reasoning; *r*=0.51, 95% CI 0.24-0.72; *P*<.001 for Spatial-Memory and Digit Span; *r*=0.45, 95% CI 0.16-0.67; *P*=.003 for Path-Tracking and Block Design; and *r*=0.45, 95% CI 0.16-0.67; *P*=.003 for Path-Tracking and Matrix Reasoning). The fixed version showed weaker correlations with the WAIS-IV subtests. The e-Cube system showed a low false detection rate (6/5990, 0.1%) and was determined to be usable, with an average SUS score of 86.01 (SD 8.75).

Conclusions: The correlations between the play complexity values and performance indicators supported the validity of the play complexity measures. Correlations between the adaptive e-Cube games and the WAIS-IV subtests demonstrated the potential utility of the e-Cube games for cognitive assessment, but a further validation study is needed to confirm this. The low false detection rate and high SUS scores indicated that e-Cube is technically reliable and usable.

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KEYWORDS

cognitive assessment; computerized block games; adaptive serious games; computerized cognitive assessment

Introduction

Background

Cognitive assessment aims to measure multiple domains of cognition, including visuospatial abilities, working memory, language, attention, executive function, fine motor skills, and orientation [1]. One's cognitive abilities affect learning outcomes, physical and mental health, social behavior, and interaction with the environment [2-4]. Identifying impairment in any of these domains, diagnosing the cause, specifying the severity, and tracking the progression of the symptoms are the common purposes of cognitive assessment in clinical settings [5]. This paper presents an innovative technology called *e-Cube* for adaptive, automated cognitive testing and reports the evaluation results in terms of preliminary utility and usability.

There are standardized instruments widely used for cognitive assessment. The Wechsler Adult Intelligence Scale (WAIS) has been broadly adopted in clinical, research, and educational settings and is often referred to as a *gold* standard [6]. The WAIS Fourth Edition (WAIS-IV) is normed for the ages of 16 to 90 years. It comprehensively assesses cognitive abilities using 15 subtests that target various cognitive domains [7]. This instrument is administered and scored by a qualified psychologist, taking approximately 60 to 90 minutes. This process is labor-intensive and costly [8]. The Stanford-Binet Intelligence Scales, Fifth Edition, is another standardized instrument commonly used in both clinical and research settings [9]. Several WAIS and Stanford-Binet Intelligence Scales subtests rely heavily on a person's verbal skills and, therefore, show limitations when administered using a non–native language version [10]. There are also nonverbal instruments aiming to eliminate cultural and language biases in the assessment. For example, the Raven Progressive Matrices consist of 60 items measuring the basic cognitive functioning of individuals, each of which is a visual geometric design with a missing piece [11,12].

The advancements in digital technologies have enabled researchers to explore computer-based methods for cognitive assessment. Computer-based methods can reduce the administrative burden, automate the scoring process, reduce cheating, and standardize test conditions once successfully validated [13]. A straightforward application is to convert a paper-and-pencil test into a computerized version while retaining the contents and formats. Q-interactive is a digital system initially developed for the WAIS-IV that uses 2 iPads, one for the administrator and the other for the test taker [14]. This digital version reduces labor-intensity but takes approximately the same time for a trained professional. Moreover, it can only automate some types of tests. In particular, one of the subtests, Block Design (BD), requires the examinee to assemble physical blocks to match the top surface with a given image displayed on an iPad. The administrator then has to check the correctness and input the results manually. In addition to the computerization of existing instruments, an increasing body of research has adopted the concept of computer- or tablet-based *serious games* to make the experience more engaging [15-17]. Some serious games use dynamic difficulty adjustment to achieve adaptive testing by tuning item difficulty autonomously [18,19]. However, most of the previously developed games for cognitive assessment do not include measurements of fine motor and hand-eye coordination skills.

Cognitive Assessment Using Tangible Objects

Cognitive assessment sometimes uses tangible objects to measure one's cognitive skills together with fine motor and hand-eye coordination skills. These skills are closely linked to many neurological diseases and brain injuries [20]. Existing research also suggests that the deterioration of fine motor control and coordination characterizes sensorimotor deficiencies in mild cognitive impairment and Alzheimer disease [15,21-23]. The BD subtest in the WAIS [5] and the Kohs Block Design test [24] use a set of cubes and require an examinee to place and assemble the top surfaces of the blocks to match the given image. Unlike the simple multiple-choice questions used in many other assessment instruments, the administrator has to inspect the correctness of the block manipulation visually while timing in these tests. This is labor-intensive and error prone owing to manual recording and subjectivity, possibly affecting the assessment results.

Automating the assessment using physical objects also involves additional challenges and requires technological innovations beyond what is expected for computerized tests. For example, a platform called ETAN supports the use of tangible user interfaces and physical objects for evaluating visuospatial cognition by implementing the Baking Tray Task [25]. Cognitive Cubes were designed to assess spatial and constructive abilities by asking users to build 3D shapes with the cubes. A pilot study involving 16 participants demonstrated that the Cognitive Cubes were sensitive to differences in cognitive ability [20].

SIG-Blocks and TAG-Game, developed for the automated assessment of cognitive and fine motor skills, were the previous research of this work [26-28]. Each SIG-Block, covered with simple black-and-white geometric shapes, can sense physical motions applied to it, detect adjacent blocks, and send sensor data to a local host computer in real time. TAG-Games are computerized games that use SIG-Blocks as a means of game control. In total, 3 types of TAG-Games, namely, Assembly, Shape-Matching, and Memory, were designed and tested. These games are all nonverbal and require hand manipulation of physical blocks. The TAG-Game technology is one of the few systems that can automate the administration and data collection of tasks involving physical object manipulation. However, despite its demonstrated potential, several challenges were identified in our previous research. Specifically, hardware costs, occasional technical failure, and high maintenance make the system unsuitable for broad and long-term adoption and use.

e-Cube Games for Automated Assessment of Fine Motor and Cognitive Skills

e-Cube is our latest technical innovation that converts the original TAG-Game system into a computer vision-based system using a set of plastic cubes and a webcam. The e-Cube system reduces the device cost from US $1500 to approximately US $50 (excluding a computing device needed for any computerized assessment), decreases potential technical errors, and nearly eliminates the maintenance burden. The entire system is fully autonomous and easy to use. In addition to these benefits, a new *adaptive* test environment was established based on the embedded algorithms for measuring play complexity and generating adaptive test items autonomously. These features enable personalized assessment based on an individual's real-time performance. e-Cube consists of 6 types of games: (1) Assembly, (2) Shape-Matching, (3) Sequence-Memory, (4) Spatial-Memory, (5) Path-Tracking, and (6) Maze. The first 3 were directly adopted and converted from TAG-Games, and the other 3 were newly created. New computational measures of play complexity were defined and implemented for each game.

The evaluation focused on testing 2 objectives. *Objective 1* was to validate the proposed play complexity measures that form the algorithmic basis of the adaptive games. Correlation analyses were performed between the developed play complexity measures and 2 performance indicators, mean correctness and mean completion time. *Objective 2* was to understand the preliminary utility and usability of the e-Cube system as an automated cognitive assessment tool. The non–age-corrected raw scores of 3 WAIS-IV subtests—BD, Digit Span (DS), and Matrix Reasoning (MR)—were adopted to compare their results with the e-Cube game scores. The WAIS-IV is a well-established instrument, and the 3 selected subtests measure the target cognitive domains of the e-Cube games. Specifically, the Assembly game was conjected to be related to BD as both require the assembly of block surfaces to match a given pattern. The Shape-Matching game requires the participant to find a shape that completes a pattern, so it was expected to tap the same cognitive abilities as the MR subtest. Sequence-Memory and Spatial-Memory were expected to be related to DS as they all target working memory skills. The remaining games, Path-Tracking and Maze, are timed games asking participants to give the shortest trajectory by reasoning, so they were both hypothesized to show a relationship with BD and MR. The *hypothesized relationships* between the e-Cube games and the WAIS subtests are summarized in Table 1. The false detection rate of the system determines whether it produces reliable and accurate data. Usability was evaluated by administering the System Usability Scale (SUS) to all participants upon the completion of the assessment session. The SUS is a 10-item questionnaire measuring usability with high validity and reliability and, thus, used as a measure of perceived usability [29-31].

Table 1. The 6 e-Cube games with their associated task descriptions and the expected associations with the Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV), subtests (Block Design [BD], Digit Span [DS], and Matrix Reasoning [MR]).

e-Cube game	Task	WAIS-IV		
		BD	DS	MR
Assembly	Assemble multiple cubes to match the top assembly configuration	✓		
Shape-Matching	Manipulate 1 cube to complete the pattern with 1 missing piece			✓
Sequence-Memory	Memorize a sequence of geometric shapes and reconstruct it using 1 cube		✓	
Spatial-Memory	Memorize a spatial assembly of geometric shapes and reconstruct it using cubes		✓	
Path-Tracking	Trace a connected path between 2 blue dots using a single cube	✓		✓
Maze	Navigate through a maze to reach a goal point from a starting point using a single cube	✓		✓

Methods

e-Cube Games

System Overview

The e-Cube system consists of a set of 9 cubes with 1.2-inch–length edges, a place mat with a brown rectangular region in the center, a computing device with a display, and a webcam with a custom-designed stand (Figure 1). The cube's 6 faces are distinctive black-and-white geometric shapes, including squares, strips, and triangles representing 4-, 2-, and 1-fold rotational symmetry (Figure 2). The cubes preserve the same design as the SIG-Blocks [28]. When the system turns on, the camera automatically detects the corners of the brown rectangular area on the place mat. This area is called the *play area*, where the cubes are expected to be placed and manipulated. The laptop with the connected webcam displays the cubes in the play area after perspective transformation projecting the original camera view onto a 2D plane and tracks their movements in real time [32]. This autonomous transformation offers flexibility in the camera location.

The e-Cube system requires the accurate identification of the top-surface images of the cubes. Individual box-shaped regions are assigned for placing the cubes (Figure 1), wherein the geometric shape and orientation detection algorithm is executed. The embedded algorithm first detects the black-and-white regions within each box to check whether a cube exists. It then identifies a polygon using the Ramer-Douglas-Peucker algorithm [33]. Finally, the specific shape and orientation of the detected polygon are determined. This simple strategy makes the system robust and reliable under different illumination conditions and limited computing capabilities. The e-Cube system can run reliably on a relatively low-end computing device, such as Intel Core i5-7200U (2.5 GHz, 3 M cache, dual core, and 4 threads).

Figure 1. The hardware of e-Cube, consisting of the cubes, a webcam with a stand, a place mat, and a host computing device running the Assembly game.

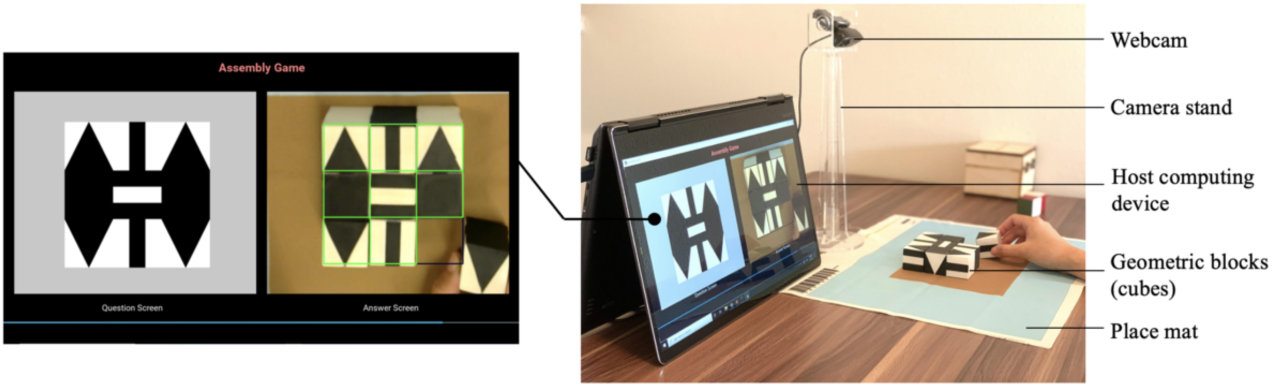
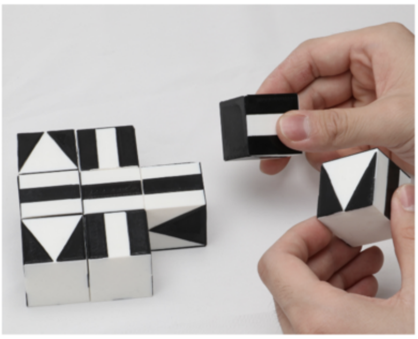


Figure 2. A total of 9 geometric cubes and 14 distinctive surface shapes with their IDs formed by rotating the images on the 6 surfaces of a cube by 0°, 90°, 180°, and 270°.



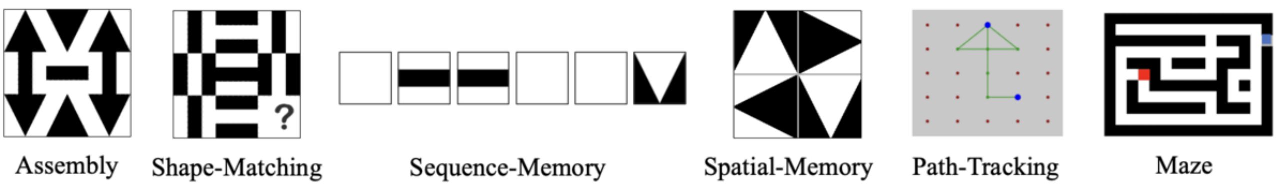
Index	1	2	3	4	5	6	7
IDs (geometry, color, orientation)	(0,0,0)	(0,1,0)	(1,0,0)	(1,0,1)	(1,1,0)	(1,1,1)	(2,0,0)
Shape							
Index	8	9	10	11	12	13	14
IDs (geometry, color, orientation)	(2,0,1)	(2,0,2)	(2,0,3)	(2,1,0)	(2,1,1)	(2,1,2)	(2,1,3)
Shape							

Game Design

We developed 6 e-Cube games: Assembly, Shape-Matching, Sequence-Memory, Spatial-Memory, Path-Tracking, and Maze. We directly converted the 3 TAG-Games (Assembly, Shape-Matching, and Memory) into the vision-based e-Cube versions (Assembly, Shape-Matching, and Sequence-Memory) [26]. Spatial-Memory, Path-Tracking, and Maze were newly added.

Table 1 presents the tasks associated with each game, and Figure 3 shows an example item for each e-Cube game. Assembly asks the player to match the given assembly figure displayed on the screen using 4 or 9 cubes, similar to the BD subtest of the WAIS-IV. Shape-Matching involves items with assembly patterns, each missing 1 piece, and the player completes the pattern using a single cube. Sequence-Memory and Spatial-Memory require the player to memorize a sequence or an assembly of geometric shapes. In Sequence-Memory, each shape is displayed for 1 second and then disappears. In Spatial-Memory, an assembly pattern of 2, 3, or 4 geometric shapes is displayed for 5 seconds. The items in the Spatial-Memory game are similar to those in Assembly, whereas visible outlines around individual shapes are added, as shown in Figure 3, to assist perceptual segmentation of the pattern [34]. Path-Tracking and Maze use only 1 cube with its white square facing up. In these 2 games, the vision algorithm detects the center of the white square and tracks it continuously on the screen; no assigned box-shaped regions are shown on the screen. Path-Tracking displays a green connected path between 2 blue dots, and the player must trace the path by moving the cube from one blue dot to the other on a 5 × 5 grid via the shortest path. The Maze game asks the player to find the shortest path of mazes shown on the screen by moving a cube from the start (blue) to the end (red).

Figure 3. Sample items for the 6 games.



Computational Measures of Play Complexity

Overview

The e-Cube system aims to dynamically adapt to individual differences in cognitive skills by generating test items autonomously based on one's real-time performance. To do so, a computational method to measure the difficulty of each item is required. The previously defined measures of play complexity presented in the studies by Lee et al [26,35] and Jeong et al [28] were highly correlated with the participants' performances measured using completion time or accuracy. These measures captured the complexities associated with individual geometric shapes without considering the spatial complexity of the assembly patterns. For example, the 3 assembly patterns shown in Figure 4 had the same complexity value using the previously defined measures. As our previous study used a handcrafted set of items, we could select the items where their difficulties could be clearly differentiated using the previously defined measures. However, for generating adaptive test items, the complexity measures must capture the difficulties associated with both the individual shapes and the assembly patterns.

Figure 4. Items formed by the same geometric shapes but with different play complexity (with identical compositional complexity but different configurational complexity).

To address this limitation, we defined new complexity measures for the 6 e-Cube games. Two mathematical concepts were applied: (1) the Shannon entropy and (2) the gray-level co-occurrence matrix (GLCM). The Shannon entropy measures the uncertainty, randomness, or disorder existing in the data [36] and is calculated as

where p_i is the probability of the ith event. When the probabilities are evenly distributed, the Shannon entropy is calculated as $H=\log_2 n$. The GLCM was originally proposed to classify image texture in grayscale [37,38]. For an image with an $m \times n$ dimension and L gray level, the GLCM of the image (f) is defined as an $L \times L$ square matrix such that

where Δx and Δy are typically defined as the horizontal, vertical, or diagonal position differences between the 2 adjacent pixels [37]. Horizontally adjacent pixels can be paired along 0° or 180°; vertically adjacent pixels can be paired along 90° or 270°; and diagonally adjacent pixels can be paired along 45°, 135°, 225°, or 315°. On the basis of the Shannon entropy and the GLCM, the computational measures of play complexity for the 6 e-Cube games are defined in the following sections.

Play Complexities of Assembly, Sequence-Memory, Spatial-Memory, and Shape-Matching

The play complexity of the items in Assembly, Sequence-Memory, and Spatial-Memory is computed using

where C_{compos} represents the compositional complexity associated with individual shapes (ie, the number of shapes and their rotational symmetry), C_{config} captures the configurational complexity associated with the orientation and color differences among the shapes in the way that they are arranged, and k is a sigmoid function defined as

If C_{config} is small, a small k leads to a lower impact of C_{compos} on C_{play}. For example, if an item is formed only by identical triangles (large C_{compos} and small C_{config}), C_{play} will still be small owing to k.

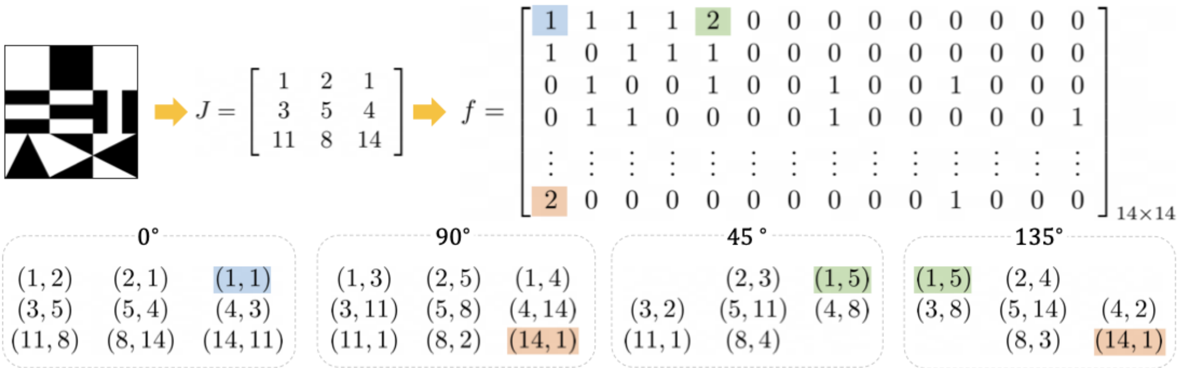
The Shannon entropy forms the basis of C_{compos} such that

where Q is the total number of shapes in the item, m_i is the number of available distinctive shapes among the 6 faces of a cube (m_i=6 if all faces of a cube are different), and r_i is the number of distinctive orientations obtained by rotating this shape 90° (r_i=1 for squares, 2 for strips, or 4 for triangles). The 3 images in Figure 4 have the same C_{compos} value.

The GLCM was adopted for capturing the configurational disorder (C_{config}) [39]. Figure 5 illustrates how it is obtained for an Assembly item. First, all geometric shapes used in each item are represented as J with the indexes corresponding to each shape defined in Figure 2 and its location. Second, all adjacent pairs along the 0°, 45°, 90°, and 135° directions on J are extracted. For example, the second row in J is (3, 5, 4), and the ordered pairs along 0°, including the circulant pair, are (3, 5), (5, 4), and (4, 3). Once all pairs are obtained, the number of each pair is imposed on the location in a 14-by-14 matrix f, that is, the GLCM, following equation 1. As shown in Figure 5, there are two (1, 5) pairs that correspond to 2 in the (1, 5) coordinate in f and one (1, 1) pair that corresponds to 1 in the (1, 1) coordinate. The weighted entropy [40] based on f is then calculated using

where

Figure 5. Gray-level co-occurrence matrix computation of a given 3 × 3 Assembly item.

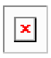


The weight $w_{i,j}$ estimates the configurational complexity of 2 adjacent elements based on their colors and orientations. To compare the differences among these 14 distinctive shapes, 3 IDs were assigned to each shape to categorize its geometric shape (square, strip, or triangle), color, and orientation (Figure 2). Regarding the IDs, 2 was assigned to the weight if the 2 adjacent shapes had different colors and orientations, and 1 was assigned otherwise.

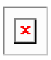
In Shape-Matching, as the player was asked to find a single shape that best completed the pattern, more shapes used in the pattern do not necessarily indicate greater difficulty in the pattern. Therefore, we only used the configurational complexity to estimate the item difficulty such that C_{play}=C_{config}, where C_{config} is defined as the summation of the weighted entropies based on the 3 GLCMs estimating how frequently a pair occurs horizontally, vertically, and diagonally.

Play Complexities of Path-Tracking and Maze

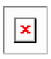
Path-Tracking and Maze do not use the geometric shapes of the cubes and, instead, use a single cube for creating a path. Therefore, the aforementioned method is not applicable. The play complexity of Path-Tracking adopts the network complexity based on the Shannon entropy [41], given by



where V is the number of vertices and a_i is the associated vertex degree. For Maze, the play complexity is defined as



where C_m is the maze complexity using equation 5 and C_s and C_l are calculated using



C_m reflects the complexity of the maze itself, but the complexity of solving a maze should also consider the start and end locations. The solution logarithmic complexity (C_s) in equation 7 represents the complexity caused by the vertex degrees, where L is the total length of the shortest path solved by the A* algorithm [42] and s_i is the degree of each grid in this solution. The solution length complexity C_l in equation 7 captures the length of the shortest path. In equation 6, the 0.4 value is multiplied to make the complexity values comparable with those of other e-Cube games. In addition, C_s + C_l is multiplied by 10 to balance with the range of C_m.

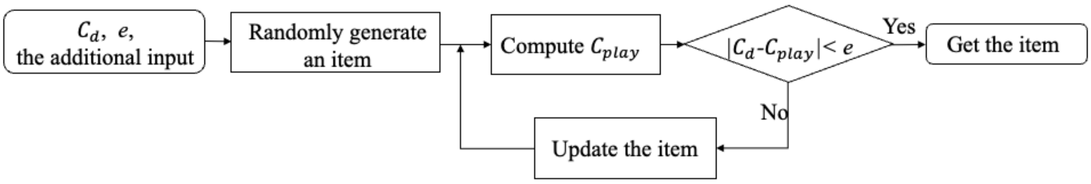
Adaptive Game Generators

The computational measures of play complexity form the basis of the adaptive algorithms, which can automatically generate test items. On the basis of the concept of dynamic difficulty adjustment, we created an adaptive e-Cube system that can adjust the item difficulty based on a player's performance measured using correctness.

The game begins with an item with a predefined low complexity. If the player answers the first item correctly, it proceeds to the next item with a higher complexity; otherwise, a new item with the same complexity is generated. If 2 consecutive incorrect answers are received, the complexity reverts to the midpoint between the latest correctly answered item complexity and the current incorrectly answered item complexity. The difference between the current and the next complexity value is referred to as a step size that can be either positive, 0, or negative. The game ends at a predefined highest complexity level or when the absolute value of the step size becomes sufficiently small.

The item generators for all games except for Shape-Matching follow a similar process, shown in Figure 6. The system takes a desired play complexity value C_d and a small tolerance e as input and generates a new item with a complexity C_{play}, where $|C_d - C_{play}| \le e$. Apart from C_d and e, additional input is needed in these games except for Maze. This input is the dimension of the pattern (eg, 2 × 2 or 3 × 3) in Assembly and Spatial-Memory, the number of images to be displayed in Sequence-Memory, and the number of dots to be connected (referred to as nodes) in Path-Tracking. The following steps generate items: (1) the system randomly generates an item based on the inputs; (2) the absolute difference between C_d and C_{play} is computed, where C_{play} is the complexity of the current item computed using the proposed measure; (3a) if the absolute difference is smaller than e, the system outputs the current item and ends the process; and (3b) if the absolute difference is not smaller than e, the system updates one feature of the current item to make the item easier or harder and then goes back to step 2. The features of the item can be geometric shapes in Assembly, Sequence-Memory, and Spatial-Memory; the paths connected by nodes in Path-Tracking; or the position of the end point in Maze.

Figure 6. The flowchart of the item generators for Assembly, Sequence-Memory, Spatial-Memory, Path-Tracking, and Maze.



Shape-Matching uses assembly configurations with embedded patterns where the types of patterns are predefined in the item generator, such as symmetry and rotation. Shape-Matching generates items from a predefined pool. For example, the easiest pattern in the predefined pool is formed by 4 identical shapes, in which one of the shapes will be hidden from players and treated as the missing piece. The item generator for Shape-Matching randomly selects a shape to form the easiest pattern, which leads to different items with the same play complexity.

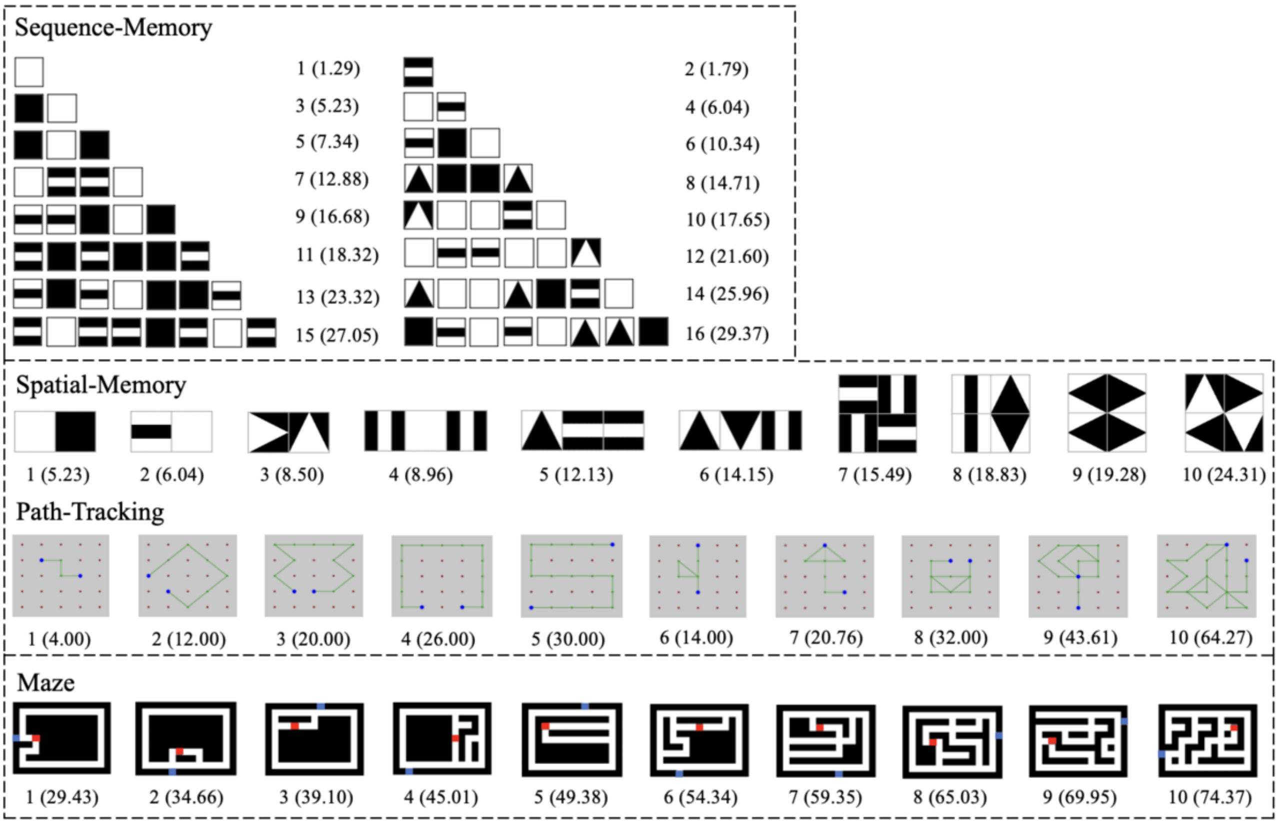
Evaluation of e-Cube

The evaluation study focused on the preliminary validation of (1) the proposed play complexity measures that form a basis for developing adaptive games (objective 1) and (2) the preliminary utility and usability of the e-Cube system as an automated cognitive assessment tool (objective 2).

Materials and Methods

The study used 2 versions of e-Cube games: e-Cube with the item generators (called *adaptive* e-Cube) and e-Cube with fixed items (called *fixed* e-Cube). Each participant was assigned to 1 of the 2 groups to experience the adaptive or fixed e-Cube games (ie, adaptive group and fixed group). The fixed games provided the same items for each player, whereas the adaptive games offered different items and different numbers of items based on the players' performance. The fixed versions of Assembly and Shape-Matching used the same items as in the study by Lee et al [26]. The fixed items of the rest of the games are shown in Figure 7.

Figure 7. Items with their ordering numbers and play complexity values in the fixed version of Sequence-Memory, Spatial-Memory, Path-Tracking, and Maze.



Objective 1 was tested by performing correlation analyses between the play complexity measures and performance indicators, including the mean correctness and mean completion time obtained by the participants for individual items in the fixed group. For objective 2, the correlations between the raw scores of 3 WAIS-IV subtests (BD, DS, and MR) and the 6 e-Cube games were analyzed to understand their relationships. We also investigated the technical reliability of the system using the false detection rate and usability based on the SUS results.

Protocol and Recruitment

This human participant study took place at Texas A&M University (TAMU). Bulk recruitment emails were sent to TAMU communities, and flyers were placed in buildings within the university for recruiting healthy participants aged 18 to 64 years. Once potential participants contacted the research team, a prescreening survey was sent via email to self-identify their eligibility before scheduling a visit. The prescreening survey consisted of 4 questions on age, date of birth, sex, and health conditions. Individuals who were beyond the target age range or had any of the following health conditions were excluded: stroke, other neurological diseases, low vision or blindness with aid, hearing loss or deafness with aid, or difficulties in arm or hand movements for manipulating small objects.

The sample size of a main trial is usually determined through a power analysis, where the variance is known from previous or pilot studies [43]. However, for this preliminary study, we applied the simplest method—sample size rules of thumb, which recommended samples of a minimum of 70 (35 per group) in pilot studies [44,45]. In our study, 80 participants (n=47, 59% male) were recruited and screened. All (80/80, 100%) were eligible and, thus, enrolled in the study. Informed consent and background information (ie, age and sex) were obtained from each participant. Most of the participants were randomly assigned to either the fixed or adaptive group, whereas efforts were made to balance the sex and age distribution between the 2 groups when we placed the participants in the groups toward the end. The fixed group included 48% (38/80) of the participants (23/38, 61% male), and the adaptive group included 52% (42/80) of the participants (24/42, 57% male). Owing to the convenience of recruitment and proximity to the study location, most participants were students from various departments and programs across the TAMU College Station campus, whereas several faculty and staff members, alumni of the university, and a few residents also participated. As a result, 82% (66/80) of the participants were aged between 18 and 30 years, 9% (7/80) were aged between 31 and 40 years, 2% (2/80) were aged between 41 and 50 years, and 6% (5/80) were aged between 51 and 60 years. There were no participants aged >60 years. Age mean, SD, and IQR; age distribution; and sex distribution are summarized in Table 2. We applied a chi-square test at a 95% confidence level to determine if there were differences in sex and age distribution between the 2 groups. The results showed no difference in the proportions of male, female, and intersex participants in the groups (χ^2_2=0.1, *P*=.76) and no difference in the proportion of age in the groups (χ^2_4=2.4, *P*=.50).

Table 2. Participant demographic data (N=80).

Characteristic	Participants	
	Fixed group (n=38)	Adaptive group (n=42)
Age (years), mean (SD; IQR)	26.71 (9.24; 22.00-28.00)	25.74 (8.50; 20.00-27.25)
Age range (years), n (%)		
18-30	31 (39)	35 (44)
31-40	4 (5)	3 (4)
41-50	0 (0)	2 (2)
51-60	3 (4)	2 (2)
>60	0 (0)	0 (0)
Sex, n (%)		
Male	23 (29)	24 (30)
Female	15 (19)	18 (22)
Intersex	0 (0)	0 (0)

The administration order between WAIS-IV and e-Cube was randomized. The order of the 3 subtests of the WAIS-IV followed the standardized protocol (BD, DS, and MR), whereas the order of the 6 e-Cube games was randomized. Upon the completion of both tests, the SUS was administered to each participant. The entire session took approximately 90 minutes: 50 minutes for e-Cube, 25 minutes for the WAIS-IV subtests, 5 minutes for the SUS, and a 10-minute break between e-Cube and the WAIS-IV subtests. Each participant was given a US $10 gift card upon the completion of participation.

Scoring System

The e-Cube games have not been standardized yet, and therefore, scoring methods are not finalized at this stage. We benchmarked the scoring methods used for the WAIS-IV subtests and our previous study [26] and modified them to suit the e-Cube games. The scoring of Assembly considers correctness, item size, and completion time—a 2 × 2 item that is correctly completed within 15 seconds or between 15 and 30 seconds yields 3 or 2 points, respectively; a 3 × 3 item correctly completed within 30 seconds, between 30 and 40 seconds, or between 40 and 60 seconds results in 4, 3, or 2 points, respectively. Shape-Matching, Sequence-Memory, and Spatial-Memory use correctness only as the scoring criteria—2 points for each correct answer and 0 for an incorrect answer. Scoring methods for Path-Tracking and Maze are based on correctness, completion time, and whether the path taken is the shortest. For Path-Tracking, the shortest path finished within 20 seconds, between 20 and 40 seconds, or between 40 and 80 seconds yields 4, 2, or 1 points, respectively; a correct path, but not the shortest, completed within 20 seconds or between 20 and 40 seconds yields 2 or 1 points, respectively. For Maze, the shortest path completed within 10 seconds, between 10 and 20 seconds, or between 20 and 40 seconds yields 4, 2, or 1 points, respectively; a correct path, but not the shortest, completed within 10 seconds or between 10 and 20 seconds yields 2 or 1 points, respectively. Others not satisfying the aforementioned conditions result in 0 points.

The adaptive e-Cube games require some additional considerations for scoring. If an item is generated with the same play complexity as the previous one answered incorrectly, the score for the correct answer is 1 point less than the score used in the fixed version. A total of 2 consecutive incorrect answers result in the system generating an easier item, and in this case, a correct answer for that newly generated item yields only 1 point.

Statistical Analysis

Correlations were computed to determine the relationships between the computed complexity values and participants' performance, the connections between the WAIS subtests and the e-Cube games, and the relationships among the 6 e-Cube games. We used the Spearman correlation to measure the monotonic association among them. The correlation is interpreted as "weak," "moderate," and "strong/high" when the coefficient is <0.36, between 0.36 and 0.67, and >0.67, respectively [46]. We used 2-tailed *t* tests to identify the mean differences in the game or subtest scores and the SUS scores between the 2 groups.

Ethics Approval and Informed Consent

This human participant study was reviewed and approved by the TAMU Institutional Review Board (IRB2019-1079D; approval date: December 22, 2020). Informed consent was obtained from all participants before taking part in this study.

Results

All enrolled participants (80/80, 100%) completed the entire session without withdrawal. The results and findings for objectives 1 and 2 are presented in the following sections.

Objective 1: Evaluation of the Measures of Play Complexity

The preliminary validity of the proposed play complexity measure (C_{play}) was evaluated by analyzing the correlations between the C_{play} values and the performance indicators from the fixed group participants. If the defined complexity measures properly reflected the difficulty associated with the individual items, participants would perform worse on the items with higher complexity values. Two performance indicators were used to evaluate the play complexity measures: (1) mean correctness and (2) mean completion time obtained for each item from the fixed group participants. The correlation analyses were performed at a 95% confidence level between the C_{play} values and all the mean values. The correlation coefficients *r* with *P* values and 95% CIs are shown in Table 3.

The C_{play} values showed strong positive correlations with the mean completion time in all e-Cube games, indicating that the items with higher C_{play} yielded a longer time to answer. Negative correlations between the C_{play} values and the mean correctness were found in Assembly, Shape-Matching, and Sequence-Memory, indicating that higher C_{play} items yielded lower accuracies. In Spatial-Memory, we found no substantial correlation between the mean correctness and C_{play}, mainly because of items 8 and 9 (Figure 7). The symmetry in these items seemed to make them easy to memorize, whereas it was not taken into account for the defined complexity measures. Without these 2 items, a correlation was found as r_8=–0.67 (95% CI –0.93 to 0.066; *P*=.06). A few participants correctly answered all the items in Path-Tracking (12/38, 32%; *P*=.58) and Maze (31/38, 82%; *P*=.07), and therefore, correctness did not yield any significant correlation with C_{play}.

Table 3. Correlations (Spearman r, 2-tailed *P* value, and 95% CIs) between the C_{play} values and the mean correctness and mean completion time for each item from the fixed group participants.

Game (*df*)	Mean completion time	Mean correctness
Assembly (20)		
r	*0.86* [a]	*–0.50*
P value	*<.001*	*.02*
95% CI	*0.67 to 0.94*	*−0.46 to 0.43*
Shape-Matching (10)		
r	*0.95*	*–0.75*
P value	*<.001*	*.009*
95% CI	*0.80 to 0.99*	*−0.94 to −0.23*
Sequence-Memory (16)		
r	*0.98*	*–0.95*
P value	*<.001*	*<.001*
95% CI	*0.94 to 0.99*	*−0.98 to −0.86*
Spatial-Memory (10)		
r	*0.94*	–0.30
P value	*<.001*	.30
95% CI	*0.76 to 0.99*	−0.78 to 0.41
Path-Tracking (10)		
r	*0.82*	–0.20
P value	*.002*	.58
95% CI	*0.39 to 0.96*	−0.74 to 0.49
Maze (10)		
r	*0.72*	–0.59
P value	*.01*	.07
95% CI	*0.17 to 0.93*	−0.89 to 0.06

[a]Italics indicate that a correlation existed.

Objective 2: Evaluation of Preliminary Utility and Usability of e-Cube Games for Cognitive Assessment

Overview

The mean, SDs, and IQR values obtained from participants in each group for the WAIS-IV subtests (raw scores) and e-Cube games are summarized in Table 4. We also conducted a 2-tailed *t* test with equal variance (Cronbach α=.05) comparing the test scores from the adaptive and fixed groups to determine whether significant differences existed in mean scores between the 2 groups. The *t* test showed no significant differences in the mean scores of the 3 WAIS subtests—BD (*P*=.37), MR (*P*=.06), and DS (*P*=.18)—between the 2 groups. Group differences were found in Shape-Matching and Sequence-Memory, but not in other e-Cube games.

Table 4. Score statistics from the Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV), subtests and e-Cube games.

	Fixed group, mean (SD; IQR)	Adaptive group, mean (SD; IQR)	2-tailed *t* test (*df*)	*P* value
WAIS-IV raw score				
BD[a]	50.95 (11,26; 41.00-60.00)	53.02 (9.35; 47.75-60.00)	–0.90 (78)	.37
DS[b]	28.34 (4.86; 24.75-32.00)	29.98 (5.83; 26.00-34.00)	–1.36 (78)	.18
MR[c]	21.55 (2.45; 11.00-14.00)	22.62 (2.49; 21.00-24.00)	–1.93 (78)	.06
e-Cube score				
Assembly	54.37 (11.10; 48.75-62.00)	58.52 (12.52; 51.75-67.25)	–1.56 (78)	.12
Shape-Matching	*16.53 (1.84; 16.00-18.00)* [d]	*14.67 (2.86; 13.00- 16.25)*	*3.42 (78)*	*.001*
Sequence-Memory	*20.63 (4.63; 16.00-24.00)*	*17.98 (3.83; 15.00-20.25)*	*2.81 (78)*	*.006*
Spatial-Memory	17.21 (2.16; 16.00-18.50)	16.88 (2.93; 15.00-19.00)	0.57 (78)	.57
Path-Tracking	26.95 (5.83; 24.00-31.00)	26.21 (7.54; 22.00-31.25)	0.48 (78)	.63
Maze	22.47 (6.27; 18.75-26.25)	22.12 (5.18; 17.00-26.00)	0.28 (78)	.78

[a]BD: Block Design.

[b]DS: Digit Span.

[c]MR: Matrix Reasoning.

[d]Italics indicate that a difference existed.

Relationship Between e-Cube Games and WAIS-IV Subtests

We presented the expected relationships between the e-Cube games and the WAIS-IV subtests in Table 1. The evaluation results are shown in Tables 5 and 6, which list the correlations between the e-Cube scores and WAIS-IV subtest scores in the fixed and adaptive groups, respectively. The 2 groups showed somewhat different trends in results. In both groups, Assembly and BD were moderately correlated, as expected in Table 1. Shape-Matching was expected to be correlated with MR, and the results from the adaptive group agreed with this. The Shape-Matching results from the fixed group showed a weak correlation with BD but no correlation with MR. Sequence-Memory and Spatial-Memory were expected to tap working memory as assessed by DS, but only the adaptive version of Spatial-Memory was moderately correlated with DS. The adaptive version of Sequence-Memory and BD also showed a weak correlation. Path-Tracking and Maze were expected to be related to BD and MR, and only the adaptive version of Path-Tracking yielded the expected results. However, no correlations were found between both versions of Maze and any WAIS subtest. Another notable finding was that both versions of Sequence-Memory showed no significant correlation with DS. Overall, the results suggested that the adaptive versions better tap into the cognitive abilities assessed by the 3 WAIS-IV subtests.

We further analyzed the intercorrelations among the e-Cube games (Multimedia Appendix 1 for fixed games and Multimedia Appendix 2 for adaptive games). The adaptive e-Cube showed fewer intercorrelations than the fixed version. In the fixed version, most of the games were somewhat correlated except for Shape-Matching. Both versions of Path-Tracking and Maze were correlated with Assembly.

Table 5. Correlations (Spearman r_{38}, 2-tailed *P* value, and 95% CIs) between the e-Cube scores and raw scores of the Wechsler Adult Intelligence Scale, Fourth Edition, subtests in the fixed group.

Fixed game	BD[a]	DS[b]	MR[c]
Assembly			
r	*0.49* [d,e]	−0.20	0.10
P value	*.002* [d]	.23	.57
95% CI	*0.20 to 0.70* [d]	−0.49 to 0.13	−0.23 to 0.41
Shape-Matching			
r	*0.33*	−0.30	0.09[d]
P value	*.04*	.07	.57[d]
95% CI	*0.01 to 0.59*	−0.57 to 0.02	−0.24 to 0.40[d]
Sequence-Memory			
r	0.31	0.14[d]	0.26
P value	.06	.40[d]	.11
95% CI	−0.01 to 0.57	−0.19 to 0.44[d]	−0.07 to 0.54
Spatial-Memory			
r	0.26	0.23[d]	0.19
P value	.12	.16[d]	.25
95% CI	−0.07 to 0.54	−0.10 to 0.51[d]	−0.14 to 0.48
Path-Tracking			
r	*0.43* [d]	0.04	0.04[d]
P value	*.007* [d]	.81	.80[d]
95% CI	*0.13 to 0.66* [d]	−0.28 to 0.36	−0.28 to 0.36[d]
Maze			
r	0.30[d]	−0.05	0.17[d]
P value	.06[d]	.78	.29[d]
95% CI	−0.02 to 0.57[d]	−0.36 to 0.27	−0.16 to 0.46[d]

[a]BD: Block Design.
[b]DS: Digit Span.
[c]MR: Matrix Reasoning.
[d]Indicates that the 2 were expected to be correlated in Table 1.
[e]Italics indicate that a correlation existed.

Table 6. Correlations (Spearman r_{42}, 2-tailed *P* value, and 95% CI) between the e-Cube scores and raw scores of the Wechsler Adult Intelligence Scale, Fourth Edition, subtests in the adaptive group.

Adaptive game	BD[a]	DS[b]	MR[c]
Assembly			
r	*0.49* [d,e]	0.18	0.31
P value	*<.001* [d]	.25	.05
95% CI	*0.21 to 0.70* [d]	−0.14 to 0.47	−0.00 to 0.57
Shape-Matching			
r	0.26	0.22	*0.34* [d]
P value	.09	.16	*.03* [d]
95% CI	−0.06 to 0.53	−0.10 to 0.50	*0.03 to 0.59* [d]
Sequence-Memory			
r	*0.34*	0.21[d]	0.11
P value	*.03*	.19[d]	.50
95% CI	*0.03 to 0.59*	−0.11 to 0.49[d]	−0.21 to 0.41
Spatial-Memory			
r	0.09	*0.51* [d]	0.17
P value	.59	*<.001* [d]	.29
95% CI	−0.23 to 0.39	*0.24 to 0.71* [d]	−0.15 to 0.46
Path-Tracking			
r	*0.45* [d]	–0.01	*0.45* [d]
P value	*.003* [d]	.93	*.003* [d]
95% CI	*0.16 to 0.67* [d]	−0.32 to 0.30	*0.16 to 0.67* [d]
Maze			
r	0.30[d]	0.07	0.11[d]
P value	.05[d]	.62	.49[d]
95% CI	−0.01 to 0.56[d]	−0.25 to 0.37	−0.21 to 0.41[d]

[a]BD: Block Design.

[b]DS: Digit Span.

[c]MR: Matrix Reasoning.

[d]Indicates that the 2 were expected to be correlated in Table 1.

[e]Italics indicate that a correlation existed.

Technical Reliability and Usability of e-Cube

The e-Cube technology operated smoothly without any substantial technical issues identified during the study. The false detection rate, defined as the percentage ratio of incorrect detections to the total number of detections, was approximately 0.1% (6/5990). We note that all the analyses and computations mentioned previously were based on the corrected data. To analyze the results of the SUS, the scores from the 10 items were converted into a scale of 0 to 100 [47]. The overall mean SUS score was 83.40 (SD 11.52). There was a significant group difference in the results. The mean of the SUS scores from the fixed group participants was 80.79 (SD 13.23), whereas the mean score from the adaptive group participants was 86.01 (SD 8.75). The 2-sample, 2-tailed *t* test with Cronbach α=.05 showed t_{78}=–2.10 (*P*=.04). The result from the adaptive group showed a significantly higher mean SUS score with a smaller SD than the fixed group. On the basis of the industry standard [48], the usability of both fixed and adaptive e-Cube games is considered grade A (ie, the games are acceptable).

Discussion

Principal Findings

We presented the design, development, and evaluation of the e-Cube system for automated cognitive assessment. e-Cube is a vision-based system converted from TAG-Games, a computerized system using a set of highly instrumented blocks [28]. e-Cube adopted a set of plastic cubes and a webcam instead, costing only approximately US $50. e-Cube also reduced the labor burden by generating adaptive items, detecting answers and behavior, and scoring autonomously. A total of 6 games—Assembly, Shape-Matching, Sequence-Memory, Spatial-Memory, Path-Tracking, and Maze—were designed using the proposed play complexity measures and adaptive item generators. The e-Cube technology and the adaptive games were evaluated by testing the 2 objectives. This human participant study was conducted on the TAMU campus, and thus, most of our study participants (66/80, 82%) were college students aged between 18 and 30 years, with only 18% (14/80) aged between 31 and 60 years. Therefore, the results must be interpreted considering the skewed age distribution and demographic characteristics.

Objective 1 was supported by the correlation analyses performed between the C_{play} values and the 2 performance indicators—the mean correctness and mean completion time obtained from the fixed group. We found that each game was correlated with at least one performance indicator. The C_{play} values of Assembly, Shape-Matching, and Sequence-Memory showed high correlations with both means. No correlations were found using the mean correctness in Spatial-Memory, Path-Tracking, and Maze. As discussed previously, correctness was not the dominant factor that widened the performance difference in Path-Tracking and Maze; thus, no correlations with correctness were found. For Spatial-Memory, 2 items involved symmetric arrangements of the geometric shapes—which made them easy to memorize regardless of the geometric complexity of the shapes. We used the same play complexity measure for both Spatial-Memory and Assembly, which appeared not to ideally reflect the difficulty associated with such memory tasks despite a high correlation in the mean completion time. This problem can be avoided at the software level by adjusting the algorithm for the item generator. Nevertheless, such symmetric images were rarely created in the adaptive version and, thus, are expected to have minimal effect on the assessment outcome.

To test the preliminary utility of the adaptive e-Cube games for cognitive assessment (*objective 2*), correlation analyses were performed between the scores from the e-Cube games and the WAIS-IV subtests. The adaptive games yielded more significant correlations with the WAIS-IV subtests than the fixed ones. This implies the potential utility of the adaptive feature of the e-Cube games based on the complexity measures. The adaptive version used a discontinuation rule (ie, the substantially small step size leading to the termination of the game), which possibly reduced the number of items in each game, fatigue, and unintended correct answers. For example, given a fixed number of items sorted by increasing difficulties, one may fail to answer correctly in the early items but can unintentionally provide correct answers in the later items. The automatic item generator in the adaptive games adjusts the item complexity based on real-time performance, enabling the system to generate a more appropriate assessment for everyone. Note that the administration of the WAIS-IV also applies the discontinuation rule in the subtests to minimize time [49]. The subtest is terminated when a participant fails to answer a certain number of consecutive items, which differs for each subtest. Intercorrelation analyses also showed that the games in the adaptive version were more independent of one another.

There were some other notable findings from the *objective 2* evaluation study. The mean scores of Shape-Matching and Sequence-Memory in the fixed group were higher than those in the adaptive group (Table 4). In the fixed group, we found that most of the participants (26/38, 68%) correctly answered items 1 to 7 and 9, whereas only 50% (19/38) answered item 8 correctly and 24% (9/38) answered item 10 correctly in Shape-Matching. This inconsistency resulted in a higher mean score in the fixed group, but the results were not correlated with MR. In contrast, the adaptive group showed a significant correlation between Shape-Matching and MR. Sequence-Memory and Spatial-Memory were evaluated to understand which game has a monotonic relationship with DS, but a correlation was only found between the adaptive version of Spatial-Memory and DS. DS measures verbal working memory, which relies on auditory recall of numbers, sequences, and orders. However, Sequence-Memory was performed through the visual recall of geometric images, and Spatial-Memory used visual-spatial images. This fundamental design difference may have led to a lack of correlation. In addition, the language differences in participants and how they differently affect DS scores were not analyzed in this study as we did not collect such background data. Some nonnative speakers mentioned slight difficulty in memorizing the numbers said in English during the DS subtest. This feedback was collected only informally. The Path-Tracking and Maze games were correlated with Assembly, implying that their game settings or measured cognitive outcomes were similar to those of Assembly. Furthermore, Maze was not correlated with any WAIS subtest.

We further analyzed the correlation between the composite scores of the 6 e-Cube games and those of the 3 WAIS subtests. The results were r_{38}=0.51 (95% CI 0.23-0.71; P=.001) for the fixed group and r_{42}=0.53 (95% CI 0.26-0.72; P<.001) for the adaptive group. When only 4 e-Cube games (ie, Assembly, Shape-Matching, Sequence-Memory, and Spatial-Memory) were considered, the results were r_{38}=0.50 (95% CI 0.21-0.71; P=.001) for the fixed group and r_{42}=0.59 (95% CI 0.34-0.76; P<.001) for the adaptive group. Path-Tracking and Maze did not result in any meaningful relationship with the WAIS, and thus, their potential utility in cognitive assessment requires further exploration.

The low false detection rate (0.1%) demonstrated the technical functionality of the e-Cube system. Regarding the usability evaluation (*objective 2*), the average SUS scores from participants in both the fixed and adaptive groups were acceptable based on the industry standard [48]. The adaptive games resulted in a considerably higher mean SUS score with a smaller SD than that of the fixed games. To understand the feedback for individual items, we combined the results from both groups and computed the average rate for each item. The results for the individual SUS items were uniformly positive. For the 5 even-numbered questions that were in a negative tone, such as "I found the e-Cube games unnecessarily complex," all rates were between 1 (*strongly disagree*) and 2 (*disagree*). For the odd-numbered questions that were in a positive tone, the rates were between 4 (*agree*) and 5 (*strongly agree*) except for the following question—"I think that I would like to use the e-Cube games frequently"—with an average rate of 3.8. This was mainly due to the e-Cube games taking relatively long (approximately 50 minutes) to complete at this preliminary stage. Most of our participants (73/80, 91%) were aged <40 years, so using the game frequently to track cognitive decline was unnecessary for them. We received the highest evaluation of 4.5 on the following item: "I found the various functions in the e-Cube games were well integrated among all questions."

Limitations

Most participants (66/80, 82%) were TAMU students aged between 18 and 30 years. The data from participants who were young, educated, and motivated do not represent the general population well. This may also explain why none of the participants withdrew from the study. Furthermore, additional demographic information such as education level, socioeconomic status, race, and ethnicity was not collected in this preliminary evaluation study. A larger-scale validation study will be needed to involve participants from various communities with diverse backgrounds.

The administration order of the 6 e-Cube games was randomized to control for an order effect. The test order can influence the test results and bring about different levels of fatigue [50], so a well-developed cognitive assessment usually requires a standardized administration order. Although order and fatigue effects were not found in some standardized tests [50,51], the impact of the administration order of e-Cube on the scores was not investigated.

The WAIS-IV DS includes Forward, Backward, and Sequencing, which measure auditory working memory and attention with information reordering. However, Sequence-Memory and Spatial-Memory rely on visual recall and do not require any manipulation of information. Therefore, DS may not be an ideal choice for validating these 2 games. Another measure, such as Spatial Span Forward in the Wechsler Memory Scale, Fourth Edition, may be selected to compare the results with those of Sequence-Memory and Spatial-Memory in measuring relevant working memory skills.

Future Work

The e-Cube technology was developed for fully autonomous administration and scoring of cognitive assessment targeting fine motor, hand-eye coordination, cognitive reasoning, and working memory skills. Building on our prior work [26,28], the technology was converted into a much simpler, cheaper, and easy-to-use form, thus showing potential for use in larger-scale research studies. Our long-term objective is for the e-Cube games to serve as a routine self-assessment tool used by individuals who require continuous monitoring of their cognitive health, such as older adults and people with mild cognitive impairment. Once fully established, e-Cube can also be adapted in clinical settings, especially for remote assessment without requiring in-person interactions with an administrator. Our future work will be geared toward this long-term objective.

This extended human participant study will involve diverse participants (eg, age, sex, education, and socioeconomic status) to better represent the general population. In this future evaluation study, the existing instruments for comparison must be revisited and selected to ensure that the measures match the target cognitive domains of individual e-Cube games. Future work will also aim to establish reliability via test-retest evaluation and the validity of self- and remote administration functions via comprehensive and comparative evaluations. The study to understand the user experiences may also be extended by including an additional set of questionnaires to compare traditional instruments and the e-Cube games to gauge their preference if the e-Cube system is proven to replace some of these. To further improve the technical performance, additional vision processing methods may be added to improve this rate, such as hand detection algorithms to prevent hand motions from interfering with block detection.

The rich data from the e-Cube games on patterns, speed, and characteristics of physical movements applied to the cubes can also be explored to further explicate individual differences and cognitive and fine motor deficits. Such behavioral data may hold important information about individuals, especially those with cognitive deficits exacerbated by fine motor deficits or other behavioral symptoms such as hand tremors. Furthermore, the data provided by e-Cube have the potential to assess one's cognitive skills in a more objective way than in standard clinical settings. Upon validating its utility as a cognitive assessment tool, our future research may explore the e-Cube games for screening of early signs of neurological diseases. For the e-Cube games to be used as a routine assessment tool, we will consider shortening and gamifying the assessment to make it more fun and engaging. Enhanced graphics and sound and visual feedback mechanisms may be added to the game design. For example, we may benchmark the features of Music Blocks and iSIG-Blocks [52,53], allowing the users to customize audio, tactile, and visual sensory feedback during the cognitive assessment. The current system runs on a low-end laptop with a webcam, whereas further developments can make the algorithms executable on a tablet or cell phone using their built-in cameras. This may further reduce the cost, make it suitable for self- or remote assessment, and support long-term adoption and broader use of the technology.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Intercorrelations (Spearman r_{38}, 2-tailed *P* value, and 95% CIs) within the scores of fixed games.

[DOCX File , 26 KB - games_v11i1e40931_app1.docx]

Multimedia Appendix 2

Intercorrelations (Spearman r_{42}, 2-tailed *P* value, and 95% CIs) within the scores of adaptive games.

[DOCX File , 25 KB - games_v11i1e40931_app2.docx]

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Abbreviations

BD: Block Design
DS: Digit Span
GLCM: gray-level co-occurrence matrix
MR: Matrix Reasoning
SUS: System Usability Scale
TAMU: Texas A&M University
WAIS: Wechsler Adult Intelligence Scale
WAIS-IV: Wechsler Adult Intelligence Scale, Fourth Edition

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Original Paper

Advantages of a Training Course for Surgical Planning in Virtual Reality for Oral and Maxillofacial Surgery: Crossover Study

Max Ulbrich[1]; Vincent Van den Bosch[2], MD; Andrea Bönsch[3], MSc; Lennart Johannes Gruber[1], DMD; Mark Ooms[1], MD; Claire Melchior[1]; Ila Motmaen[1], DMD; Caroline Wilpert[2], MD; Ashkan Rashad[1], MD, DMD; Torsten Wolfgang Kuhlen[3], PhD; Frank Hölzle[1], PhD, MD, DMD; Behrus Puladi[1,4], MD, DMD

[1]Department of Oral and Maxillofacial Surgery, University Hospital RWTH Aachen, Aachen, Germany

[2]Department of Diagnostic and Interventional Radiology, University Hospital RWTH Aachen, Aachen, Germany

[3]Visual Computing Institute, Faculty of Mathematics, Computer Science and Natural Sciences, RWTH Aachen University, Aachen, Germany

[4]Institut of Medical Informatics, University Hospital RWTH Aachen, Aachen, Germany

Corresponding Author:
Behrus Puladi, MD, DMD
Department of Oral and Maxillofacial Surgery
University Hospital RWTH Aachen
Pauwelsstraße 30
Aachen, 52074
Germany
Phone: 49 241 80 88231
Fax: 49 241 80 82430
Email: bpuladi@ukaachen.de

Abstract

Background: As an integral part of computer-assisted surgery, virtual surgical planning (VSP) leads to significantly better surgery results, such as for oral and maxillofacial reconstruction with microvascular grafts of the fibula or iliac crest. It is performed on a 2D computer desktop screen (DS) based on preoperative medical imaging. However, in this environment, VSP is associated with shortcomings, such as a time-consuming planning process and the requirement of a learning process. Therefore, a virtual reality (VR)–based VSP application has great potential to reduce or even overcome these shortcomings due to the benefits of visuospatial vision, bimanual interaction, and full immersion. However, the efficacy of such a VR environment has not yet been investigated.

Objective: This study aimed to demonstrate the possible advantages of a VR environment through a substep of VSP, specifically the segmentation of the fibula (calf bone) and os coxae (hip bone), by conducting a training course in both DS and VR environments and comparing the results.

Methods: During the training course, 6 novices were taught how to use a software application in a DS environment (3D Slicer) and in a VR environment (Elucis) for the segmentation of the fibula and os coxae, and they were asked to carry out the maneuvers as accurately and quickly as possible. Overall, 13 fibula and 13 os coxae were segmented for each participant in both methods (VR and DS), resulting in 156 different models (78 fibula and 78 os coxae) per method (VR and DS) and 312 models in total. The individual learning processes in both environments were compared using objective criteria (time and segmentation performance) and self-reported questionnaires. The models resulting from the segmentation were compared mathematically (Hausdorff distance and Dice coefficient) and evaluated by 2 experienced radiologists in a blinded manner.

Results: A much faster learning curve was observed for the VR environment than the DS environment (β=.86 vs β=.25). This nearly doubled the segmentation speed (cm^3/min) by the end of training, leading to a shorter time (*P*<.001) to reach a qualitative result. However, there was no qualitative difference between the models for VR and DS (*P*=.99). The VR environment was perceived by participants as more intuitive and less exhausting, and was favored over the DS environment.

Conclusions: The more rapid learning process and the ability to work faster in the VR environment could save time and reduce the VSP workload, providing certain advantages over the DS environment.

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KEYWORDS

virtual surgical planning; virtual reality; Elucis; 3D Slicer; oral and maxillofacial surgery

Introduction

Malignant or benign tumors, advanced osteomyelitis, osteoradionecrosis, and complex fractures can lead to extensive bone and soft tissue defects with the need for reconstruction. Therefore, soft and hard tissue reconstruction is an important and commonly used procedure in oral and maxillofacial surgery [1]. Microvascular reconstruction with fibula or iliac crest bone transplants is one of the best options for mandible bone reconstruction [2,3], and it has the highest success rate and delivers the best functional and esthetic results [4,5]. Microvascular reconstruction has been performed using a conventional technique, specifically manual free transplant raising, adjustment, and insertion [6,7].

Given its numerous clinical advantages, a virtual surgical planning (VSP) approach prior to microvascular reconstruction of the jaw has seen increased popularity. This approach involves using preoperative medical imaging within computer-assisted surgery (CAS) applications [8,9]. The advantages of VSP include reduced ischemia, a shorter defect reconstruction time, a shorter surgical procedure [10], a shorter length of hospital stay [10], a lower number of necessary osteotomy revisions, an overall lower volume of bone removed, a lower rate of osseous injury [11], and a better match of removed bone volume to defect volume [12].

However, VSP is associated with a higher preoperative workload [8] and is therefore often delegated to younger fellows or technical staff [13,14]. Despite this, VSP still remains an integral part of the surgical process and should be done or supervised by the performing surgeon [15]. Furthermore, learning VSP is time-consuming and requires an appropriate amount of learning time, but these investments are required to ultimately achieve good clinical outcomes [15-18].

One of the main bottlenecks is the preparation of 3D models by segmentation [19]. This process is still performed on a 2D computer desktop screen (DS) with 2D controls, such as a mouse and keyboard [20], which however seems unsuitable per se for such a task [21]. Furthermore, working in a DS environment differs from working in a surgical site since the DS environment lacks stereoscopic vision, and the use of a mouse and keyboard does not resemble working with surgical instruments at all. This leads to discrepancies between the VSP performed in a DS environment and the surgery performed in an operating theater.

A potential way to overcome the disadvantages of VSP performed in a DS environment could be the use of virtual reality (VR) [22] since it offers stereoscopic vision, allows the user to work manually, and allows more focused work due to immersion [21,23]. VR environments better resemble realistic work routines in the operating theater, as users can rotate and flip anatomical structures and observe different intraoperative viewing angles [24], thus enabling an enhanced understanding of the anatomy [25]. Although VR more broadly has been applied to surgery, it has often been basic or partially immersive VR. This must be distinguished from enhanced, fully immersive, binocular head-based VR [26]. With the so-called second wave that began in 2012, this technology has significantly spread in the consumer market and must be distinguished from augmented reality–based systems, which have become widespread under the terms mixed or extended reality [27]. Areas of application for these new VR head-mounted displays (HMDs) are surgical education, surgical training, and surgical planning [28]. VR simulations have been shown to lead to an improvement in surgical skills among subjects [29]. VR was also used for the visualization of medical images in radiology [22]. Recently, VR has been used for spatial understanding [30] or in the course of multiuser conferences during surgical planning [31]. However, to our knowledge, the potential for performing all steps or substeps of VSP using VR HMDs has not yet been explored.

This study aimed to demonstrate the possible advantages of a VR environment through a substep of VSP, specifically the segmentation of the fibula (calf bone) and os coxae (hip bone), which is typically applied in oral and maxillofacial surgery, by conducting a training course in both DS and VR environments and comparing the results.

Methods

Cases

We retrospectively selected 78 (13 cases for every 6 participants) planning computed tomography (CT) scans acquired between 2015 and 2020 at the University Hospital RWTH Aachen originally intended for VSP for the mandible, maxilla, or other viscerocranial sites for microvascular reconstruction. The CT scans were first scored by 2 trained radiologists based on image quality (1, good; 2, moderate; 3, poor), bone quality (1, good; 2, moderate; 3, poor), and artifacts (1, none; 2, moderate; 3, plenty), and from this, a total score (range 3-9) was then derived for each case and radiologist. A mean value was then calculated for each case based on the 2 radiologists’ total scores.

Ethics Approval

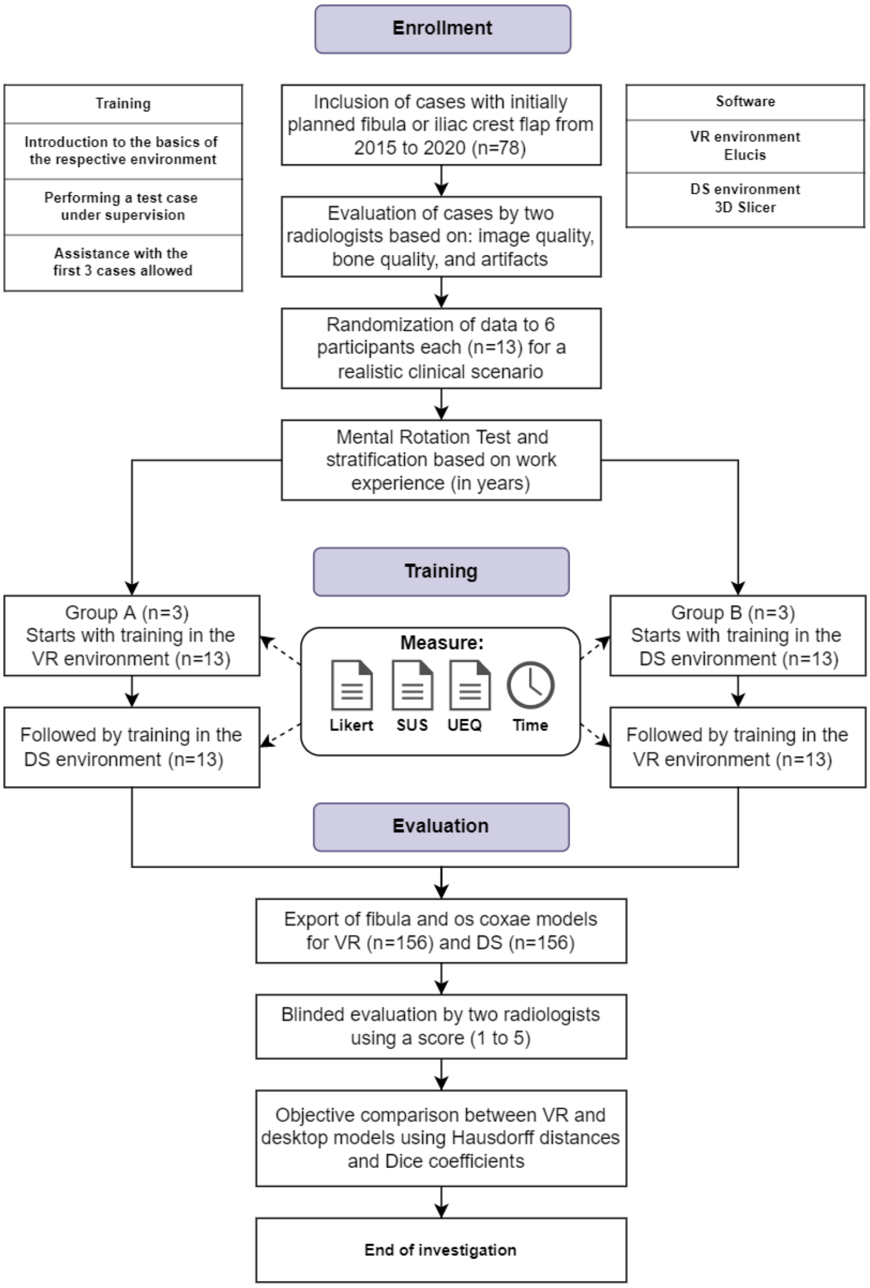
The local ethics committee of the Medical Faculty of RWTH Aachen University approved our study (approval number EK 471/20). The experimental protocol was carried out in accordance with the guidelines set by the Declaration of Helsinki. Informed consent was obtained from all participants involved in the study.

Study Design

A total of 6 novices in VSP (5 oral and maxillofacial surgery residents and 1 final-year dentistry student) took part in the study. Each participant’s age (mean 33.2, SD 2.6 years), gender (1 female, 5 males), surgical work experience (0-4 years), prior experience with computers, and prior experience with VR were recorded. Each participant performed a mental rotation test [32] before training to examine the influence of their baseline visuospatial ability on segmentation performance.

All novices received an introduction to the basic principles of the VSP application. The participants were stratified into the following 2 groups based on surgical work experience: Group A (4 years, 3 years, and 0 years in residency) and Group B (4 years, 2 years, and 1 year in residency). Group A was trained with 13 (3 cases for initial warm-up and 10 cases for autonomous training) randomly selected (for a realistic clinical scenario) cases per participant, first in the DS environment and thereafter in the VR environment. In contrast, Group B was trained with 13 randomly selected cases per participant, first in the VR environment and thereafter in the DS environment (Figure 1). This ensured that a potential learning effect gained in one environment and transferred to the other was evenly distributed between both [18,33]. The given task of the training was the segmentation of the fibula (a simpler model) and os coxae (a more complex model) of the right side of the body in the corresponding working environment. The participants were asked to carry out their tasks as accurately and quickly as possible. In the case of relevant bone defects, the left side was used.

Figure 1. Graphic illustration of the study protocol. A total of 78 computed tomography scans were included, scored by 2 radiologists for image quality, and randomized to 6 participants, who additionally performed a mental rotation test before training. Subsequently, the 6 participants were stratified into Groups A and B, each of which started with the virtual reality (VR) or desktop screen (DS) environment, respectively. During the training, Likert-type questionnaires were filled out, and segmentation time was measured. After training, the System Usability Scale (SUS), the User Experience Questionnaire (UEQ), and a final Likert-type questionnaire were administered. After training, all fibula and hip bone models were compared using the Hausdorff distance and the Dice coefficient, and additionally evaluated in a blinded fashion by the same 2 radiologists.



Each participant received an appropriate briefing in the corresponding working environment (DS or VR) with an explanation of all important functions, whereby the standard analog functions of both applications had to be used within a test case. Subsequently, the task was carried out based on a test case under the supervision of an experienced user who offered verbal guidance throughout each work step. The participants then started to work on the 13 cases. The opportunity to ask questions was allowed only for the first 3 cases to ensure a realistic clinical scenario. After each case, the procedure time was recorded (for fibula and os coxae segmentation, respectively), and a Likert-type questionnaire was completed [34]. All participants successfully completed the training. After completing the training for both environments, a final Likert-type questionnaire was completed. Additionally, for each application, the User Experience Questionnaire (UEQ) [35] and System Usability Scale (SUS) [36] were administered.

DS-based training was performed using 3D Slicer version 4.11.20210226 [37], and VR-based training was performed using Elucis version 1.4 (Realize Medical Inc). The VR hardware included an HTC Vive Pro with an HTC Vive Controller 2.0 (Valve Corporation). All training was done seated (Figures 2-5) at the same workstation (AMD Ryzen 3900X CPU with 64 GB of memory and an RTX 2080 Ti graphics card).

Figure 2. The virtual reality working environment (Elucis) and a segmented hip bone model in yellow in the middle.

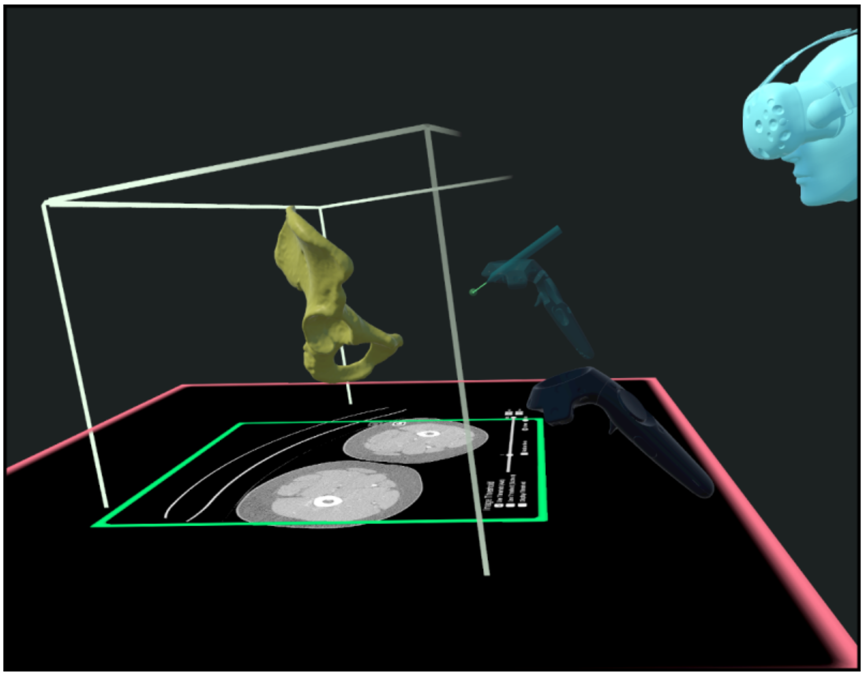


Figure 3. The virtual reality working environment from a third-person perspective.

Figure 4. The classic desktop screen working environment (3D Slicer) with an already segmented os coxae (hip bone) model in yellow.

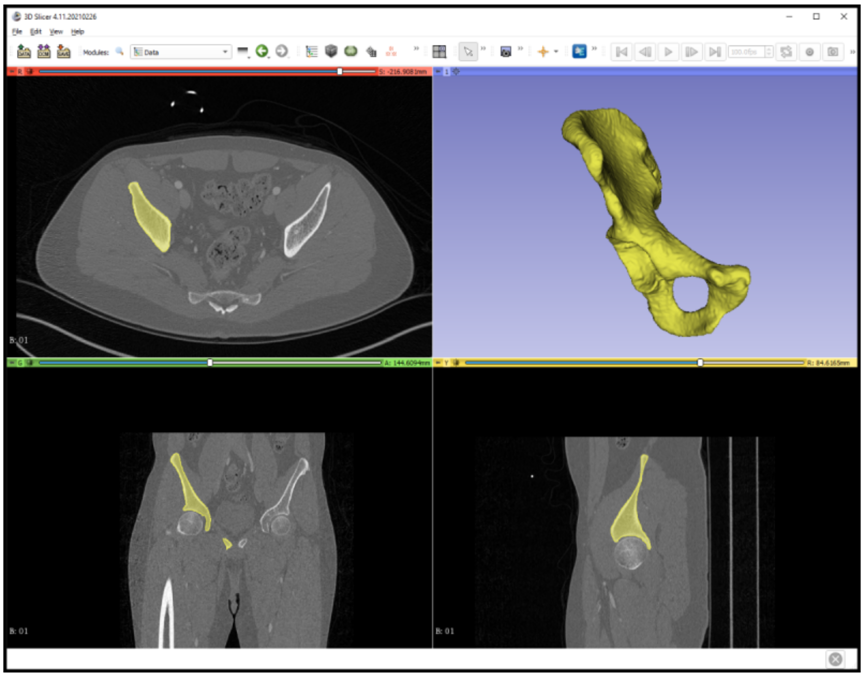
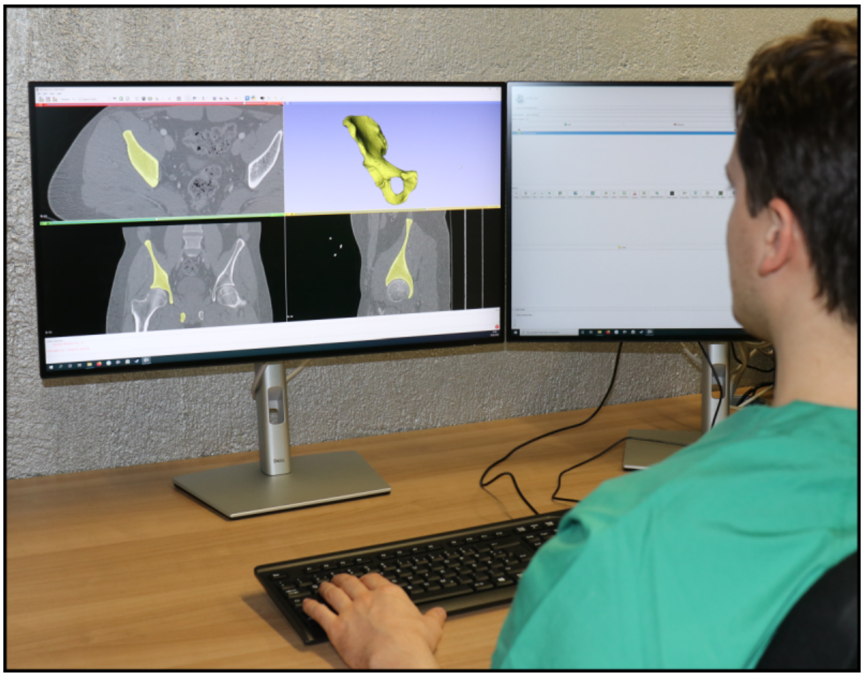


Figure 5. The desktop screen working environment from a third-person perspective.



Evaluation

All segmented models of the fibula and os coxae (n=156) were assessed in a blinded setting by the same 2 trained radiologists using an absolute category rating (1, excellent; 2, good; 3, fair; 4, poor; 5, bad). Based on the evaluation of both radiologists, a mean value was calculated.

Afterwards, the postprocessing of all cases was performed using the 3D Slicer add-on Surface Wrap Solidify [38] to remove cavities in the models. This was necessary to avoid bias when comparing the volumes or surfaces of the models. Hausdorff distances and Dice coefficients [39] were then computed using the 3D Slicer add-on segment comparison [40] between the DS model and the VR model. Finally, intersection volumes (cm^3) between the VR and DS models were divided by segmentation duration (minutes) to calculate common segmentation performance (cm^3/min).

Statistical Analysis

Statistical analysis was performed using the programming language R (Version 4.1.1; R Foundation for Statistical Computing). A *P* value <.05 was considered significant. We used a *t* test, a Wilcoxon signed-rank test, or a chi-square test to assess differences between VR and DS. The training effect as a function of the environment was determined as the duration of task completion using a linear mixed effect model with the

R package lme4. For the model-based evaluations, a likelihood ratio test of the corresponding parameters was used to evaluate the relationships between dependent and independent variables. *P* values were adjusted for multiple testing using the Holm-Bonferroni method [41]. The 95% CIs were calculated by conventional bootstrapping with 1000 replications [42]. Plots were visualized using the R package ggplot2.

Results

Segmentation

The average overall radiologist ratings for the segmentation results were 1.40 (1, excellent; 5, bad) for the VR models and 1.29 for the DS models, and were not significantly different (Wilcoxon signed-rank test, *P*=.29). Similarly, there was no significant difference in radiologist assessment for the os coxae (VR 1.62 vs DS 1.39; Wilcoxon signed-rank test, *P*=.14) or fibula (VR 1.17 vs DS 1.17; Wilcoxon signed-rank test, *P*=.99; Table 1). Furthermore, regarding clinical use (models with a score ≤2/good), there was no relevant difference between VR and DS for all models, os coxae models, and fibula models (χ^2, *P*=.99, *P*=.99, and *P*=.99, respectively). Thus, the VR models are equally suitable for clinical use as the DS models.

Table 1. Results of metric evaluations and blinded assessments by 2 radiologists.

Model and characteristics (n=312)	VR[a] environment, mean (SD)	DS[b] environment, mean (SD)	Difference, mean (SD)
Os coxae (hip bone)			
Bone volume (cm^3)	341 (65)	329 (62)	12 (12)
Segmentation duration (min)	22.5 (13.0)	38.7 (22.6)	−16.2 (21.3)
Segmentation performance (cm^3/min)	19.2 (12.8)	12.0 (8.6)	7.2 (4.2)
Segmentation quality (range 1-5)	1.62 (0.76)	1.39 (0.63)	0.23 (0.78)
Hausdorff distance (mm)	N/A[c]	N/A	0.43 (0.19)
Dice coefficient (%)	N/A	N/A	0.96 (0.02)
Fibula (calf bone)			
Bone volume (cm^3)	60 (12)	58 (11)	2 (3)
Segmentation duration (min)	12.1 (8.0)	17.0 (11.1)	−4.9 (8.3)
Segmentation performance (cm^3/min)	6.5 (2.9)	4.7 (4.0)	1.8 (1.1)
Segmentation quality (range 1-5)	1.17 (0.38)	1.20 (0.44)	−0.03 (0.52)
Hausdorff distance (mm)	N/A	N/A	0.29 (0.12)
Dice coefficient (%)	N/A	N/A	0.96 (0.02)

[a]VR: virtual reality.

[b]DS: desktop screen.

[c]N/A: not applicable.

In contrast, the segmentation results from the VR environment were considered better than those from the DS environment by the participants themselves for both the os coxae models (7-point Likert scale [1, strongly disagree; 7, strongly agree], VR 5.5 vs DS 4.0) and fibula models (7-point Likert scale, VR 5.8 vs DS 5.1; Table 2). For the os coxae, the mean Hausdorff distance between VR and DS was 0.43 (SD 0.19) mm with a Dice coefficient of 96% (SD 2%). For the fibula, the mean Hausdorff distance between VR and DS was 0.29 (SD 0.12) mm with a Dice coefficient of 96% (SD 2%) (Table 1). The mean segmentation time of the os coxae models was 22.5 (SD 13.0) minutes for VR and 38.7 (SD 22.6) minutes for DS, and that of the fibula models was 12.1 (SD 8.0) minutes for VR and 17.0 (SD 11.1) minutes for DS (Figure 6; Table 1).

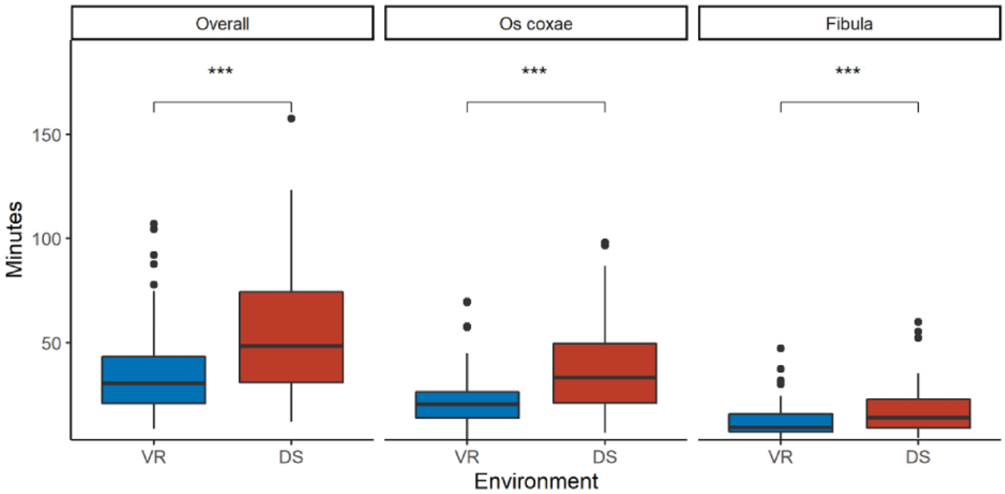
Table 2. Results of the Likert-scale questionnaire after each of the 13 training cases.

Likert (7-point) questions	Score in the VR[a] environment (n=78), mean (SD)	Score in the DS[b] environment (n=78), mean (SD)	Difference, mean (SD)
I learned something through this segmentation process.	5.7 (1.2)	4.9 (1.2)	0.8 (1.2)
I feel exhausted after the segmentation process.	4.4 (1.5)	5.2 (1.5)	−0.8 (1.8)
I had to repeat steps during segmentation.	4.3 (1.6)	5.0 (1.6)	−0.7 (1.6)
I consider this fibula to be adequately segmented.	5.8 (1.1)	5.1 (1.2)	0.7 (1.2)
I find this iliac crest to be adequately segmented.	5.5 (1.1)	4.0 (1.6)	1.5 (1.6)
I was able to orient myself spatially well during segmentation.	6.3 (0.7)	4.4 (1.3)	1.9 (1.7)

[a]VR: virtual reality.

[b]DS: desktop screen.

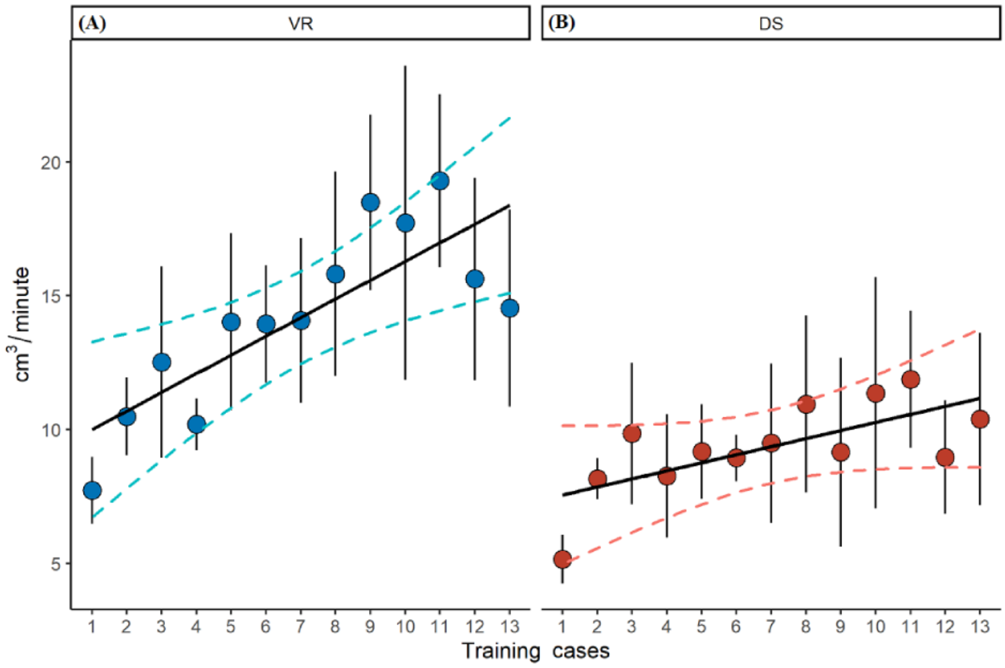
Figure 6. Comparison of segmentation time in minutes between the virtual reality (VR) environment (Elucis) in blue and the desktop screen (DS) environment (3D Slicer) in red shown as box-and-whisker plots. Box-and-whisker plots: boxes represent the IQR, thus representing 50% of data (Q1-Q3); the lower whisker is defined as Q1 − 1.5 × IQR; the upper whisker is defined as Q3 + 1.5 × IQR; the horizontal line in the middle of the box represents the median; and points are outliers. Additionally, the significance level of the respective Wilcoxon signed-rank test is shown above. The y-axis shows the segmentation time in minutes, and the x-axis shows the environment (VR vs DS). ****P*<.001.



Training Curve

The linear mixed effect model (adjusted for work experience, mental rotation test, CT quality, segmentation quality, and training group) showed a significant increase in segmentation volume per minute (cm^3/min) for the VR environment (β=.86; *P*<.001). While the training effect for the DS environment was not significant anymore after *P* adjustment (β=.25; *P*=.26; Figure 7). Lower CT quality had no influence on the segmentation process (*P*=.25). Segmentation performance was significantly higher in the VR environment than in the DS environment for the os coxae models (mean 19.2, SD 12.8 vs mean 12.0, SD 8.6 cm^3/min; paired *t* test, *P*<.001) and for the fibula models (mean 6.5, SD 2.9 vs mean 4.7, SD 4.0 cm^3/min; paired *t* test, *P*<.001; Table 1). These results correlated with the results of the Likert-type questions concerning the learning effect, exhaustion, and the perceived need to repeat steps (Table 2).

Figure 7. The segmented volume (cm3) per minute over the course of the 13 training cases in the (A) desktop screen (DS) environment and (B) virtual reality (VR) environment. The error bars represent the standard error of the mean, and the individual points are the mean values for the corresponding training case. The black line represents a linear model, and the dashed lines represent the 95% CIs of the model.



Environment

Overall, the participants clearly preferred the VR environment over the DS environment in a poststudy questionnaire (Tables 3 and 4). The UEQ results showed that the participants assessed the VR environment to be better in terms of attractiveness, dependability, efficiency, novelty, perspicuity, and stimulation (Figure 8). The SUS results showed that Elucis was rated 83.3 (95% CI 75.3-90.8) and 3D Slicer was rated 30.4 (95% CI 20.1-38.3).

Table 3. Results of the Likert-scale questionnaire after completion of training.

Likert (7-point) questions	Score in the VR[a] environment (n=6), mean (SD)	Score in the DS[b] environment (n=6), mean (SD)	Difference, mean (SD)
Segmentation in this environment was easy for me.	6.5 (0.5)	3.8 (1.9)	2.7 (2.0)
I would prefer this environment for VSP[c].	7.0 (0.0)	2.5 (0.5)	4.5 (0.5)
This work environment seems intuitive to me.	6.8 (0.4)	2.3 (1.0)	4.5 (1.0)
I suspect this work environment will continue to be the gold standard in clinical practice for VSP.	6.7 (0.8)	2.2 (0.8)	4.5 (1.4)
Monoscopic (DS) or stereoscopic (VR) vision in this environment made segmentation easy for me.	6.7 (0.5)	2.2 (1.2)	4.5 (1.5)
I prefer learning segmentation with a mouse and keyboard (DS) or VR controller (VR).	6.7 (0.5)	2.3 (0.8)	4.3 (1.2)
I found learning segmentation easy in this environment.	6.3 (0.5)	3.2 (1.2)	3.2 (1.2)
I felt the training scheme was appropriate for learning in this environment.	6.2 (0.8)	5.7 (1.5)	0.5 (1.5)
I felt the number of cases to learn segmentation was sufficient in this environment.	6.3 (0.8)	5.3 (1.2)	1.0 (1.7)
I had fun while learning segmentation in this environment.	7.0 (0.0)	3.8 (1.9)	3.2 (1.9)

[a]VR: virtual reality.

[b]DS: desktop screen.

[c]VSP: virtual surgical planning.

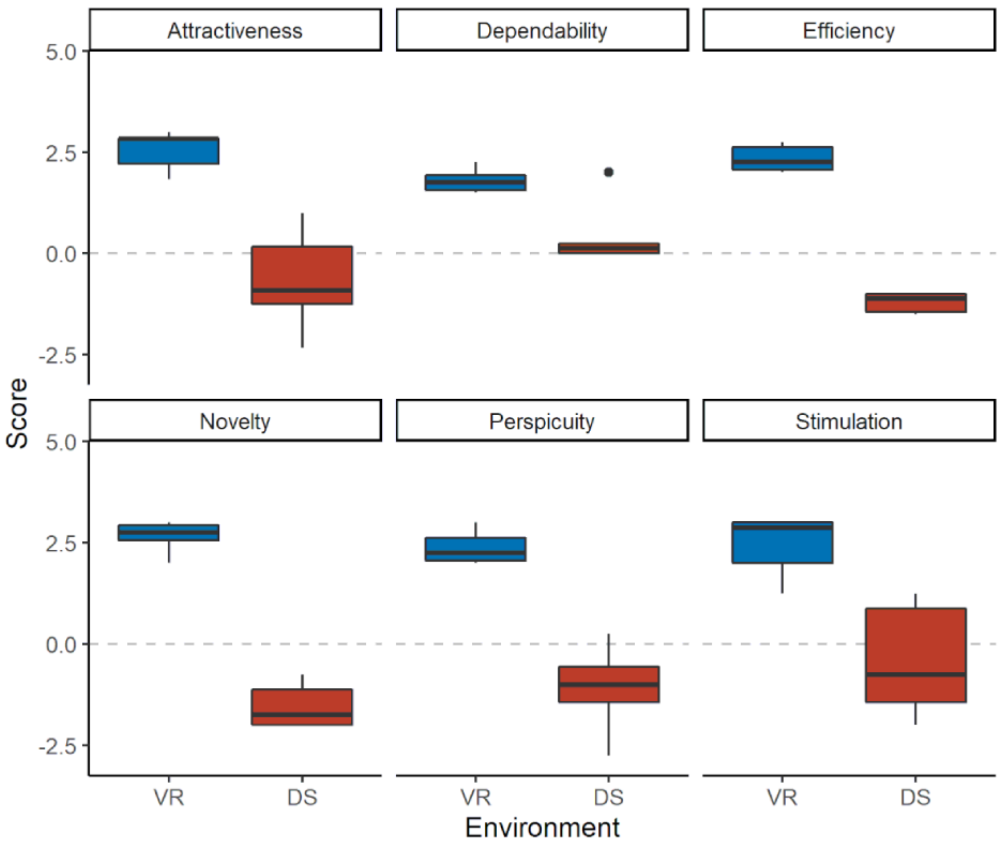
Table 4. Comments of the participants comparing the virtual reality and desktop screen environments.

Participant No.	What aspects of the VR[a] environment do you prefer over the DS[b] environment?	What aspects of the DS environment do you prefer over the VR environment?
1	Spatial vision, working with controllers, similarity to OP site.	Plausibility (you don't have to take off the HMD), work more precisely with the mouse at times, other applications usable.
2	Similarity of actions to surgical activity, stereoscopic vision, good spatial and anatomical orientation.	Island tool.
3	3D perception, rotating and handling the dataset in your own hands, direct segmentation in rendered state; you can directly see the result of segmentation without segmenting in 2D layers.	The possibility of labeling each voxel separately in each layer, if desired; thus, higher accuracy is possible.
4	Intuitive handling, spatial representation, fast learning progress.	Conventional desktop workplace.
5	Very intuitive in comparison, optimal spatial orientation, orientation also with regard to the future operation area, faster learning.	It was possible to use "ADD" function in difficult cases (e.g. calcified vessels in direct neighborhood); calcified vessels and bones often have similar Hounsfield units and cannot be visualized separately in Elucis.
6	Easier to learn, 3D environment easier to control, better spatial overview, much better control.	Lower acquisition costs.

[a]VR: virtual reality.

[b]DS: desktop screen.

Figure 8. User experience questionnaire (UEQ) comparison between the virtual reality (VR) environment (Elucis) in blue and the desktop screen (DS) environment (3D Slicer) in red shown as box-and-whisker plots. Box-and-whisker plots: boxes represent the IQR, thus representing 50% of data (Q1-Q3); the lower whisker is defined as Q1 − 1.5 × IQR; the upper whisker is defined as Q3 + 1.5 × IQR; the horizontal line in the middle of the box represents the median; and points are outliers. The Y-axis shows the UEQ score, and the X-axis shows the environment (VR vs DS). A total of 6 categories were examined (attractiveness, dependability, effectiveness, novelty, perspicuity, and stimulation).



Discussion

VSP in a traditional DS environment is still considered the gold standard, despite its disadvantages, such as being tedious and time consuming [43]. This negates the benefit of time saved in the operating theater due to additional time spent on VSP [13,14]. In this context, VR is a promising approach that might attenuate the mentioned disadvantages of VSP performed in a DS environment.

In this study, the processes of learning VSP, using segmentation as a surrogate parameter, between traditional DS and fully immersive VR environments were compared, as segmentation is a common substep in VSP, a bottleneck in terms of time [19,44], and a crucial factor that determines the accuracy of the final computer-aided design (CAD) result [45]. In general, segmentation is important for not only oral and maxillofacial surgery but also many other medical specialties that require 3D models created by segmentation for the subsequent steps in CAD [45]. Therefore, segmentation was used as a surrogate parameter to measure performance in VR compared to performance in a traditional DS environment during a structured training course. For a representative number of cases (n=156), all participants had to create models of the fibula and os coxae, which are commonly used for microvascular reconstruction of the mandible [2,3], in both environments.

Many studies have shown that VSP is beneficial to patients [14,46]. However, VSP is only feasible if the surgeon is proficient in VSP software. For this reason, the process of learning how to operate such CAS-related software has already been the subject of research in the literature. For example, learning curves upon repetition have been found for VSP for the treatment of orbital fractures or in orthognathic surgery [15,47]. In addition, differences in learning curves when it comes to CAD programs used in dentistry have been found between different software and professional groups (students, technicians, and dentists) [18,33]. Furthermore, the learning curve has been shown to be a function of the complexity of the task for model creation using CAD [48]. However, all these studies used applications in a 2D DS environment, where a computer mouse and keyboard were utilized. This type of work environment is counterintuitive to surgeons who are accustomed to ambidextrous, manual, and visuospatial activity while being very focused. In contrast, VR is more similar to surgical work and therefore offers a promising approach.

The results of our study showed that working in a VR environment is significantly more efficient than working in a DS environment. At the same time, VR has a much faster learning curve (Figure 7). To have a comparable measure between models with different volumes, we used segmentation volume per minute (cm^3/min), assuming that it significantly reflects the number of attempts to solve the task during the acquisition of cognitive and motor skills [48]. At the end of the training program, this was almost twice as high in the VR environment compared to the DS environment. To account for a transfer effect from one method to the other due to the crossover study design, we split the groups in correspondence to similar studies [18,33] and adjusted our model for training method order. To exclude bias from the multiple steps of the VSP as described in other studies that have evaluated the learning process for an entire VSP/CAS based on the final surgical outcome [15,49], we focused on the process performance itself. The measurable stronger learning effect in the VR environment was also perceived by the participants (Table 2). This is important, as the faster learning of CAD software, such as that for VSP, is also accompanied by increased planning and surgical accuracy, and improved anatomical understanding of the target structures [15,47]. Independent of segmentation performance, it is assumed that for different DS software, with correspondingly longer training periods, the differences will eventually cease to exist [33]. However, this does not explain the large differences observed between the DS and VR environments.

These differences can be explained by the principally different natures of the DS and VR environments. Subjects in our study reported a high degree of anatomical orientation in the VR environment compared to the DS environment (P<.001). One reason for the superior anatomical orientation might be the possibility of obtaining different viewing angles in the VR environment. Specifically, Cha et al demonstrated this advantage [24]. Furthermore, in our study, subjects preferred to work with both hands using 2 VR controllers, appreciated the advantages of stereoscopic vision, and preferred the intuitive perception provided by the VR environment, which might explain their preference for the VR environment over the DS environment overall (Table 3). In summary, this study highlighted the benefits of spatial perception and working in 3D in a VR environment with good orientation in terms of the anatomy and strong similarity to surgical work. Similar results have been found in the use of nonfully immersive VR for CAS of the liver [21]. In the literature, various approaches to using at least nonfully immersive VR in the medical context can be found. For example, stereoscopic monitors have been used in oral and maxillofacial surgery to determine facial soft tissue or orbital volumes [50,51]. Furthermore, they have been used in neurosurgery to train surgeons to resect intracerebral tumors [52] and assess surgical risk as a rehearsal before surgeries [25,53].

Yet, all of the aforementioned approaches lacked the full immersion that comes with using VR HMDs and controllers in both hands, as in our study. In our setting, users held control elements in both hands and worked with them within arm's reach (Figures 2 and 3). This could be another reason for the rapid learning and efficiency of working in VR, as proprioception can then be used. Therefore, subjects felt particularly comfortable, and the highest precision could be achieved [54]. In contrast, working with a computer mouse and keyboard in the DS environment does not allow this. For complex models (os coxae) in comparison to simpler models (fibula), this advantage was even more pronounced in VR than in DS. In addition to the advantages of the stereoscopic visualization of complex models in VR [55], the reasons for this are that complex models require more commands for their implementation [48] and, at the same time, bimanual work in VR is particularly faster [56].

Regarding the segmentation quality of the os coxae model, a certain discrepancy between the radiologists' evaluations and that of the subjects appeared to be a shortcoming, as the subjects tended to overestimate themselves. However, this had no impact on clinical practice, since with a given clinically relevant score of ≤2 (good or excellent), we found no significant difference between the 2 environments. A possible reason for this overestimation could be that in the VR environment by default, usually only 1 slice (axial, coronal, or sagittal) was displayed. In contrast, all 3 slices were displayed in parallel in the DS application. One solution would be to display all 3 slices by default in VR. In addition, a different perception of the 3D models (stereoscopic during segmentation by participants vs monoscopic during evaluation by radiologists) could have influenced this. Another reason could be the resolution capacity of the used VR HMD, causing individual voxels to be blurred. Improved hardware or better delineation of individual voxels in the single-layer view could probably solve this.

Overall, our results suggest that the intrinsic feedback learning effect of VSP, which a surgeon achieves by multiple repetitions of VSP and consecutive surgeries [15], could potentially be at least partially replaced by a training program in this manner for novices in VSP. Therefore, the results of our study suggest that VR should be the environment of choice, given its similarity to actual surgical activity. Furthermore, subjects consistently reported less fatigue and more enjoyment while working in the VR environment (Tables 2 and 3). This was also in line with the SUS results, which clearly rated VR better than DS. The reduced exhaustion can be explained by the shorter time needed to complete the task and possibly by the manual 3D interactions in VR, resembling the surgical working environment more realistically (Table 2). Participants perceived the VR software to be superior to the DS software according to the UEQ results for multiple qualities of experience (Figure 8) and preferred the VR environment over the DS environment (Table 3). This was in line with the results of a study on VR user interfaces for medical marking on 3D models [57]. Yet, these differences are surprising, since both applications basically fulfill the same task.

Experiencing the burden of today’s required levels of documentation, surgeons have long been demanding to spend less time at the computer [58]. This could probably also explain the poor rating for the DS environment, which is similar to the typical unpopular work on a DS computer. However, VR has a more playful character, which might explain the higher ratings for the VR environment. However, this clear difference in rating also shows that VSP applications should be adapted to the needs of surgeons. VR seems to meet these requirements, at least in the case of our test persons. In this context, the following things should be considered. Using a VR environment can lead to VR sickness. However, this was not reported by any of the participants, probably because they were sitting and no dynamic scenes were used [59]. In addition, it should be considered that older adults take longer to adapt when learning new technologies [60]. In this regard, studies have shown that older adults also adapt well to VR [61]. Unlike DS with the use of a keyboard and mouse, in the performance of VSP by older adults, VR can be advantageous, as VR is closer to actual surgery due to the immersive environment, stereoscopic vision, and bimanual working. Another point that needs to be considered is cost. Such a system would have to be acquired first. On the other hand, the use of VR, as shown in our study, is time-saving and could thereby reduce the overall cost of VSP. However, an investigation of cost was outside the scope of our study.

Trials featuring the completion of VSP in a nonfully immersive manner have been described to be very promising in the field of liver surgery [21]. However, to our knowledge, no studies have yet assessed VSP performed completely in fully immersive VR. Future studies should address, aside from segmentation, the other steps of full VSP, with the goal to perform VSP completely in VR.

Apart from the approach shown in our study, semiautomated or fully-automated segmentation algorithms are increasingly being used to accelerate or completely take over segmentation [20]. Yet, our study is concerned about which is the better working environment to perform any kind of VSP. This is even more important since the most common segmentation algorithms require a high amount of time for manual postprocessing [45], and the sole use of fully automated algorithms has still not gained general acceptance in clinical practice due to their high sensitivity to image-related artifacts, a resulting inadequate structure recognition, and a low functional stability [20]. In the future, however, artificial intelligence and VR could be combined, especially to further accelerate tasks in VR.

We not only demonstrated the feasibility of segmentation in VR but also highlighted the advantages of this. Possible explanations for these findings are the more intuitive work interface provided by the VR environment, the better spatial orientation, and the stereoscopic vision [21], which were perceived as great advantages for the purposes of VSP.

Through the crossover design, the subjects represented their own control group, and with a total of 312 experiments, the study achieved good internal validity. To improve the generalization of the results, that is, the external validity, we performed the study with subjects having different surgical experience. However, a greater diversity of subjects could lead to different results. The external validity should be evaluated in a further study, and a multicenter study is preferred to include subjects with experience from other clinics. However, this does not diminish the significance of this study. As with the various phases of drug studies, it is worthwhile to first examine the internal validity. Based on the findings of this study, a subsequent study for good external validity can be planned with more subjects but fewer examinations per subject. Furthermore, it should be considered that 2 different software programs (3D Slicer and Elucis) were compared with each other. Although both programs have a comparable command set, a slight impact cannot be excluded. However, this would not explain the large differences observed.

In contrast to the DS environment, the VR environment offers a more rapid learning curve, provides the ability to work faster, results in increased time saved, and is less exhausting when engaging in segmentation as an important substep of VSP. The VR environment was rated by participants to be easier to learn and to be their environment of choice, possibly due to its similarity to actual surgical activities. Therefore, VR-based VSP could be better integrated into clinical practice. This study can serve as a basis for investigating other common substeps of VSP.

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Data Availability

The data presented in this study are available from the corresponding author upon reasonable request.

Authors' Contributions

BP, MU, AB, FH, and TWK conceptualized the study; MU, BP, and VV contributed to the methodology; MU, BP, VV, CW, and AR contributed to validation; MU, BP, AB, and LJG performed formal analysis; MU, BP, LJG, MO, CM, and IM performed the investigation; BP, FH, and TWK managed the resources; MU, BP, and VV contributed to data curation; MU wrote the original draft; BP, MU, MO, VV, AB, LJG, CM, IM, CW, AR, TWK, and FH reviewed and edited the manuscript; MU, BP, and MO contributed to visualization; BP and FH contributed to supervision; and BP managed project administration. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CAD: computer-aided design
CAS: computer-assisted surgery
CT: computed tomography
DS: desktop screen
HMD: head-mounted display
SUS: System Usability Scale
UEQ: User Experience Questionnaire
VR: virtual reality
VSP: virtual surgical planning

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Original Paper

Design and Evaluation of Using Head-Mounted Virtual Reality for Learning Clinical Procedures: Mixed Methods Study

Siew Tiang Lau[1], BHS, MHS, PhD; Rosalind Chiew Jiat Siah[1], BHS, MHS, PhD; Khairul Dzakirin Bin Rusli[1], BSc; Wen Liang Loh[1], BA, Grad Dip (Psych); John Yin Gwee Yap[1], BA, MA; Emily Ang[1], DNurs; Fui Ping Lim[1], BHSN, MNurs; Sok Ying Liaw[1], BHS, MHS, PhD

Alice Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore, Singapore

Corresponding Author:
Siew Tiang Lau, BHS, MHS, PhD
Alice Centre for Nursing Studies
Yong Loo Lin School of Medicine
National University of Singapore
Level 2, Clinical Research Centre, Block MD 11
10 Medical Drive
Singapore, 117597
Singapore
Phone: 65 66011299
Email: nurlst@nus.edu.sg

Abstract

Background: The capacity of health care professionals to perform clinical procedures safely and competently is crucial as it will directly impact patients' outcomes. Given the ability of head-mounted virtual reality to simulate the authentic clinical environment, this platform should be suitable for nurses to refine their clinical skills for knowledge and skills acquisition. However, research on head-mounted virtual reality in learning clinical procedures is limited.

Objective: The objectives of this study were (1) to describe the design of a head-mounted virtual reality system and evaluate it for education on clinical procedures for nursing students and (2) to explore the experience of nursing students using head-mounted virtual reality for learning clinical procedures and the usability of the system.

Methods: This usability study used a mixed method approach. The stages included developing 3D models of the necessary instruments and materials used in intravenous therapy and subcutaneous injection procedures performed by nurses, followed by developing the procedures using the Unreal Engine (Epic Games). Questionnaires on the perception of continuance intention and the System Usability Scale were used along with open-ended questions.

Results: Twenty-nine nursing students took part in this questionnaire study after experiencing the immersive virtual reality (IVR) intervention. Participants reported largely favorable game perception and learning experience. Mean perception scores ranged from 3.21 to 4.38 of a maximum score of 5, while the mean system usability score was 53.53 of 100. The majority found that the IVR experience was engaging, and they were immersed in the game. The challenges encountered included unfamiliarity with the new learning format; technological constraints, such as using hand controllers; and physical discomfort.

Conclusions: The conception of IVR for learning clinical procedures through deliberate practice to enhance nurses' knowledge and skills is promising. However, refinement of the prototypes is required to improve user experience and learning. Future research can explore other ways to use IVR for better education and health care purposes.

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KEYWORDS

user experience; acceptability; usability; virtual patient; clinical procedure; immersive; nursing student; virtual reality; education; performance

Introduction

Overview

Generation Z students are well recognized to have different learning needs and preferences than previous generations [1]. With the advancement of medical technology and treatment, coupled with dynamic clinical settings, the ability of nurses to perform clinical procedures safely and competently is of paramount importance. The issue of ensuring competency prior to performance on actual patients remains crucial for patient safety. Therefore, new teaching strategies are needed to bridge the teaching-learning gap to create an effective learning environment. The use of technology to meet the challenges of medical education has been well documented [2,3]. Simulation sessions using manikins in clinical laboratory settings have been established for more practice. However, these simulation sessions are usually conducted in small groups and are labor and resource intensive. Studies also suggest that these conventional teaching methods do not fully meet the needs, interests, and learning preferences of Generation Z students [4,5]. The novel discovery of virtual technology has been explored for its effectiveness in enhancing students' learning in nursing education [3,6,7].

Immersive virtual reality (IVR) is highly visual and conducive to procedure-focused learning. IVR provides first-person active learning where learners can interact with 3D objects and characters [8]. With immersive 3D virtual reality (VR), learners can perform clinical procedures in a real clinical environment. It is well established that IVR as a medium of instruction facilitates interaction and immersion [9]. This enhances learning through the learner's psychological constructs, such as presence and agency. Presence forms the conditions, and agency gives autonomy of control to gain experience through immersive technology [9]. In designing IVR training, it is important to understand the factors influencing learning. Factors such as perceived realism, usability, and learning are crucial to learners' attitude toward the use of VR [10]. Hence, VR features, learning experiences, usability, and learning theories that guide the learning process are vital constructs when designing an IVR training environment [10].

The transformation of nursing education has been rapidly evolving with the advancement of VR technology. IVR allows learners to obtain repeated hands-on practice to understand concepts and master procedures, exercise their problem-solving skills, and develop confidence prior to managing actual patients in clinical settings. IVR allows learners to practice safely without risk to patients and empowers them for self-directed and regulated learning. IVR was reported to be used frequently to teach procedural-practical knowledge [11]. Although there have been nursing VR simulations conducted to improve technical knowledge and proficiencies, these studies focused mainly on linear step-by-step intervention, and the order of the steps played an important role [12,13]. Systematic reviews evaluating the effectiveness of IVR report that it improved knowledge and learning experiences, but the reviews' findings were inconclusive for skills, satisfaction, confidence, and performance in health care education [14-17].

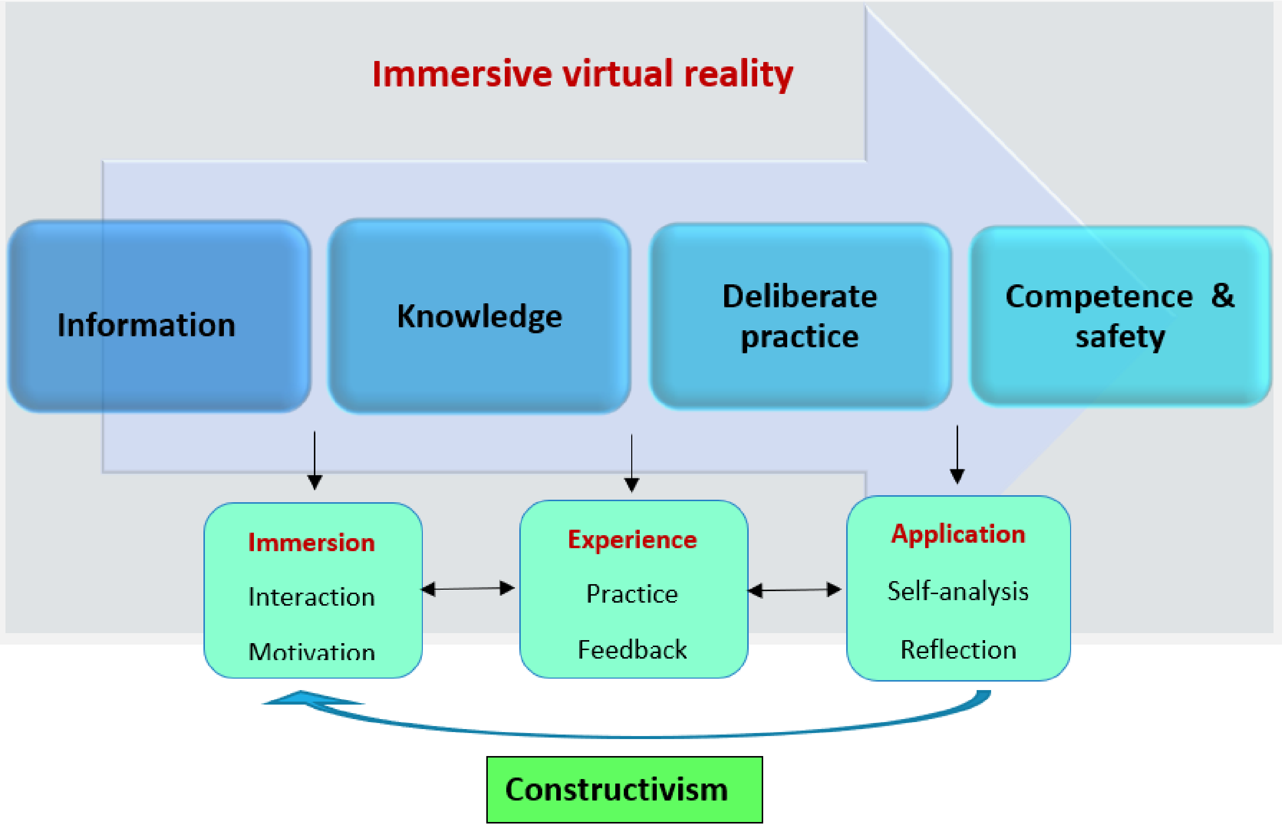
Theoretical Framework

The conceptual frameworks that guided this study are cognitivism, constructivism, and experiential learning through deliberate practice [18]. Cognitivism theory has been used for information processing in the context of VR. Learning in VR involves immersion, interaction, imagination, motivation, and transformation of new knowledge to enhance problem-solving capability [18,19]. Through the constructivism approach, students engage with the environment and are actively involved in building a scaffold for their learning to construct and develop new skills and meaningful knowledge [20,21]. Experiential learning refers to knowledge creation through the acquisition and transformation of experiences [22]. Through first-hand individual experiences using IVR, students are motivated to learn more in a safe and convenient environment for practice. The interaction with a task in VR allows the construction of learning experiences via abstract, active, and reflective processes of the experiential learning cycle [21,23]. With experiential learning and timely built-in feedback, students will be able to work on areas that they need to improve through self-analysis and reflection and achieve competence through meaningful learning.

Deliberate practice is the repetitive performance of a cognitive or psychomotor task in a focused domain combined with rigorous skills assessment [24]. Through deliberate practice, students learn new knowledge, analyze, reflect, and problem-solve cyclically for self-improvement [22,25]. With mastery of their experience, students can use deliberate practice, receive feedback on their own performance, improve self-efficacy, and construct new knowledge through experience, as shown in Figure 1.

The aims of this study were (1) to describe the design of a head-mounted virtual reality system and evaluate it for education on clinical procedures for nursing students and (2) to explore the experience of nursing students with head-mounted VR for learning clinical procedures and the usability of the system.

Figure 1. Conceptual framework for learning clinical procedure using virtual reality.



Methods

Design and Implementation of IVR Clinical Procedures

Design and Development

Overview

In this study, 4 key elements were considered when designing the VR prototype to create an engaging and immersive experience for users. The first element was accessibility and inclusivity for all learners and involved software components, adjustable height, and visual and audio design to minimize cybersickness. The second element was locomotion and navigation to allow the learners to navigate the virtual space intuitively. The third element was visual fidelity; the graphics were designed in a detailed and realistic way to provide good immersion for the IVR experience. The fourth element was motion tracking, where the learner's head and hand movements were detected to allow real-time interaction. An additional consideration was the degrees of freedom and interactivity whereby the learner was given control of their learning [9].

A real-time 3D creation tool, Unreal Engine 5 (Epic Games), was used to support the development of the IVR procedures, which reinforced the real-time interaction of the learner, clinical instructor, and patient in a virtual ward [26]. The design and development of the IVR clinical procedures were a close collaborative effort among the nursing school, health care institution, and IT experts in a systematic process. First, the faculty and nurse clinicians discussed and created clinical scenarios and consolidated common errors, critical steps, and safety issues pertinent to each procedure during the developmental stage.

Then, students accessed the proposed immersive simulation of the clinical procedures by wearing a 3D VR headset with 2 handheld controllers (Oculus Quest 2; Reality Labs), shown in Figure 2. Using the Oculus Quest, each student could visually experience a typical clinical session modeled after a real laboratory with its procedures, which they might have experienced before in their typical laboratories. The simulation was highly interactive, leveraging the handheld controllers for the left and right hands to enable and engage the students in executing the same simulated procedures vividly seen in their facilitated laboratory demonstrations. With the rich visual media and interactive experience, students could practice the simulated virtual procedures in their own time and space without mental stress, external distractions, fear of hazardous consequences, or creation of any clinical waste.

Within the IVR program, 3 stages for playing using the scaffold learning approach, namely, the orientation, practice, and assessment modes, were developed.

Figure 2. Oculus Quest (with 2 hand-held controllers).

Orientation

New users were guided by a tutor and an instructional video on the features and safety aspects of using the IVR clinical procedures for learning. When they put on the Oculus Quest 2 for the first time, they were required to complete virtual tutorials on how to maneuver the controllers, how to perform handwashing by rubbing 2 hands together using the controllers (Figure 3) and putting on and removing gloves to optimize their gaming experience.

Figure 3. Hand hygiene.

Practice Mode

Visual cues were provided when the learners learned how to proceed from one step to the next. With the built-in checklist, ample opportunities were given for the learners to learn from their experiences. With timely feedback based on the student's responses, they could rationalize their actions and reactions and thus decide the next course of action or repeat the session. Finally, after the learners gained confidence through practice, made sense of the procedures, and built on their prior learning, they were ready for assessment. No cues were given, and the students could see their results and repeat the practice when required. This approach aimed to allow the construction of knowledge through experience and deliberate practice. It boosted self-regulated learning, as learners could adjust their learning according to their own pace to either move to the next level or remain in the practice mode until they were ready for assessment [27].

Assessment Mode

No cues were provided, as this was a simulation of an actual clinical situation. The learner was expected to proceed according to what they had already learned and practiced. Reward systems were incorporated, with a maximum of 3 stars when the learner completed the procedures correctly. Deliberate practice and timely feedback on the learner's performance were integrated into the case scenarios and situations to develop critical thinking and problem-solving abilities. Each IVR experience lasted 15-20 minutes to ensure no learner fatigue.

Implementation

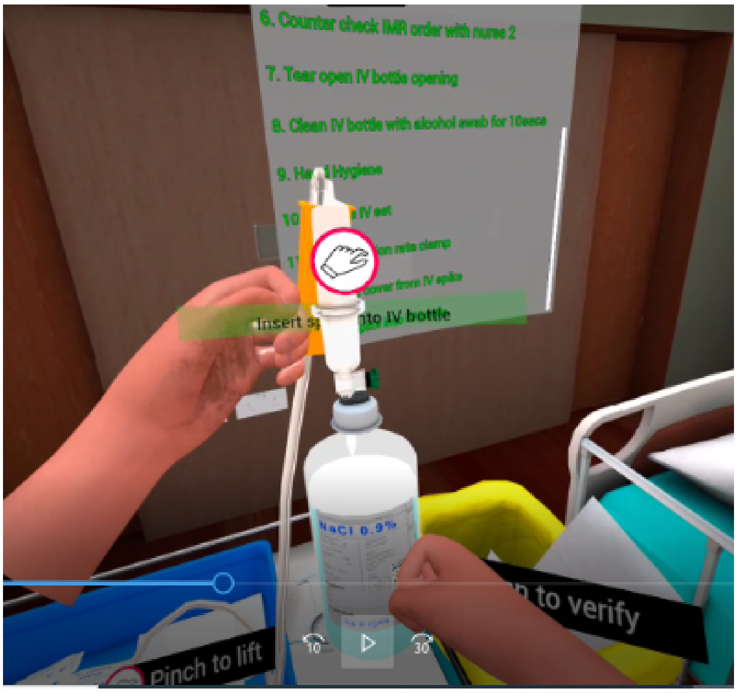
Figures 4 and 5 illustrate the subcutaneous injection and intravenous therapy procedures. In each scenario, the learners performed the procedures using the 2 handheld controllers. They also interacted with the patient and clinical instructor during critical steps such as checking identifiers and the "5 rights" when administering medication to ensure patient safety. The learners could click on a text box, and the patient would reply verbally with prerecorded responses. For example, if the learner asked, "May I know what your name and NRIC number are?" the virtual patient would reply, "My name is Ahmad, NRIC number is S1234567x." An electronic scanner and medication record were created to provide realism for learners to check the patient and medication prior to the administration.

The virtual simulation of administering a subcutaneous injection (Figure 4) included the critical component of checking the correct instruments and materials, type of insulin, and techniques in withdrawing air prior to withdrawing the correct unit from the vial. The appropriate injection site and any complications were identified, such as pain, edema, erythema, temperature, and lipohypertrophy. Critical components, such as checking patient identifiers, hand hygiene, the correct 5 rights, and injection techniques, had to be performed correctly to pass the procedure.

For the intravenous therapy procedure (Figure 5), learners studied critical concepts such as using the correct fluids and the accurate rate of infusion when administering intravenous therapy. Safety aspects, such as maintaining aseptic techniques while spiking the drip set and connecting to the intravenous plug, and steps to prevent phlebitis were incorporated into the scenarios. The learners were also expected to examine the risk of air embolism by checking the intravenous tubing.

Figure 4. Subcutaneous injection.

Figure 5. Intravenous therapy.



Evaluation of IVR Clinical Procedure

Study Design

This usability study used a mixed methods approach using convenience sampling. The recruitment and intervention of participants took place from June to August 2021 upon receiving approval from the institutional ethics review board.

Participants

The participants comprised undergraduate nursing students in their second academic year who had completed the pathophysiology and pharmacology modules and the Nursing Practice 1 and Clinical Experience Practicum 1.2 modules.

Data Collection

To achieve the aims of the study, three questionnaires were administered to the participants, which collected the following information: (1) basic demographics and past VR experience, (2) perception of continuance intention, with an instrument developed by Roca et al [28], and (3) the System Usability Scale (SUS) developed by Brooke [29]. To maintain consistency, we explained how to use the head-mounted device and how to put it on to ensure it was in good working condition. Any device issues were rectified, and then the participants brought the IVR device home for 2 weeks of testing on their own time. Upon returning the device, they were invited to complete the questionnaires.

The scale for perception of intention to continue was adapted from Roca et al [28] and had the following subscales: (1) usefulness, (2) cognitive absorption, (3) ease of use, (4) system quality, (5) confirmation, (6) satisfaction, and (7) continuance intention. All items were rated on a 5-point scale (1=strongly disagree to 5=strongly agree), except for item 1 on the system quality subscale, which was scored in reverse. The subscales adapted in this study had Cronbach α values of .81 (usefulness), .94 (cognitive absorption), .93 (ease of use), .68 (system quality), .96 (confirmation), .96 (satisfaction), and .91 (continuance intention).

The SUS is a 10-item self-report measure investigating one's reaction toward IVR procedures [29]. Items were assessed on a 5-point scale (1=strongly disagree to 5=strongly agree). The participants had to rate themselves on items like "I thought the VR procedure was easy to use." For items 1, 3, 5, 7, and 9, the score is the scale position minus 1. For items 2, 4, 6, 8, and 10, the score is 5 minus the scale position. The scores for each item were summed and multiplied by 2.5 to calculate a total score ranging from 0 (lowest) to 100 (highest). There was no cutoff score, but higher total scores indicated higher levels of usability for the IVR procedures. The Cronbach α values for the scale ranged from .85 to .91 [30].

Quantitative Analysis

Descriptive statistics using percentages, means, and SDs were computed to examine the study variables using SPSS (version 28.0; IBM Corp) [31].

Qualitative Analysis

Qualitative data from the open-ended questions were imported into an Excel spreadsheet for coding. Content analyses were used to understand the users' experiences of the IVR procedure [32]. Two researchers (STL and WLL) conducted the content analysis and extracted the codes, categories, and themes [33]. The research team reviewed the frequencies of the coded themes to reach a consensus. Trustworthiness, credibility, and transferability were ensured by including all 29 participants' responses, selecting units of meaning, and presenting the findings in a rich and vigorous way (Multimedia Appendix 1).

Ethics Approval

Ethical approval was obtained from the National University of Singapore Institutional Review Board (NUS-IRB 2021-305).

The participants were briefed thoroughly, and the participant information sheet was provided prior to recruitment. Participants were informed that their participation was voluntary and that they could withdraw from the study at any time. Confidentiality and anonymity were ensured.

Results

Participants

In this study, 29 participants were recruited, and all completed the study. The mean age of the participants was 23.03 (SD 6.59) years, with the majority being female (n=18, 62%). There were 22 Chinese participants (76%), 3 Malay participants (10%), and 1 Indian (3%) participant, with 3 participants of other ethnicities (10%). Most had no experience using VR prior to the user testing (n=27, 93%).

Quantitative Analysis

As presented in Table 1, for perception on intention, all the subscales in the perception scale had a mean score greater than 3 (of a total score of 5). This indicated that the students had a positive perception of the quality and usability of IVR, which is a key determinant for their continuity intention. The subscale with the highest mean score was "cognitive absorption" (mean 4.05, SD 0.61), suggesting that the students enjoyed and found the IVR engaging. The top 2 items with the highest scores supported this notion: "I have fun interacting with VR procedure" (mean 4.38, SD 0.68) and "When I am using the VR procedure, I am absorbed in what I am doing" (mean 4.14, SD 0.74). From another aspect, the 2 items with the lowest scores were "It is easy for me to become skillful at using VR procedure" (mean 3.21, SD 1.01) and "I will frequently use the VR procedure in future" (mean 3.24, SD 0.95).

However, for the student's perception of the usability of IVR, the mean SUS score was 53.53 (SD 16.18). This score was below the acceptable score of 68, indicating that more work needed to be done to improve the usability of IVR. Two items with poor perception, that was, items with >10 participants, indicating "Do not agree for positively worded item" or "Agree for a negatively worded item," were "I thought the VR procedure was easy to use" and "I think that I would need assistance to be able to use the VR procedure" (Table 2).

Table 1. Perception scale (N=29).

Subscales or items	Mean (SD)
Usefulness	3.71 (0.92)
Using the VR[a] procedure can improve my learning performance	3.79 (0.90)
Using the VR procedure can increase my learning effectiveness	3.66 (0.97)
I find the VR procedure to be useful to me	3.69 (1.11)
Cognitive absorption	4.05 (0.61)
Time flies when I am using the VR procedure	4.00 (0.96)
Most times when I get on to the VR procedure, I end up spending more time than I had planned	3.69 (0.81)
When I am using the VR procedure, I am absorbed in what I am doing	4.14 (0.74)
I have fun interacting with VR procedure	4.38 (0.68)
I enjoy using the VR procedure	4.03 (0.82)
Ease of use	3.32 (0.86)
Learning to operate the VR procedure is easy for me	3.31 (1.04)
It is easy for me to become skillful at using VR procedure	3.21 (1.01)
My interaction with the VR procedure is clear and understandable	3.45 (0.91)
System quality	3.50 (0.53)
Number of steps per task is too many[b]	3.55 (0.63)
Steps to complete the task follow a logical sequence	3.62 (0.86)
The organization of information is clear	3.41 (0.98)
The VR procedure has natural and predictable screen changes	3.55 (0.91)
The VR procedure system is responsive	3.34 (1.01)
Confirmation	3.52 (0.84)
My experience with using the VR procedure was better than I expected	3.48 (1.12)
The service level provided by the VR procedure was better than I expected	3.55 (0.87)
Overall, most of my expectations from using the VR procedure were confirmed	3.52 (0.78)
Satisfaction	3.70 (0.87)
I am satisfied with the performance of VR procedure	3.31 (1.04)
I am pleased with the experience of using the VR procedure	3.83 (0.89)
My decision to use the VR procedure was a wise one	3.97 (0.98)
Continuance intention	3.46 (0.96)
I will use the VR procedure on a regular basis in future	3.34 (1.08)
I will frequently use the VR procedure in future	3.24 (0.95)
I will strongly recommend others to use it	3.79 (1.11)
Overall score	3.63 (0.63)

[a]VR: virtual reality.

[b]Scored in reverse.

Table 2. System usability scale (N=29). The total score was 53.53 (SD 16.18).

Items	Strongly agree or agree, n (%)	Neutral, n (%)	Strongly disagree or disagree, n (%)
Positively worded			
I think I would like to use VR[a] procedure frequently	14 (48)	10 (34)	5 (17)
I thought the VR procedure was easy to use	10 (34)	8 (28)	11 (38)
I found the various functions of VR procedure were well integrated	12 (41)	10 (34)	7 (24)
I would imagine that most people would learn to use VR procedure very quickly	11 (38)	10 (34)	8 (28)
I felt very confident using the VR procedure	8 (28)	12 (41)	9 (31)
Negatively worded			
I found the VR procedure unnecessarily complex	7 (24)	10 (34)	12 (41)
I think that I would need assistance to be able to use the VR procedure	13 (45)	6 (21)	10 (34)
I thought there were too much inconsistency on the VR procedure	6 (21)	7 (24)	16 (55)
I found VR procedure very cumbersome or awkward to use	9 (31)	8 (28)	12 (41)
I needed to learn a lot of things before I could get going with the VR procedure	8 (28)	9 (31)	12 (41)

[a]VR: virtual reality.

Qualitative Analysis

Overview

Key themes were derived from the content analysis of the open-ended questions on the questionnaires regarding the experience of using VR procedures for learning. The themes derived from the analyses included the usefulness of IVR, learning experiences using IVR, challenges encountered, technical glitches, and suggestions for improvement. Themes and frequencies from the content analysis can be found in Multimedia Appendix 1.

Usefulness of IVR

Participants were excited about the new experience of using IVR. They found that the realism and relevance to the clinical setting and the ability to interact with a virtual patient and clinical environment promoted immersion in experiential learning:

> *It is intriguing as a first-time user; hence it caught my attention from the start. I could practice the nursing procedures at my own comfortable pace and get back to practicing the procedures again on my own time. There was an improvement in terms of accuracy in the procedure as I practiced more often on my own. Having a virtual patient in front of our eyes helped mimic clinical settings.* [P11]

Participants appreciated this learning format and found it a useful resource for students to practice and learn at their own pace, time, and convenience. “I can see this being a very useful resource for students to practice and learn in their own time” (P15).

Learning Experiences

Participants reported that performing the procedure using IVR encouraged them to consciously revise the sequence for the procedure and ensure accuracy as they built on their knowledge and skill through practice. This experience enhanced their thinking skills as they reviewed their performance:

> *I liked that the VR prompted me to think through the sequence of steps I have to do before a procedure. It helped me revise the steps and rationale behind the steps. I also like that the VR tracks your activity and lets you know which step you have forgotten to perform.* [P3]

Some participants commented that learning on the VR platform allowed novice learners to correct mistakes without putting an actual patient at risk:

> *The fact that I can practice clinical skills anywhere is an advantage of VR. Also, I would not be causing any real patient harm if I tried something out for the first time.* [P23]

> *It will make me understand my mistakes there, so I will be more aware not to repeat them the next try or during real-life clinical procedures.* [P11]

In particular, the participants appreciated the important concepts that might be overlooked in real clinical settings. One of these aspects was performing the “5 moments of hand hygiene” for any patient encounter. With IVR, the participants could not proceed, and they could see the “dirt” visually on their hands. “The visualization of soiled hands was also very useful as I see the importance of hand hygiene” (P21).

Challenges Encountered

Participants reported some limitations of the IVR system. The participants shared that adapting to the device and controls took time. Some concerns included physical discomfort, such as feeling dizzy, and that participants could not complete the entire procedure in 1 sitting:

> *I could not complete the tasks because I felt dizzy after a certain amount of time, and though I do revise*

> *the steps before I put on the headgear to do the task.* [P27]

Some of them also commented on their unfamiliarity with the device and instructions. Moreover, others were unable to communicate with the virtual patient and had a decreased level of enjoyment in using IVR:

> *I feel like there can be clearer instructions, possibly step by step, during my first attempt of the procedure to refresh and familiarize myself with the items. I could not communicate with the patient, grasp objects, put on gloves, and check the patient's body.* [P18]

Technical Glitches

The most technical glitches involved the withdrawal and administration of the medication procedure. The participants shared that they experienced irritation when virtual items were not responding according to commands despite multiple attempts. This impeded their progress and learning as they needed to restart the procedures:

> *Some IT interface needs to be adjusted to smoothen the flow of procedural execution. Sometimes there is a glitch where the packaging of the alcohol swabs, needle, and IV line gets stuck to our hand, thus hindering our next steps.* [P26]

> *It was very frustrating that I could not inject the needle into the insulin vial and manipulate it too.* [P22]

Suggestion for Improvement

Three main areas for improvement were suggested: provide orientation and more specific instructions, include more audio and haptic feedback in the game, and optimize the controls and joystick. Some other suggestions included adding a progress bar to motivate students to practice, including more procedures, and extending the use to hospitals:

> *More instructions can be given. A good example would be IV priming, where additional instructions are taught to us.* [P5]

> *Please include more procedures...look forward to it. If it works well, this can be a good technology to bring into hospitals for staff re-education or enrichment purposes. And any updates to a particular nursing skill can be updated in the software as well...that will be excellent.* [P6]

Discussion

Overview

The objectives of this study were to describe the development and to evaluate the learning experience of undergraduate nursing students. Creating these 2 clinical procedures in VR involved multiple stakeholders, including multiple reviews and refinements prior to this study. A new teaching approach was incorporated to create an effective learning environment to promote competencies among nurses. This study was a timely development during the period of the pandemic, when there were movement restrictions, safe distancing, and physical segregation of staff and students. More essentially, this study met the learning needs of the next generation.

Principal Findings

This study indicated that undergraduate nursing students found IVR satisfying and most of them enjoyed the experience. They were most intrigued by the contextualization of the VR procedures and felt that the experience was better than they had expected. This result reflects findings in the broader literature [34]. Once in the VR environment, they were absorbed in performing the procedures and tended to spend more time than intended. One of the reasons could be the high degree of realism, as the VR environment was a close representation of the actual ward setting. The participants could interact with patients when guided by the clinical instructor, just like in real life. From the study, the scores in the perception scale and qualitative data showed that the participants were highly engaged and immersed and forgot the time when performing the VR procedures, which is congruent with other studies [35].

Some participants shared that when practicing at home with practice versions of necessary instruments and materials, they were only able to practice psychomotor skills and that there was no holistic patient experience. They liked the VR system as it simulated the actual ward with instruments and materials readily available. The high-resolution visuals were stimulating for the students as they performed the task. In addition, the VR procedures were rolled out during the COVID-19 pandemic, when in-person practice sessions were largely reduced. The lack of hands-on practice experience might be an impetus for students to embrace using technology for learning more readily. The students were keen to experience a new approach to learning and viewed it as a valuable learning opportunity.

In this study, most participants agreed that VR effectively allowed them to practice steps, enabled repeatable learning, and helped them form good habits, including hand hygiene habits, such as when they touched a patient or the environment with their hands and prior to performing any procedures. They were able to remain focused without being distracted by the external environment. In addition, IVR allowed the participants to proceed at their own pace and enabled them to construct new knowledge through the reflective thinking process. With the checklist embedded in the VR procedures, the students could receive timely feedback during their practice. Moreover, they had a sense of achievement when they completed the procedures successfully. The real-time feedback motivated the participants, and they strived to do better in each practice session. Such a feature is critical to enhancing learning, as Generation Z students look for instant results [4,5]. Most participants agreed that VR provided a good learning platform and that it helped them to be more focused on finer details to improve their competencies. The interactive clinical procedures were valuable as they encouraged self-regulated learning. The learners were able to develop new knowledge linked to previous learning when they eventually progressed from virtual practice to actual practice. This explains the willingness of undergraduate students to explore the IVR system, as it provided opportunities for them to put theory into practice and could improve their confidence in real-life practice [34].

Comparison to Prior Work

These findings are aligned with other studies showing that IVR is promising for improving engagement and motivating students to learn. Hence, this learning platform is suitable to be included as a teaching approach [36,37]. However, in this study, the ease of use and system quality of the VR procedures scored lower than the rest of the perception subscales. Similarly, the SUS also showed that more than half of the participants felt they required assistance to use the VR system, and that it was not easy to use. This signifies the importance of improving the efficiency and quality of the VR prototypes. The participants shared in their qualitative feedback that the controls were not intuitive and were confusing, as they were unsure which button to click. In addition, they reported technical issues, such as that the items kept sticking to their hands or dropping. This feedback helped the IT staff improve the procedures before implementing them for the entire cohort of students.

The participants expressed that they needed time to get used to and learn to use the VR device. Some used the VR set for a prolonged period, resulting in physical discomfort and cybersickness. This study highlighted that not all users find IVR comfortable, and that more refinement needs to be made to reduce technical difficulties. Therefore, IVR might not be suitable for everyone [38]. To ensure cyber safety, more precise tutorials and instructions should be developed to guide users. The user guide for the VR technology and the controllers will be revised. Maximum play duration and cautions and instructions for safety must be included in the orientation for users.

Finally, the participants also found the application lacking in audio and haptic feedback. They suggested including more cues by having vibration or buzzing when errors are made or having a visual dialogue box or audio prompt to inform players to increase interactivity. They shared that students would learn more if there were more challenging situations, such as including several types of intravenous solutions or insulins to stimulate students’ thinking. These ideas were valuable feedback for enhancing the learning experience, and the team has considered refining the prototypes.

Strengths and Limitations

The strengths of this study included, first, that all interactive clinical scenarios were reviewed and refined by the various parties. Second, faculty and students conducted several rounds of user acceptability testing to refine the prototypes prior to this study. Finally, developing the clinical procedures was a collaborative effort among clinical, academic, and IT professionals. All comments received were valuable, and improvements suggested by the participants were incorporated into the future refinement of the IVR procedures. The limitations included the IT professionals using Unreal Engine software for the first time, which led to teething issues. As they gained expertise in using the program, the IVR procedures significantly improved. Although the sample size was small, considering that it was a usability study, 29 participants was considered a sufficient size, and data collection for reviewing the design and evaluating its usefulness reached saturation. Going forward, more participants will be recruited to test the effectiveness of the IVR procedures.

Conclusions

IVR for simulating intravenous therapy and subcutaneous injection procedures was designed and developed for nursing students to perform the procedures at their own convenience and the time and place of their choosing. Our evaluation supports the feasibility of using IVR in learning clinical procedures. It highlighted the value of deliberate practice and scaffold learning via VR procedures. The study also supported the usability of the VR device, although improvements and revisions are needed for a better user experience. With the enhanced features, future research can examine the effectiveness of health care students’ learning clinical procedures at home using IVR. Given its portability and flexibility, IVR is potentially an effective adjunct to support health care students in learning and performing clinical procedures.

Acknowledgments

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Data Availability

The data sets generated and analyzed during this study are not publicly available for privacy and ethical reasons but are available from the corresponding author upon reasonable request.

Authors' Contributions

STL, SYL, JYGY, and EA conceptualized and designed the study. STL, KDBR, FPL, and WLL conducted the data collection. STL, KDBR, and WLL carried out the data management, analysis, and synthesis of data. STL, RCJS, KDBR, and WLL wrote the study. All authors critically reviewed, read, and approved the final version of the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Content analysis.
[DOCX File , 23 KB - games_v11i1e46398_app1.docx]

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Abbreviations

IVR: immersive virtual reality
SUS: system usability scale
VR: virtual reality

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Original Paper

Comparing the Outcomes of Virtual Reality–Based Serious Gaming and Lecture-Based Training for Advanced Life Support Training: Randomized Controlled Trial

Mehmet Emin Aksoy[1], MSci, MD, PhD; Arun Ekin Özkan[2], BSc; Dilek Kitapcioglu[3], MD, PhD; Tuba Usseli[4], BSc, MS

[1]Department of Biomedical Device Technology, Center of Advanced Simulation and Education, Acibadem Mehmet Ali Aydinlar University, Istanbul, Turkey

[2]Institute of Biomedical Engineering, Bogazici University, Istanbul, Turkey

[3]Department of Medical Education, Medical Faculty, Center of Advanced Simulation and Education, Acibadem Mehmet Ali Aydinlar University, Istanbul, Turkey

[4]Vocational School for Anaesthesiology Technicians, Acibadem Mehmet Ali Aydinlar University, Istanbul, Turkey

Corresponding Author:
Mehmet Emin Aksoy, MSci, MD, PhD
Department of Biomedical Device Technology
Center of Advanced Simulation and Education
Acibadem Mehmet Ali Aydinlar University
Kayisdagi cad No: 32
Istanbul, 34752
Turkey
Phone: 90 5052685158
Email: dreminaksoy@gmail.com

Abstract

Background: Simulation-based Advanced Cardiac Life Support (ACLS) or Advanced Life Support (ALS) training for health care professionals is important worldwide for saving lives. Virtual reality (VR)–based serious gaming can be an alternative modality to be used as a part of simulation-based ALS training.

Objective: The aim of this study is to investigate whether a VR-based ALS serious game module can replace classroom-based ALS lectures, the latter being part of existing conventional ALS training protocols in addition to skills training.

Methods: Participants were students from Acibadem Mehmet Ali Aydinlar University's Vocational School for Anesthesiology (N=29) randomly divided into 2 groups with 15 (conventional training group) and 14 (VR-based training group) participants each. Participants in the conventional training group had to complete the pretest consisting of multiple-choice questions at the beginning of the study. Afterward, they took part in an interactive classroom-based ALS lecture. The next step involved skills training with task trainers to teach them compression skills. Following this, the conventional training group was divided into Code Blue teams, each consisting of 5 participants for the simulation session. Two independent instructors evaluated video recordings in terms of technical and nontechnical skills. The score acquired from the manikin-based simulation session was considered the main performance indicator in this study to measure the learning outcome. A similar workflow was used for the VR-based training group, but this group was trained with the VR-based ALS serious game module instead of the theoretical lecture. The final stage of the study involved completing the posttest consisting of multiple-choice questions. A preference survey was conducted among the study participants. Mann-Whitney *U* and Wilcoxon signed-rank tests were used to analyze the 2 groups' performances in this study.

Results: The improvement in posttest results compared with pretest results was significant in the conventional training group (P=.002). Hands-on technical scores of the conventional training group were higher than those of the VR-based training group during manikin-based simulation, but total scores, including those for technical and crisis resource management skills, acquired from the manikin-based simulation session did not reveal any significant difference between the 2 groups. The results of the VR preference survey revealed that the majority of the participants prefer VR-based serious game–based training instead of classroom lectures.

Conclusions: Although hands-on technical scores of the conventional training group during the manikin-based simulation session were higher than those of the VR-based training group, both groups' total performance scores, including those for technical and crisis resource management skills, did not differ significantly. The preference survey reveals that the majority of the participants would prefer a VR-based ALS serious gaming module instead of lecture-based training. Further studies are required to reveal the learning outcome of VR-based ALS serious gaming.

Trial Registration: ClinicalTrials.gov NCT05798910; https://clinicaltrials.gov/study/NCT05798910

(JMIR Serious Games 2023;11:e46964) doi:10.2196/46964

KEYWORDS

Advanced Cardiac Life Support; virtual reality; serious game; randomized controlled trial; Advanced Life Support

Introduction

Advanced Cardiac Life Support Course (ACLS) developed by American Heart Association (AHA) and Advanced Life Support (ALS) course developed by European Resuscitation Council (ERC) with a similar content to ACLS, aim to train healthcare professionals in managing adult patients suffering from cardiac arrest. The target group consists of medical doctors, nurses, and paramedics [1-4]. Around 1.3 million candidates take part in ACLS or ALS courses worldwide every year [5]. These training sessions have to be repeated at certain intervals depending on local regulations or institutional requirements [6].

Participants learn how to deliver high-quality cardiopulmonary resuscitation (CPR) to adult patients and to manage cardiac arrest cases. Besides technical skills, another aim of these courses is to provide training for nontechnical skills, which are essential when working as a multidisciplinary team. Blended learning techniques including didactic lecture-based, video-based learning; serious gaming; and simulation-based training modalities are used for ALS training [1,2,5].

Like in other industries, serious gaming is becoming an additional training modality for simulation-based education for healthcare over the last decade. A significant amount of time is spent in lecture-based sessions, which are generally organized before hands-on training for ALS in order to teach cardiac rhythm interpretation, drug dosage, the defibrillation procedure, and differential diagnosis [6,7]. By using serious gaming modules for this aspect of training, the educators can reduce the time spent on theoretical lectures and alleviate logistical difficulties, such as coordinating the training with a clinician from the hospital [6]. Another advantage is the ability to minimize the instructors' workload by delivering these training sessions with virtual reality (VR) modules [6]. Besides immersive features and interactivity, serious gaming modules also provide learners the opportunity to improve their skills in a safe environment anywhere and anytime they want [8-13]. PC-based, tablet-based, and VR-based serious gaming modules for health care training are available commercially. Due to their immersive effect, VR-based serious gaming modules are now widely used in health care training [6-8,14-19]. As VR hardware has already become more affordable, significant growth of VR-based learning is expected [20]. With technological developments, the new generation of VR headsets is becoming more affordable than the older ones, which cost much more and required a cable connection to a PC with an expensive graphics card to operate. The new generation of VR headsets also eliminate the huge logistical and hardware requirements for using VR. Another advantage of such a VR-based serious gaming module is the ability to be used with wireless VR headsets without the need for a PC and an expensive cable-based VR headset. Therefore, Meta Quest 2 headsets (Meta) were used in this study [21].

It is obvious that nontechnical skills are as important as technical skills when performing an ALS procedure as part of the Code Blue team [22,23]. Nontechnical skills including teamwork, resource management skills, and situational awareness are very important competencies that are required when performing an ALS procedure, as ALS is a team-based procedure [22,23]. Several serious gaming modules for ALS training are available in the market [6,24]. The existing VR-based ALS serious gaming modules are mostly focused on technical skills when calculating the total score upon final evaluation of the ALS learning outcomes. Therefore, the development of a new serious gaming module for ALS training has been decided, which can also evaluate and score nontechnical skills of the trainee in parallel with technical skills required to perform ALS. The objective of this study is to investigate whether a VR-based ALS serious game module has the potential to replace classroom-based ALS lectures, the latter being part of existing ALS training protocols in addition to skills training.

Methods

Study Design

This study was designed as a randomized controlled trial comparing the results of a VR-based serious gaming module and conventional training for ALS. Pretest, posttest, preference survey outcomes and hands-on training scores of the participants, which is the main performance indicator of the study, were compared.

Recruitment

In total, 30 third-semester students of Acibadem Mehmet Ali Aydinlar University's Vocational School for Anesthesiology volunteered to participate in this study. Simulation-based ALS training is part of their regular curriculum. The participants were randomly divided into 2 groups, with 15 participants each in the conventional (hereinafter called "group C") and VR-based (hereinafter called the "VR group") training groups. The VR headsets were cleaned with an antiseptic solution before each training session.

Data Exclusion

Exclusion criteria for the study were having previously experienced VR-induced motion sickness or other medical conditions such as vertigo. One participant from the VR group was not able to attend at the study due to personal reasons and was excluded from the study.

Statistical Analysis

Mann-Whitney *U* and Wilcoxon signed-rank tests were used to analyze the 2 groups' performances in this study.

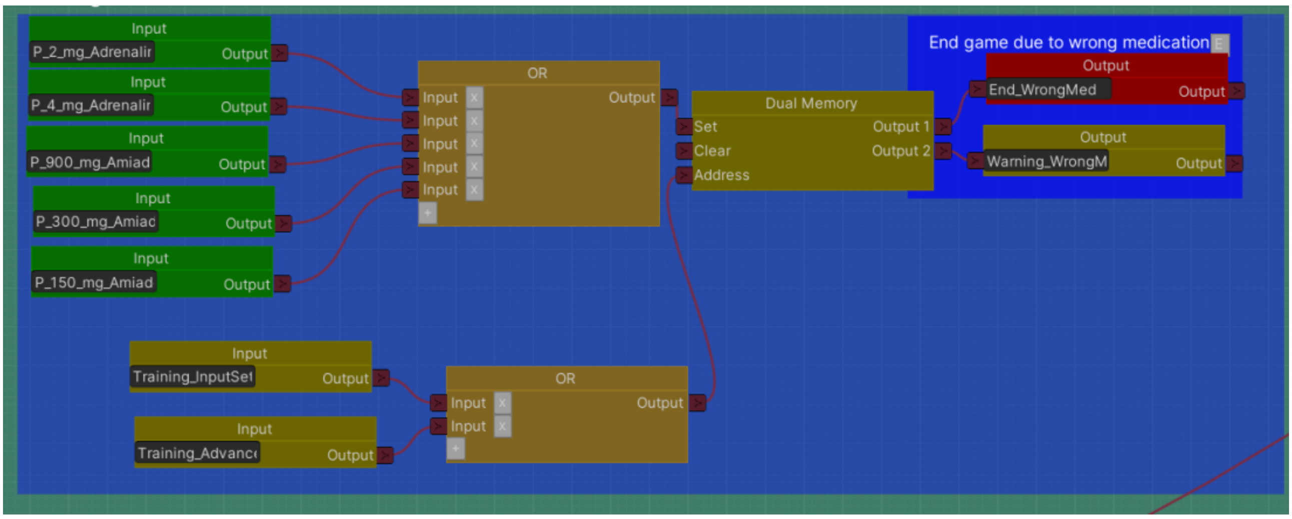
VR-Based Serious Gaming Module for ALS

The serious game module for ALS has been developed for this study and named "3DMedsim ALS VR." During the initial phase of development, the latest versions of international ALS or ACLS protocols from the AHA and ERC were reviewed together with the clinicians and software developers [1,2]. Crisis resource management (CRM) criteria adapted from those used in aviation and used for team-based training were also reviewed [22,25,26].

In the next phase, the development process of the VR-based gaming module was initiated. The VR-based serious game module developed for this study was designed to be compatible with the 2020 ALS algorithm of the ERC and AHA [1,2]. It comprises a learning management system and a learning record store (LRS), which allow users' credentials to be stored in a shared database [27-29]. The 3D visualization engine is also included and is integrated with the LRS to track the users' actions and generate experience application programming interface (xAPI) calls for each action carried out [28]. When the user triggers a predefined interaction with a significant object in the virtual environment, a xAPI event is automatically generated [27,30]. To enable this, a software library has been developed as a Unity extension, which makes the necessary xAPI web service calls to the LRS servers over the HTTP protocol. All user actions were defined in terms of actor, verb, and object parameters. The library automatically generates xAPI calls for each action, which are recorded by the LRS. The library can automatically generate xAPI calls for actions that have not been performed within a given time limit or in the proper order. Finally, the library also implements security and user authentication features required for record-keeping using the basic access authentication method included in the HTTP protocol standard.

To accelerate the development process and increase flexibility subsequently, a scenario building Unity plugin was developed [31]. This tool helps create and edit serious game scenarios as logic nodes outside of the virtual environment, independent from 3D objects. Thus, scenarios can be edited without altering Unity objects, which normally take the most time during the development process. The scenario building tool was only used during the development process and cannot be used by trainers to change the scenario flow during gameplay. The scenario building tool returns function calls to Unity in accordance with the logic flow, and these calls are linked to 3D objects as triggers for certain actions. As actions are triggered, they, in turn, trigger the next steps in the scenario until the serious game is over. A part of a scenario flow can be seen in Figure 1.

Figure 1. Screen capture of scenario logic flow.



The serious game consists of 3 different stages in multiple languages: basic training, advanced training, and a test mode. Initially, the serious game consisted of only training and test modes. However, during early testing, it became clear that a third stage was necessary, as the increase in difficulty and complexity was too much between the 2 modes. Another slightly more difficult training mode was added for this purpose. These stages can be completed in a virtual hospital or an examination room environment as seen in Figure 2.

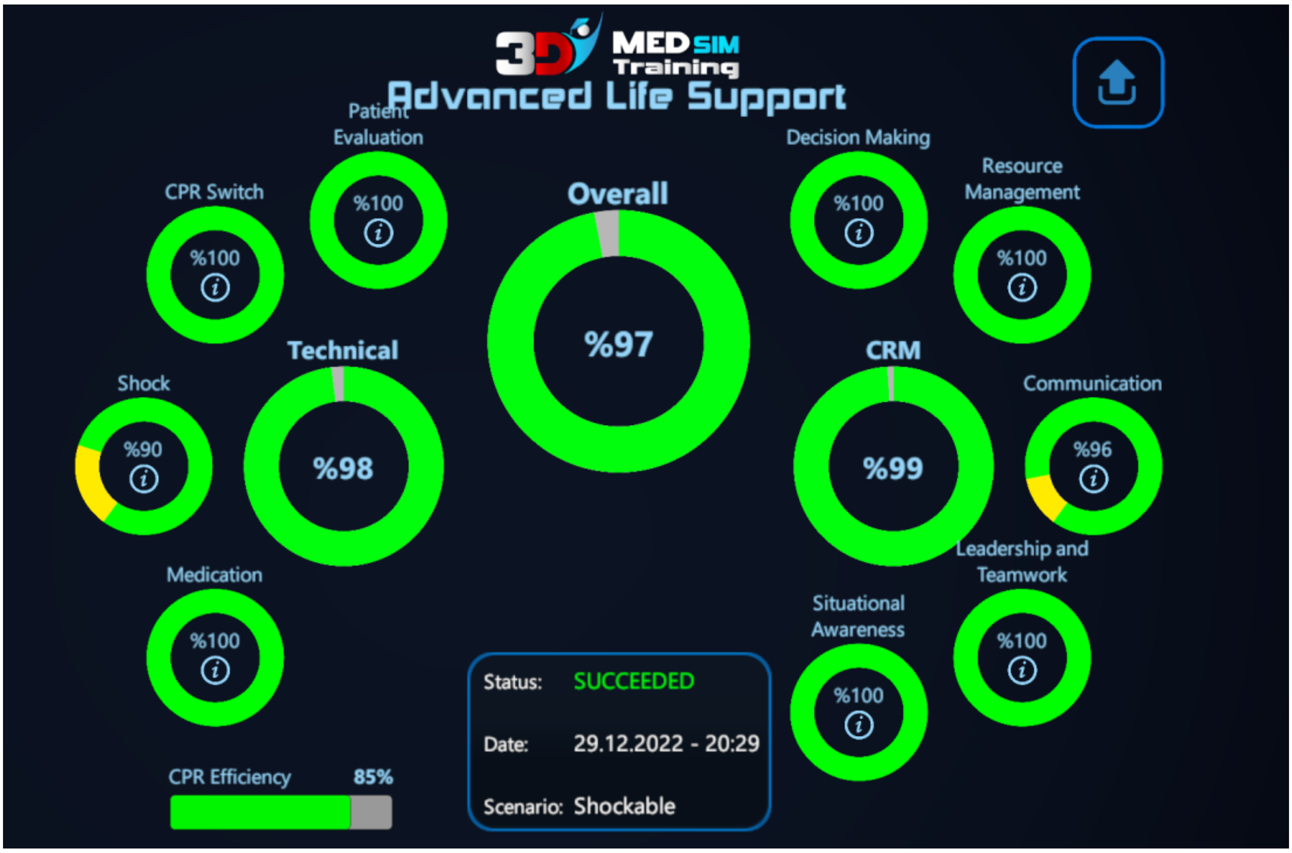
Figure 2. Screen capture from the virtual reality–based serious game for advanced life support.

The first stage, the basic training mode, is for beginners who wish to learn the fundamentals of the ALS algorithm. This version provides visual and audio guidance to the user at every step of the algorithm. An announcer verbally directs the user to perform specific actions, while corresponding buttons are highlighted on the interface. The user is not allowed to interact with anything that is not highlighted, and the risk of failure is thus eliminated. Additionally, time limits are removed, and the user is reminded to undertake the next step if user stays idle for a particular period.

The next stage is advanced training, which is intended for users who have completed the beginner-level training of the game. The advanced training version does not provide any visual or audio assistance, and the user is free to take any action; thus, mistakes are now possible. If users make significant mistakes or miss a time constraint, they receive a warning, but the game is not terminated.

The third stage is the test mode. The users' actions are evaluated on the basis of their order and timing during this mode. The evaluation is carried out under 2 categories: technical and CRM skills. The scores can be accessed by using the review section. Unlike the training stages, if the user commits a significant error, such as selecting the wrong rhythm, the game terminates with a warning indicating the mistake. The technical and CRM scores are segregated as shown in Figure 3. The subcategories of these grades are specified to pinpoint the users' errors during review.

Figure 3. Screenshot from the serious game showing technical, crisis resource management, and total scores of a trainee. CPR: cardiopulmonary resuscitation; CRM: crisis resource management.

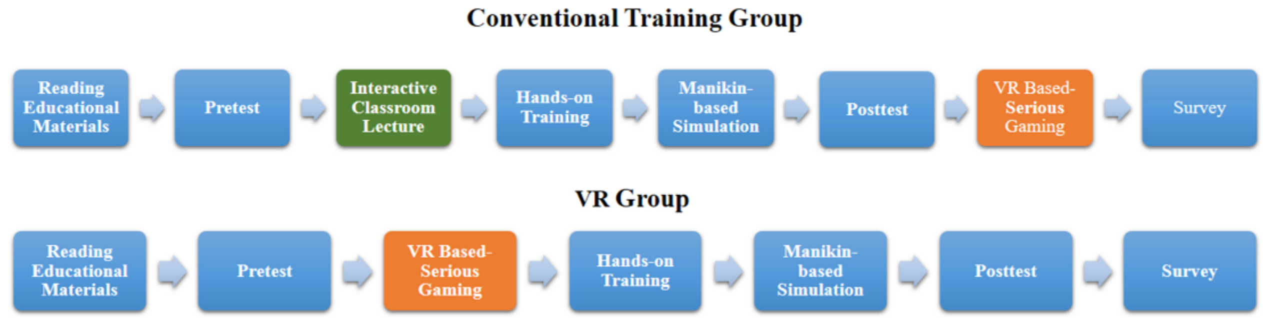


The total score of a participant was calculated as the sum of the technical and CRM scores during the game. The maximum total achievable score was 100, that for technical skills was 70 points, and that for CRM skills was 30 points. In order to avoid risk of failure due to problems concerning the content, scenario flow, and scoring, the first version of the game was presented to clinicians for evaluation. Depending on the feedback and critiques from the content experts, changes were made. The version used in this study is the second version of the software optimized depending on user feedback.

Study Flow

The details of the study flow are shown in Figure 4.

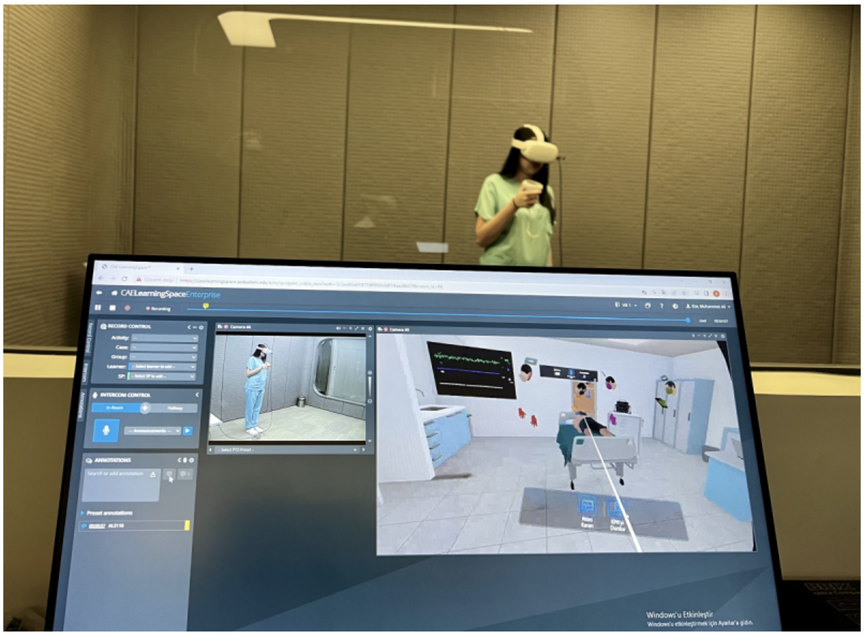
Figure 4. The study flow of the conventional training group and virtual reality (VR)–based training group.



During the initial stage of the study, all participants were asked to read the educational material sent to them. Then, both groups were asked to complete the pretest form shown in Multimedia Appendix 1.

The pretest and posttest consisted of the same multiple-choice questions, and the test content is aligned with the curricular content required for ALS training at Acibadem Mehmet Ali Aydinlar University. This test is being used to assess of ALS training at our university and is compatible with the content of the latest version of the ERC's training algorithm. The two-rounded Delphi technique was used with content experts when generating the pretest and posttest questionnaires. Group C participants took part in an interactive lecture with the instructors. VR group participants took part in a VR familiarization session and played 1 round of the VR beginner training mode followed by 1 round of the VR advanced training mode (Figure 5). The total time spent for these 2 rounds with VR training was equal to the time the other group spent during the classroom lecture.

Figure 5. Real-time video of the trainee and virtual reality–based advanced life support serious game screen recorded during training sessions.



Afterward, participants of both groups took part in a skills training session in order to learn effective CPR and ventilation with a CPR manikin (CPR Lilly Pro+, 3BScientific GmbH; Figure 6) [32].

Figure 6. Hands-on training sessions performed using Basic Life Support manikin (CPR Lilly Pro+, 3BScientific GmbH).

After the skills training, both groups took part in simulation-based ALS scenario using a patient simulator (Apollo Patient Simulator, CAE Healthcare; Figure 7) [33]. The participants were divided into Code Blue teams, each consisting of 5 participants during each simulation session. The content and flow of the scenario were identical to the scenario used for the VR-based ALS serious gaming module. The manikin-based simulation sessions of all participants were video recorded for evaluation. Two independent instructors evaluated the video-recorded performances of the participants during the manikin-based simulation scenario with the same scoring criteria used for the VR-based ALS serious gaming module. Following the manikin-based simulation session, all participants were asked to complete the posttest, which was identical with the pretest. Group C participants were given the opportunity to try the VR-based module at the end of the study; however, as the VR group participants were attending classroom-based lectures during their standard educational program, there was no need for them to take part in a classroom-based lecture at the end of the study. At the end of the study, all study participants were asked to answer the preference survey form shown in Figure 8.

Figure 7. Manikin-based simulation of an advanced life support scenario with a high-fidelity patient simulator (Apollo Patient Simulator, CAE Healthcare).

Ethical Considerations

This study has been approved by Acibadem Mehmet Ali Aydinlar University's Ethical Committee (approval number 2022-19/04). After being informed about the content of the study, the participants signed informed consent forms. The collected data were anonymized in order to safeguard participant information. No compensation was provided to the participants.

Results

The VR group's pretest scores ranged from 21 to 79 (mean 43.36, SD 15.47); those of group C ranged from 21 to 79 (mean 46.53, SD 15.05). The pretest scores did not differ significantly between the 2 groups (*P*=.62). The VR group's posttest scores ranged from 32 to 89 (mean 53.79, SD 14.01); those of group C ranged from 47 to 84 (mean 64.20, SD 9.96). The posttest scores were significantly higher in group C than in the VR group (*P*=.01). The results of the pretest and posttest are summarized in Table 1.

Table 1. Evaluation of pretest and posttest results (N=29).

	Total	VR[a] Group (n=14)	Group C[b] (n=15)	*P* value[c]
Pretest, range (median); mean (SD)	21 to 79 (45); 45 (15)	21 to 79 (44); 43.36 (15.47)	21 to 79 (45); 46.53 (15.05)	.62
Posttest, range (median); mean (SD)	32 to 89 (58); 59.17 (12.99)	32 to 89 (53); 53.79 (14.01)	47 to 84 (63); 64.20 (9.96)	.01
Difference[d] (posttest versus pretest), range (median); mean (SD)	–11 to 42 (13); 14.17 (13.30)	–11 to 32 (10); 10.43 (11.99)	–6 to 42 (16); 17.67 (13.90)	.19

[a]VR: virtual reality.

[b]Group C: conventional training group.

[c]Mann-Whitney *U* test.

[d]Wilcoxon signed-rank test. Overall difference in pretest and posttest scores: *P*=.001; difference in pretest and posttest scores in the VR group: *P*=.02; difference in pretest and posttest scores in the group C: *P*=.002.

A comparison of the mean pretest and posttest scores is shown in Multimedia Appendix 2. There was no significant difference in the pretest scores between the 2 groups (*P*=.62). The increase in posttest scores compared to that in the pretest scores was significant in both groups (*P*=.001). The increase in the posttest scores compared to that in the pretest scores was significant in the VR group (*P*=.02). The increase in the posttest scores compared to that in the pretest scores was significant in group C (*P*=.002). A significant difference was found between the posttest scores in the 2 groups, and the scores of group C were found to be significantly higher than those of the VR group (*P*=.01).

The score of the manikin-based simulation session, which was considered the main performance indicator in this study, was evaluated with the same scoring criteria of the serious gaming module. The scores of manikin-based simulation session are summarized in Table 2. The total score of each participant consists of the CRM score and the technical score depending on their performances in the manikin-based simulation session. The maximum achievable CRM score was 30, and the maximum achievable technical score was 70. The total score was calculated as the sum of the participant's technical and CRM scores.

Table 2. Evaluation of manikin-based simulation session scores (N=29).

	Total	VR[a] group (n=14)	Group C[b] (n=15)	*P* value[c]
CRM[d] (maximum 30), range (median); mean (SD)	3-16 (13); 12.84 (4.20)	13-16 (14.5); 14.45 (1.23)	3-16 (13); 11.33 (5.37)	.23
Technical (maximum 70), range (median); mean (SD)	44-69 (59.3); 57.11 (8.41)	44-60.5 (58); 53.80 (7.63)	51-68.25 (63); 60.20 (8.13)	.03
Total (maximum 100), range (median); mean (SD)	57-85 (66); 69.95 (9.37)	57-76.5 (72.5); 68.25 (8.81)	64-85 (66); 71.53 (9.89)	.53

[a]VR: virtual reality.

[b]Group C: conventional training group.

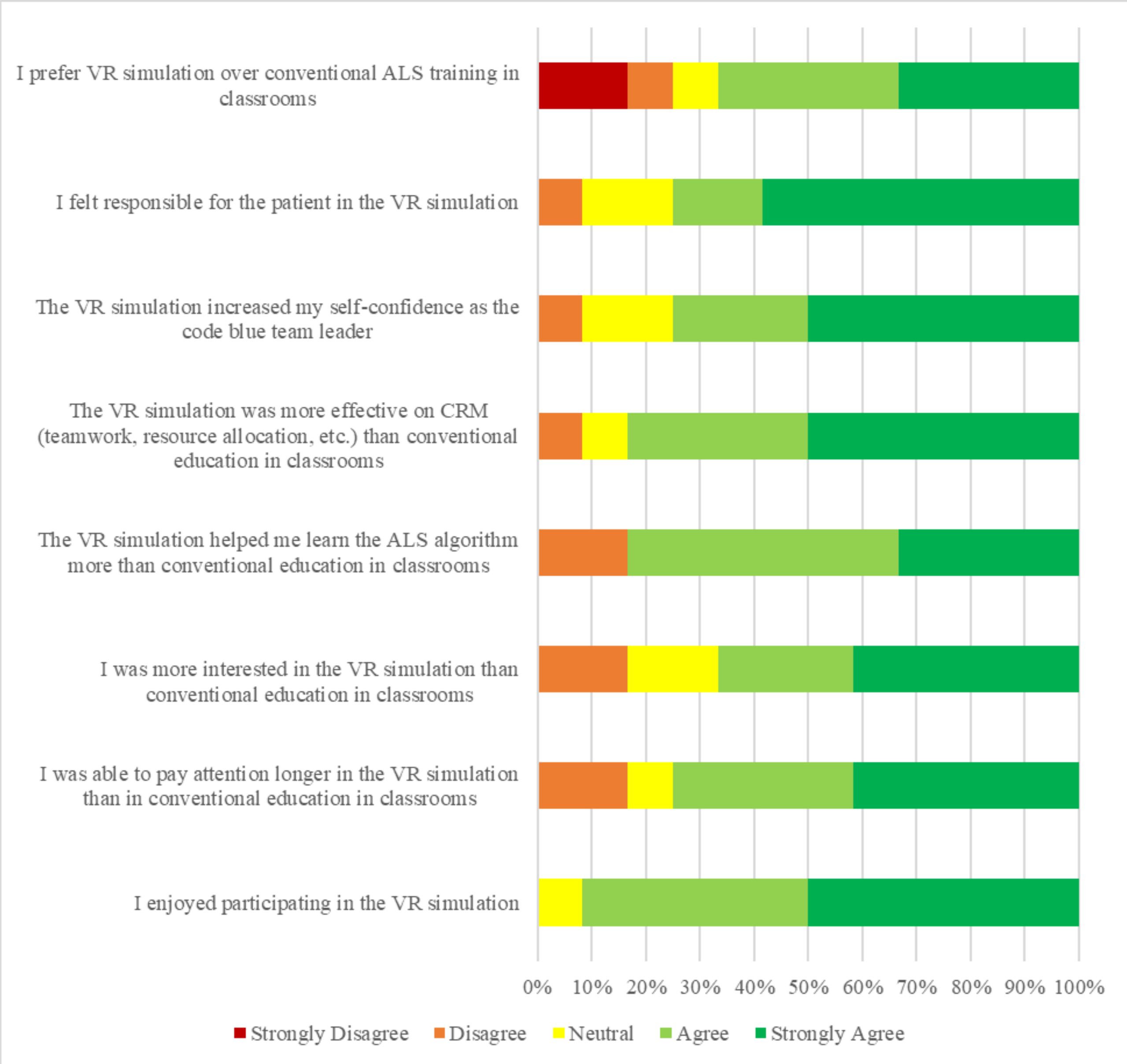
[c]Mann-Whitney *U* test.

[d]CRM: crisis resource management.

The VR group's CRM scores ranged from 13 to 16 (mean 14.45, SD 1.23); those of group C ranged 3 to 16 (mean 11.33, SD 5.37). CRM scores were not significantly different between the 2 groups (*P*=.23). Mean values of the CRM and technical scores of both groups during the manikin-based simulation session are shown in Multimedia Appendix 3. The technical scores of the VR group ranged from 44 to 60.5 (mean 53.80, SD 7.63); those of group C ranged from 51 to 68.25 (mean 60.20, SD 8.13; Multimedia Appendix 3). The technical scores of the conventional group were significantly higher than those of the VR group (*P*=.03). The VR group's total scores during the manikin-based simulation session ranged from 57 to 76.5 (mean 68.25, SD 8.81); those of group C ranged from 64 to 85 (mean 71.53, SD 9.89; Multimedia Appendix 3). The total scores of both groups during the manikin-based simulation session do not differ significantly (*P*=.53).

At the end of the study, a preference survey was sent to the participants to evaluate VR as a learning modality. The outcome of this survey is shown in Figure 8. More than 65% of the participants agreed or strongly agreed that they would prefer VR-based serious game–based training instead of classroom-based lectures before manikin-based simulation sessions. The survey also revealed that more than 80% of the participants agreed or strongly agreed that VR-based training is more effective for them in terms of teaching CRM skills. More than 70% of the participants agreed or strongly agreed that VR-based training also increased their level of self-confidence during the manikin-based simulation scenario. More than 90% of the participants enjoyed participating VR-based gaming.

Figure 8. Results of the preference survey.



Discussion

Principal Results

It has been investigated whether the use of serious gaming modules could replace lecture-based sessions that are mostly organized prior to medical simulation sessions. Several studies have compared serious games with lecture-based sessions in terms of providing knowledge to the trainees [10,30,34]. Several studies have revealed that learning outcomes in the serious gaming groups were significantly better than those in the lecture groups [10,26,30]. Depending on our results, the increase in the posttest scores compared to that in the pretest scores was significant in both VR group (*P*=.02) and in group C (*P*=.002). A significant difference was found in the posttest scores between the 2 groups, and the scores of group C were significantly higher than those of the VR group (*P*=.01). A significant difference was found between the technical scores during the manikin-based simulation session between the 2 groups, and the scores of group C were higher than those of the VR group (*P*=.03). CRM scores during the manikin-based simulation session were not significantly different between the 2 groups (*P*=.23): the mean score of the VR group was 14.45 (SD 1.23), whereas that of group C was 11.33 (SD 5.37). As the maximum achievable CRM score was 30, both groups had low CRM scores, indicating that participants may require extra additional training to improve their CRM performances.

The total score of manikin-based simulation session was considered the main performance indicator of the study for measuring the participants' learning outcome. The VR group's total scores during the manikin-based simulation session ranged from 57 to 76.5 (mean 68.25, SD 8.81), while those of group C ranged from 64 to 85 (mean 71.53, SD 9.89). According to the statistical analysis of the 2 groups' performances, the total scores during the manikin-based simulation session did not differ significantly (*P*=.53).

Comparison With Prior Work

The advantages of using serious gaming as an additional training modality for simulation-based education in health care have been revealed in several studies [6,9,10,34,35]. As CPR performances of trainees deteriorate after a certain time, refresher training is required to maintain knowledge [36]. It has been shown that VR-based serious gaming for ALS is an adequate method to sustain knowledge [36,37]. Serious game–based ALS training has the potential to prevent deterioration of knowledge between updates due to its potential to be used anytime or anywhere [36]. However, for skills training, there is still the requirement to take part in simulation-based ALS training at regular intervals to maintain motor skills. A unique feature of the VR-based serious gaming module, which has been developed for this study, is that the serious game automatically scores CRM skills of the trainees apart from technical scores. When serious gaming modules for ALS training available on the market are compared with the module developed for this study, the available serious gaming modules on the market are not capable of evaluating nontechnical skills in addition to technical skills.

Limitations

The first limitation was that only limited gameplay time for the ALS serios gaming module could be given to the VR group participants due to the busy schedule of the training center. The second limitation was that only the heads of the avatars could be displayed during the game, as wireless VR headsets available on the market can only provide limited processing power and memory capacity. The third limitation of the study was the limited number of participants. The fourth limitation was limited generalizability of our results due to this being a single-center study and recruiting only 1 type of participants.

Conclusions

After comparing posttest and pretest outcomes, all participants improved their knowledge, but the posttest scores of group C were higher than those of the VR group. Both groups' overall performances in the manikin-based simulation session did not differ significantly. The preference survey reveals that the majority of the participants would prefer a VR-based ALS serious gaming module instead of lecture-based education. The benefits of using a VR-based serious gaming module are the scalability of trainees' performances and its flexibility to be used anywhere and anytime by the users. Further studies are required to reveal the learning outcomes of VR-based ALS serious gaming. Future studies could further reveal whether the performance of the VR group may improve if more time were given for users to interact with the VR-based serious game.

Acknowledgments

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Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author on request.

Authors' Contributions

MEA was responsible for study conceptualization, methodology, and resources and drafting, reviewing, and editing the manuscript. AEÖ was responsible for the software and methodology. DK was responsible for study conceptualization, methodology, and reviewing and editing the manuscript. TU was responsible for the study methodology and data collection. The authors did not use generative AI to write any portion of the manuscript.

Conflicts of Interest

None declared.

Editorial notice: This randomized study was retrospectively registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the risk of bias appears low and the study was considered formative, guiding the development and initial evaluation of the application. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
The pre-test and post-test questionnaire used to evaluate the knowledge level of the participants.
[PNG File , 236 KB - games_v11i1e46964_app1.png]

Multimedia Appendix 2
Distribution of pre-test and post-test scores.
[PNG File , 52 KB - games_v11i1e46964_app2.png]

Multimedia Appendix 3
Mean scores of the VR and conventional group acquired from manikin-based simulation.
[PNG File , 55 KB - games_v11i1e46964_app3.png]

Multimedia Appendix 4
CONSORT E-Health Checklist.
[PDF File (Adobe PDF File), 4489 KB - games_v11i1e46964_app4.pdf]

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Abbreviations

ACLS: advanced cardiac life support
AHA: American Heart Association
ALS: advanced life support
CPR: cardiopulmonary resuscitation
CRM: crisis resource management
ERC: European Resuscitation Council
LRS: learning record store
VR: virtual reality
xAPI: Experience Application Programming Interface

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Original Paper

Effect of Voice and Articulation Parameters of a Home-Based Serious Game for Speech Therapy in Children With Articulation Disorder: Prospective Single-Arm Clinical Trial

Seong-Yeol Kim[1], MD; Minji Song[2], SLP, MS; Yunju Jo[3], SLP, MS; Youngjae Jung[4], PhD; Heecheon You[4], PhD; Myoung-Hwan Ko[1,3], MD, PhD; Gi-Wook Kim[1,3], MD, PhD

[1]Department of Physical Medicine and Rehabilitation, Jeonbuk National University Medical School, Jeonju-si, Republic of Korea

[2]Department of Speech-Language Therapy, Graduate School, Jeonbuk National University, Jeonju, Republic of Korea

[3]Research Institute of Clinical Medicine, Biomedical Research Institute of Jeonbuk National University Hospital, Jeonju-si, Republic of Korea

[4]Department of Industrial and Management Engineering, Pohang University of Science and Technology, Pohang, Republic of Korea

Corresponding Author:
Gi-Wook Kim, MD, PhD
Department of Physical Medicine and Rehabilitation
Jeonbuk National University Medical School
20, Geonji-ro, Deokjin-gu
Jeonju-si, 54907
Republic of Korea
Phone: 82 010 5279 1421
Fax: 82 063 254 4145
Email: k26@jbnu.ac.kr

Abstract

Background: Articulation disorder decreases the clarity of language and causes a decrease in children's learning and social ability. The demand for non–face-to-face treatment is increasing owing to the limited number of therapists and geographical or economic constraints. Non–face-to-face speech therapy programs using serious games have been proposed as an alternative.

Objective: The aim of this study is to investigate the efficacy of home therapy on logopedic and phoniatric abilities in children with articulation disorder using the Smart Speech game interface.

Methods: This study is a prospective single-arm clinical trial. Children with articulation disorders, whose Urimal Test of Articulation and Phonology (U-TAP) was –2 SDs or less and the Receptive and Expressive Vocabulary Test score was –1 SD or more, were enrolled. A preliminary evaluation (E0) was conducted to check whether the children had articulation disorders, and for the next 4 weeks, they lived their usual lifestyle without other treatments. Prior to the beginning of the training, a pre-evaluation (E1) was performed, and the children trained at home for ≥30 minutes per day, ≥5 times a week, over 4 weeks (a total of 20 sessions). The Smart Speech program comprised oral exercise training, breathing training, and speech training; the difficulty and type of the training were configured differently according to the participants' articulation error, exercise, and vocal ability. After the training, postevaluation (E2) was performed using the same method. Finally, 8 weeks later, postevaluation (E3) was performed as a follow-up. A voice evaluation included parameters such as maximum phonation time (MPT), fundamental frequency (F_0), jitter, peak air pressure (relative average perturbation), pitch, intensity, and voice onset time. Articulation parameters included a percentage of correct consonants (PCC; U-TAP word-unit PCC, U-TAP sentence-unit PCC, and three-position articulation test) and alternate motion evaluation (diadochokinesis, DDK). Data obtained during each evaluation (E1-E2-E3) were compared.

Results: A total of 13 children with articulation disorders aged 4-10 years were enrolled in the study. In voice parameters, MPT, jitter, and pitch showed significant changes in repeated-measures ANOVA. However, only MPT showed significant changes during E1-E2 (P=.007) and E1-E3 (P=.004) in post hoc tests. Other voice parameters did not show significant changes. In articulation parameters, U-TAP, three-position articulation test (TA), and DDK showed significant changes in repeated-measures ANOVA. In post hoc tests, U-TAP (word, sentence) and TA showed significant changes during E1-E2 (P=.003, .04, and .01) and E1-E3 (P=.001, .03, and .003), and DDK showed significant changes during E1-E2 only (P=.03).

Conclusions: Home-based serious games can be considered an alternative treatment method to improve language function.

Trial Registration: Clinical Research Information Service KCT0006448; https://cris.nih.go.kr/cris/search/detailSearch.do/20119

(JMIR Serious Games 2023;11:e49216) doi:10.2196/49216

KEYWORDS

articulation disorder; home-based therapy; serious game; children; speech; voice

Introduction

Articulation disorder is a condition characterized by difficulties in producing speech sounds due to a structural abnormality or a neurological or auditory cause. Among children aged 3-11 years, approximately 75% show an articulation problem that demands treatment [1]. Speech and language disorders reduce children's academic performance and can cause inequality in social and job opportunities in adulthood [2]. Early intervention in children with speech disorders can prevent several problems that may arise later. Effective speech therapy requires treatment sessions to be individualized, frequent, and intensive [3].

The goal of the treatment of articulation disorder is to train the patient to maximize verbal clarity in articulation to ensure an adequate understanding by the listener to increase the efficiency of the function of mutual communication, which would reinforce motivation toward linguistic expressions [4].

Conventionally, treating articulation disorder involves 2 main approaches: the phonetic approach, which focuses on the physiological aspects of the articulation problem, and the phonological approach, in which the treatment focuses on the linguistic aspects of the problem. The phonetic approach includes the phonetic placement method, sensorimotor training, paired-stimuli technique, motor skill learning, and biofeedback technique. The phonological approach to speech therapy includes various methods, such as the phonemic contrast method, cycle training, and Metaphon therapy. The critical point for children with articulation disorders is a suitable early diagnosis and interventions by specialists [5]. Prior to the treatment of articulation disorder, the clinician conducts assessments of voice and articulation to obtain data from the children. The most commonly used parameters for voice evaluation include maximum phonation time (MPT), frequency (F_0), jitter, relative average perturbation (RAP), pitch, intensity, and voice onset time (VOT). Moreover, commonly used parameters for articulation include percentage of correct consonants (PCC) regarding Urimal Test of Articulation and Phonology (U-TAP) and TA and the diadochokinesis (DDK) rate [6]. In principle, speech therapy is generally performed in face-to-face situations; however, the mode of delivery can vary depending on the situation [7]. Non–face-to-face speech therapy was initially proposed as an alternative method in countries with huge lands, such as the United States and Australia, even before the pandemic. In fact, studies have shown that this method can be effective in treating patients with neuro-lingual disorders, such as dysarthria and apraxia [8].

A computer-assisted home therapy has several advantages. It can offer personalized treatment to each patient, increase accessibility for residents in far-flung regions, and provide intensive training and autonomy, which is impossible when using conventional programs [9]. This could lead to increased treatment effects. A domestic study has found that applying non–face-to-face therapy to children with speech disorders who show articulation errors improved consonant accuracy of the target phoneme [10].

The definition of a functional game varies; nonetheless, it is generally known as a type of game to achieve a goal other than play using the same "motivational effect to cause voluntary participation," "fun," and "immersion" as in any game [11]. Smart Speech (Humanopia Co) is a functional game program for vocalization and articulation training designed to assist logopedics. The program allows repetitive and intensive treatments by way of the installed games. Jo et al [12] have treated adult patients with dysarthria using Smart Speech and observed significant positive changes in the following acoustic variables: pitch, intensity, jitter, RAP, and MPT. Additionally, they reported significantly increased scores for word-unit consonant accuracy, articulation accuracy, and sentence-unit consonant accuracy [12]. Currently, several studies have evaluated the efficacy for adults; however, only a few studies have assessed it for children.

This study investigated the efficacy of home therapy on logopedic and phoniatric abilities in children with articulation disorders using the Smart Speech game interface for speech therapy.

Methods

Ethical Considerations

This prospective single-arm clinical trial was registered and approved by the institutional review board of Jeonbuk National University Hospital (2019-02-026-015).

Participants

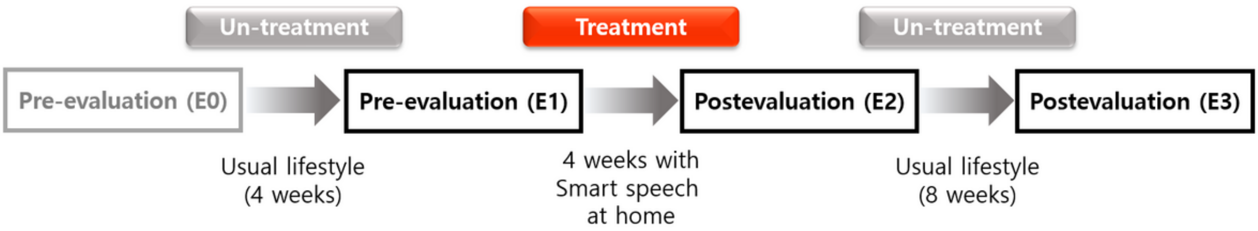
The study participants included children with articulation disorder who visited our institution's Department of Rehabilitation Medicine between September 2019 and January 2021. The participants were recruited via an advertisement. The inclusion criteria were as follows: (1) children aged 4 years or older and 12 years or younger; (2) U-TAP score of ≤–2 SD; (3) Receptive and Expressive Vocabulary Test score of ≥–1 SD; and (4) children showing no severe internal pathology without treatment. Before proceeding with the experiment, the participants and their guardians were provided with a full explanation regarding the purpose of the study, procedure, required time, and compensation, and only those who consented to participate were included in the experiment. Since it was a study involving children, signed informed consent was obtained from their guardians.

Study Protocol

Overview

This study was based on an exploratory design with the following phases: pre-evaluation 1 (E0), pre-evaluation 2 (E1), postevaluation 1 (E2), and postevaluation 2 (E3), in the given order (Figure 1).

Figure 1. Study protocol.



Pre-Evaluation 1 (E0)

Considering that the study participants were children, we conducted a preliminary evaluation (E0) to adapt the evaluation method before measuring the baseline (E1). The participants' voice, articulation, and alternate motion were assessed in the E0 phase.

Pre-Evaluation 2 (E1)

Before treatment using the Smart Speech program, following phase E0 and 4 weeks of usual lifestyle, the same variables as in E0 were assessed in the pre-evaluation 2 (E1) phase within 3 days.

Treatment and Postevaluation 1 (E2)

After the E1 phase and within 1 week, the same participants were provided with a laptop with the Smart Speech program and a microphone and were guided to perform the program at home for ≥30 min per day, ≥5 times a week, for the 4-week period (a total of 20 sessions). In addition, the participants were instructed to record the time of training on the set log during the 4-week period and have telephone counseling with the speech therapist once a week. After the treatment and within 3 days, postevaluation 1 (E2) was performed.

Postevaluation 2 (E3)

After E2 and 8 weeks of usual lifestyle, the same variables were assessed in postevaluation 2 (E3) to verify whether the changes induced by the treatment had been retained.

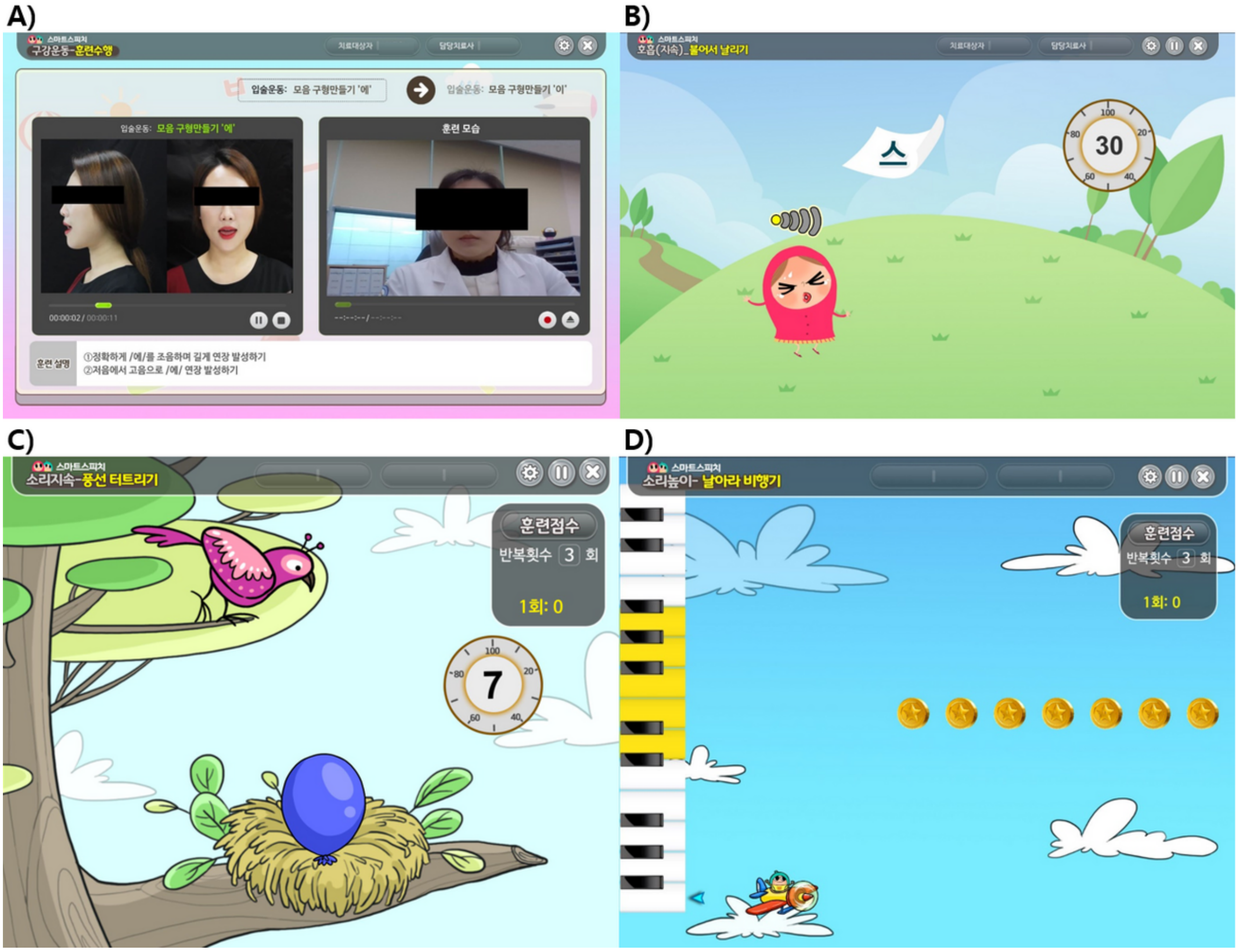
Intervention Procedures

The Smart Speech is a serious game program for vocalization and articulation training designed to assist logopedics. Structured games relate to oral exercise, breathing, vocalization, and articulation training. The game for vocalization training is subcategorized into sound duration, intensity, pitch, syllable, and word training. Before the intervention, the guardians are given the necessary instruction and training. Each session is designed to provide oral exercises, breathing, vocalization, word, and syllable training in the given order.

Oral Exercise Training

The training consisted of lip, tongue, and chin exercises. In addition, the participants were instructed to watch a recorded video and imitate what they saw while checking how they appeared on the screen. According to the participants' unique articulation errors and their ability to perform oral exercises, we could select the target of intensive training (Figure 2A).

Figure 2. Training program in Smart Speech. Training program in the Smart Speech (Humanopia Co, Korea). (A) In oral exercise training, participants are guided to follow the example on the left screen. They can check their appearance on the right screen and compare the differences with examples. (B) To improve breathing, participants keep breathing for a few seconds continuously so that the paper on the screen does not fall on the floor. (C) In sound duration training, participants can blow up balloons or blow out candles by maintaining a long vocalization in one breath. (D) Participants continued vocalization with the given pitch to fly the birds or airplanes seen on the screen in sound pitch training.



Breathing Training

The difficulty level was divided into easy, moderate, and difficult, and the duration could be selected. The training was performed by setting the difficulty level and duration based on the participants' articulation errors and vocalization ability (Figure 2B).

Speech Training

Duration

Increasing the MPT duration was used to train long vocalization maintenance in a single breath. As the duration and number of repetitions could be set, the difficulty level of the training was adjusted based on the participants' individual abilities (Figure 2C).

Intensity

We could train participants to maintain a suitable voice intensity for a set time by controlling the intensity. As the duration and number of repetitions could be set, the difficulty level of the training was adjusted based on the participants' individual abilities.

Pitch

Controlling the pitch was used to train the ability to maintain a suitable voice pitch for a set time. As the duration and number of repetitions could be set, the difficulty level of the training was adjusted based on the participants' individual abilities (Figure 2D).

Word-Unit Training

In the word-unit training, the user selected a target word to initiate the program and then could set the duration and number of repetitions. The training was designed to allow words containing the target phoneme as the initial, middle, or final consonant to be selected according to the unique articulation errors exhibited by the participants.

Syllable Unit Training

In the syllable unit training, the constituent programs allowed the vocalization of a sound with one or more syllables with consonants rather than the simple vocalization of vowels. The programs could be selected according to the phonetic and articulatory abilities of the participants.

Outcome Measurement

Instruments

The voice data were recorded at the Department of Rehabilitation Medicine Language Therapy Laboratory, where external noise was maximally prevented. The recording was performed using the SM48 microphone (Shure). The child was guided to hold the microphone at an approximately 10 cm distance from the mouth and to produce the voice in a relaxed state. For the recording and analysis of voice, the Computerized Speech Lab (Model 4150, CSL, Kay Elemetrics, Co) was used. The sample ratio for the voice files was as follows: CSL 11,025 Hz; multidimensional voice program, 50,000 Hz; voice range profile, 44,100 Hz; and real-time pitch, 50,000 Hz.

Intervention Environments

Since this study is a home therapy using serious games, treatment was conducted at home in the presence of guardians. Outcome measure was assessed at Jeonbuk National University Hospital by a skilled speech therapist with >3 years of clinical experience.

Voice Parameters

MPT (seconds) and F0 (Hz)

To measure the MPT using the real-time pitch module, the participants were instructed to vocalize/a/ for the longest possible duration. The F_0 was measured at the 3-second point from the initial vocalization along the entire stretch of the voice sample.

Jitter (%) and RAP (%)

Using the multidimensional voice program module, the participants were instructed to vocalize/a/ for ≥3 seconds three times to obtain the mean of triplicate measurements.

Pitch (Hz) and Intensity (dB)

To measure the pitch range using the voice range profile module, the participants were instructed to vocalize/a/ from the lowest range to the highest range he or she could make and, then, vocalize the same sound from the highest range to the lowest range. In addition, the participants were instructed to vocalize/a/ from the highest intensity of voice to the lowest intensity, while the intensity range was measured.

VOT

The participants were provided with a set of picture cards corresponding to the word list containing words with a plosive as the initial consonant (/p/, /p^h/, /p'/, /t/, /t^h/, /t'/, /k/, /k^h/, /k'/). Subsequently, they were instructed to look at the card to say or read the word. The word list contained the words used in a study by Gregory and Lee [13] on the development of Korean plosive sounds.

Articulation Parameters

U-TAP

The U-TAP was used to estimate the articulation accuracy of 43 consonants and 10 vowels at initial, middle, and final positions in words. The word picture cards were used, whereby the participants were instructed to look at the picture card and articulate the word. The sentence-picture cards were used, followed by the articulation of the sentence by the rater, whereby the participants were instructed to repeat after the rater.

Three-Position Articulation Test (TA)

The TA was used so that the participants could articulate words containing 2-4 syllables with 19 target consonants at the initial, middle, and final positions in words. The picture cards were presented, and the participants were instructed to articulate the respective words. In analyzing the U-TAP and TA results, the PCC was applied for consonant accuracy using the following equation for PCC calculation:

PCC (%)=the number of correctly articulated consonants/the total number of target consonants×100.

The PCC is widely used as an indicator of the level of articulation disorder because consonants generally reflect a multitude of articulation errors.

Alternate Motion Evaluation (DDK)

The DDK rate allows for the evaluation of the oral cavity structure and function and the oral exercise ability. After one or two demonstrations by the rater, the participants were instructed to articulate /p /, /t /, and /k / to determine the alternating motion rate and /p t k / for the sequential motion rate (SMR) within 5 seconds, as rapidly and regularly as possible. The number of syllables articulated per second was estimated.

Statistical Analysis

Evaluation results at each phase were comparatively analyzed to compare the treatment period with the nontreatment period of the functional game–based home therapy and verify the effects' retention. All voice data were analyzed using IBM SPSS Statistics (version 24.0; IBM Corp). Repeated-measures ANOVA (RM-ANOVA) was used to compare components of the voice and articulation parameters. The post hoc test was performed as planned with Bonferroni correction at $P<.05$ for variables showing significant values. The significance level was set at .05 in all analyses.

Results

A total of 13 children (9 males and 4 females) were investigated in this study. The mean age of the participants was 6.94 (SD 2.22) years, with their ages ranging from 4 years to 10 years and 5 months (Table 1).

Table 1. Demographic data of the participants.

Participant No.	Age (years)	Sex	U-TAP[a] (%)	REVT[b] receptive	REVT expressive
1	7	Male	93.02	106	98
2	6	Male	90.7	68	69
3	8	Male	93.02	97	96
4	7	Male	93.02	82	91
5	6	Male	93.02	73	69
6	4	Male	60.47	44	61
7	4	Male	48.84	59	47
8	7	Female	76.74	82	78
9	4	Male	67.44	61	48
10	10	Female	83.72	130	149
11	4	Male	67.44	54	60
12	4	Female	86.05	64	61
13	4	Female	79.07	36	47

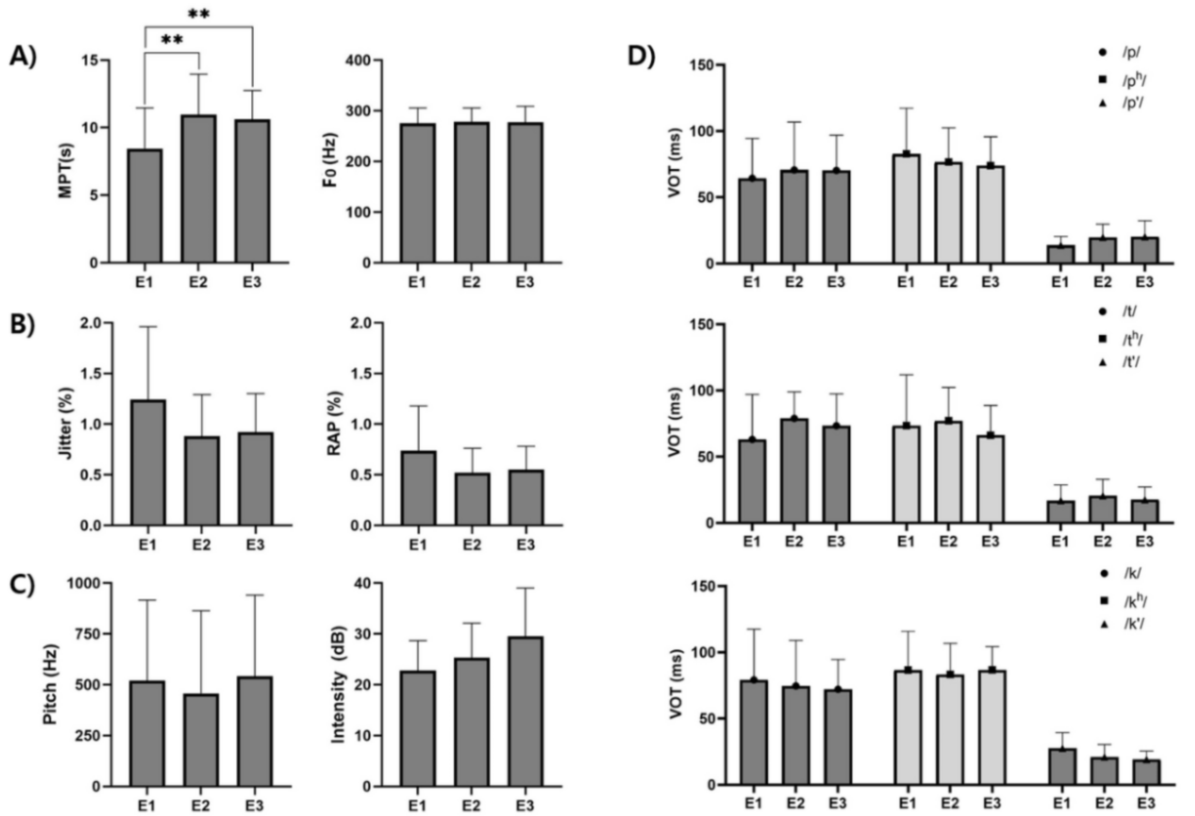
[a]U-TAP: Urimal Test of Articulation and Phonology.

[b]REVT: Receptive and Expressive Vocabulary Test.

Voice Parameters

A comparison between the treatment and nontreatment periods of functional game–based home therapy indicated a significant effect of the treatment in voice parameters (Figure 3).

Figure 3. Changes in voice parameters from pre to posttraining. (A) MPT and F0, (B) jitter and RAP, (C) pitch and intensity, and (D) VOT. Data are shown as mean (SD). Repeated-measures ANOVA (RM-ANOVA) with Bonferroni tests was used for statistical analysis. *P<.05, **P<.01. E1: pre-evaluation 1; E2: postevaluation 1; E3: postevaluation 2; F0: frequency; MPT: maximum phonation time; RAP: relative average perturbation; VOT: voice onset time.



MPT

The MPT showed significant variations across the 3 time points (E1-E2-E3, $P<.05$). In post hoc test, MPT showed differences between phases E1 (mean 8.44, SD 3.02 seconds) and E2 (mean 10.96, SD 2.99 seconds), indicating a significant increase after treatment. In addition, the difference of MPT between phases E1 and E3 (mean 10.62, SD 2.12 seconds) was significant to indicate that the treatment effects had been maintained until 2 months after the training ($P<.05$; Table 2).

Table 2. Post hoc analysis of outcome measures.

Variation	Overall Sig Diff[a]	Post hoc[b]		
		△(E1[c]-E2[d])	△(E1-E3[e])	△(E2-E3)
MPT[f]	.001	0.007	0.004	1.000
U-TAP[g] word	<.001	0.003	0.001	1.000
U-TAP sentence	.008	0.037	0.026	1.000
TA[h]	<.001	0.010	0.003	1.000
SMR[i]	.013	0.034	0.061	0.204

[a]Sig Diff: significant difference; analyzed by repeated-measures ANOVA.

[b]Post hoc: Bonferroni test ($P<.05$).

[c]E1: pre-evaluation 1.

[d]E2: postevaluation 1.

[e]E3: postevaluation 2.

[f]MPT: maximum phonation time.

[g]U-TAP: Urimal Test of Articulation and Phonology.

[h]TA: three-position articulation test.

[i]SMR: sequential motion rate.

Jitter and RAP

The jitter and RAP showed significant variations in RM-ANOVA were noted across the time points ($P<.05$). However, the post hoc test did not indicate significant values for jitter and RAP.

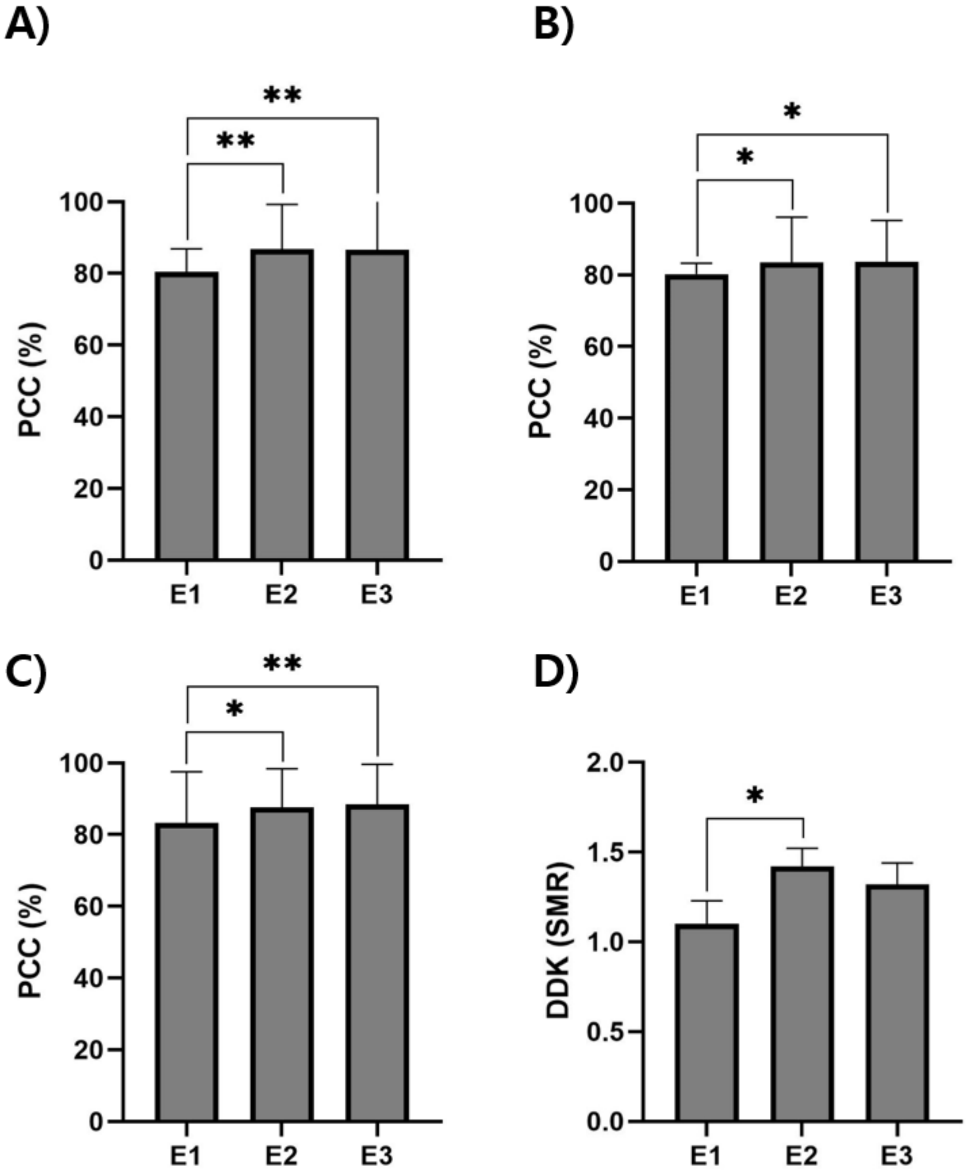
Other Parameters (F0, Pitch, Intensity, and VOT)

For other materials (F_0, Pitch, Intensity, and VOT), no significant difference was found between the time points.

Articulation Parameters

The functional game–based home therapy achieved a significant effect on articulation parameters (Figure 4).

Figure 4. Changes in articulation parameters from pre- to post-training. (A) U-TAP word, (B) U-TAP sentence, (C) TA, and (D) frequency of SMR /p t k / of DDK. Data are shown as mean (SD). Repeated-measures ANOVA (RM-ANOVA) with Bonferroni tests was used for statistical analysis. **P*<.05, ***P*<.01. DDK: diadochokinesis; E1: pre-evaluation 1; E2: postevaluation 1; E3: postevaluation 2; PCC: percentage of correct consonants; SMR: sequential motion rate (/p t k /); TA: three-position articulation test; U-TAP: Urimal Test of Articulation and Phonology.



U-TAP

The subcategories U-TAP word-unit PCC and sentence-unit PCC showed significant variations in analysis across the 3 time points (*P*<.05). The post hoc test revealed differences between phases E1 (word: mean 80.47, SD 6.38 per sentence; mean 80.23%, SD 3.07%) and E2 (word: mean 86.74, SD 12.55 per sentence; mean 83.49%, SD 12.62%), indicating a significant increase in the U-TAP after treatment. In addition, since there were significant differences between phases E1 and E3 (word: mean 86.51, SD 14.16 per sentence; mean 83.72%, SD 11.50%) and no significant differences between phases E2 and E3, it can be assumed that the treatment effects had been maintained until 2 months after the training (*P*<.05).

Three-Position Articulation Test (TA)

The subcategories TA PCC showed significant variations in the RM-ANOVA across the time points (*P*<.05). In the post hoc test, TA showed differences between phases E1 (mean 83.18%, SD 14.38%) and E2 (mean 87.50%, SD 10.89%), representing a significant effectiveness after treatment. In addition, as there were significant differences between phases E1 and E3 (mean 88.41%, SD 11.21%) and no significant differences between phases E2 and E3, it can be assumed that representing effectiveness until 2 months after the training (*P*<.05).

Alternate Motion Evaluation (DDK)

The SMR /p t k / of DDK showed significant variations across the time points (*P*<.05). In post hoc test, SMR showed significant differences between phases E1 (mean 1.1, SD 0.14) and E2 (mean 1.42, SD 0.1), indicating improvement of the articulation frequency per second for /p t k / after treatment (*P*<.05). However, no significant changes were found between phases E1 and E3 and phases E2 and E3 in the post hoc test.

Discussion

Overview

This study conducted a 4-week intervention applying the Smart Speech program consisting of functional games for logopedics to children with articulation disorder. The results of the speech program conducted in this study showed significant changes in both voice and articulation parameters. In voice parameters, MPT, jitter, and pitch showed significant changes in RM-ANOVA. However, post hoc tests showed significant changes between phases E1 and E2 and phases E1 and E3 in the MPT only. Other voice parameters did not show significant differences. In articulation parameters, U-TAP, TA, and DDK showed significant changes in RM-ANOVA. In post hoc tests, U-TAP and TA revealed significant changes between phases E1 and E2 and phases E1 and E3; however, DDK showed significant changes during E1-E2 only.

Several studies have confirmed the effectiveness of conventional treatment methods. However, there is a limitation in that children have to endure time and geographical restrictions for face-to-face treatment [14]. Although the optimum frequency of treatment remains unclear, Williams [15] has suggested that children with articulation disorders may require 30-40 sessions of treatment, depending on the severity and selected treatment method. Long-term intensive training may be effective in children with joint problems; however, economic or geographical constraints may make it difficult to provide treatment adequately [16]. In addition, the stress level in children could increase as the period of intervention increases; hence, a system without time constraints that minimizes training stress in children and allows a guardian's presence during training should be developed. The importance of home therapy with a parent has been emphasized in the study conducted by Bowen (1998) [17], which further described the available treatment techniques for therapists. The home-based serious game for school-age children enables more flexible scheduling while providing shorter but more frequent intervention sessions, thus, maximizing the usefulness of non–face-to-face treatment.

Computer-assisted logopedics would be advantageous in increasing the treatment frequency even if the treatment is not performed in a direct face-to-face session with a clinician. A computer-assisted home therapy could increase the treatment effects by providing personalized treatment to each patient allowing accessibility for residents living in far regions from the facility or center and, most importantly, providing intensive training and the autonomy that is not possible in conventional programs. Moreover, a familiar and natural environment could ensure psychological stability in children to maximize the treatment effects [18]. Logopedics using a computer program allows for a therapeutic approach at the desired level. As the participants can complete the task the clinician assigned without increasing the time of direct face-to-face treatment, the desired effects can be achieved more rapidly. Moreover, visual representations are provided, and the treatment effects and efficiency of the conventional programs can be improved. Voluntary training is essential in maximizing the treatment effects; however, it may not reach an adequate level because of physical or mental fatigue or lack of volition [19]. In contrast, functional games can motivate children through the added element of fun alongside the advantages of computer-assisted logopedics. Thus, a diversity of functional games for logopedics have been developed to allow the potentially tedious training to be conducted with enhanced focus and fun. The "Vox Games" in Brazil is a logopedics program for children's vocalization and speech training. "Dr. Speech" in the US offers logopedic-related games based on vocalization, including pitch and intensity. In addition, in Spain, Saz et al [20] have developed a logopedic program for vocalization and articulation training called "Comunica." In contrast, in Portugal, Grossinho et al [21] have developed "Visual Speech," a functional game for children with articulation disorder. In the Netherlands, Ganzeboom et al [22] had recently applied the "Treasure Hunters," a functional game of logopedics, in 5 patients with Parkinson disease or stroke and reported its positive effects on speech intelligibility. Hair et al [23] have developed the "Apraxia World," a game of logopedics for children with difficulty in speech production, and investigated the preference and satisfaction with using the game in 14 children with articulation disorder (4-12 years). Therefore, various speech therapy games have been developed based on each country's language, and "Smart Speech" is a serious game based on the Korean language.

Recently, various functional games have been applied in logopedics, whereas numerous computer-assisted logopedics for articulation disorder have been developed and tested; however, there is a comparative lack of studies investigating the clinical effects. Thus, this study applied a functional game–based home therapy to children with articulation disorder and, through preintervention and postintervention tests of voice, articulation, and alternate motion, investigated whether the therapy had positive effects on phonation ability and whether positive changes were maintained. In voice parameters, only MPT showed significant changes during E1-E2 and E1-E3 in post hoc study. Other voice parameters did not show significant changes. The ability to maintain vocalization is associated with the expiratory pressure in the respiratory organs. The MPT is a task of speech-motor evaluation that can predict the level of coordination among the muscles related to respiration, vocalization, articulation, and resonance [24]. Thus, the MPT results in this study indicated an increased ability of coordination in breathing and vocalization mechanisms by breathing and vocalization training through functional games. Breathing training of "Smart Speech" focused on expiration, and therefore, it positively affected the increase in phonation time. The acoustic analysis as voice parameters could be useful for identifying improvement in patients with cerebral palsy who showed dysphonia or dysarthria. For the articulation parameters, U-TAP and TA showed significant changes during E1-E2 and E1-E3, whereas DDK showed significant changes during E1-E2 only. It suggests that the effects of oral exercise and articulation training increased the PCC and DDK. In the "Smart Speech" program, oral exercise and speech training had many components that may have improved articulation rather than vocalization. It can be assumed that these factors made the following results. This coincided with the findings of Ahn [25], who reported the positive effect of oral exercise training on consonant accuracy, and with those of Lee et al [26], who applied an AR game–based word and sentence training to improve the word and sentence articulation accuracy in children with articulation disorder. Further, the results agreed with the findings of Lohman-Hawk [27], who reported that the DDK rate in patients with articulation disorder increased by 50% through treatment involving oral exercise training. Our findings suggested that functional game–based home therapy could prove useful in planning logopedic interventions in clinical practice. When children used Smart Speech programs at home, the guardians ensured proper treatment compliance. A clinical researcher contacted the guardian by telephone once a week to monitor the home-based therapy. It should be noted, however, that patients and guardians would be faced with difficulties in planning and conducting suitable training, and the participation and counseling of clinicians will be required.

Principal Results

In this study, children showed significant therapeutic effects in most articulatory indicators but did not show significant therapeutic effects other than MPT in negative indicators. A previous study on the VOT of children with functional articulation disorders has reported that the change in VOT according to the articulation position of plosives and vocalization type of children with functional articulation disorders was the same as that of ordinary children and that speech motor control skill was normally developed in the production of the plosives [28]. This suggests that speech problems in children with functional articulation disorders are more likely to occur owing to the decline of motor control of other articulation structures, compensation for speech motor control, and speech programming skills than in the upper laryngeal structure. The F_0 representing the frequency of vocal cords per second, the jitter representing vibration speed, and the shimmer representing vibration size are directly related to the anatomical structure of the larynx and can be affected by age or sex. This is more related to anatomical factors, and it is difficult to expect a significant therapeutic effect through training because it is less likely that children's articulation disorders will occur due to dysregulation of the upper and laryngeal structures [29]. The results of this study showed a correlation with previous studies and confirmed that the speech motor control or programming ability of articulation structures is likely to be sufficiently improved through a systematic home-based serious game. As the children who participated in this study did not have anatomical problems, it is highly possible that there was no problem with the tremor of the vocal cords. Except for 2 children, most participants showed initial evaluation for F_0 and jitter within the normal range. Thus, in this study, voice parameters may have shown no significant changes. Additionally, in the composition of the "Smart Speech" program, the treatment time of oral exercise and speech training was relatively longer than that of the breaking training, which would have affected the improvement of the articulation parameter.

Limitations

Our study had several limitations. First, the sample size was relatively small. The small sample size may have led to unstable results. Follow-up studies need to analyze a wider population. Second, this study was a single-arm, nonrandomized study. This study was designed as a randomized controlled trial, but it was difficult to set up sham groups because all guardians wanted treatment, and it was difficult to set up other home-based treatments to apply to control groups other than serious games. Therefore, the period of maintaining daily life without treatment was set as a control, and a single-arm design was adopted to assess and compare the period of home-based therapy as an experimental period. As there was no control group, follow-up studies, including the control group, are required to accurately verify the treatment effect. Third, the same treatment was performed regardless of the patient's baseline score, and there is a limitation in that selective treatment according to the patient's condition was not provided. Fourth, Children with a substantially wide range of age and severity were included in the study. In further studies, we need to narrow the scope of participants' age or seriousness of speech sound disorders. Fifth, In this study, we tried to analyze various indicators, but not all articulation parameters were measured due to limited time and human resources. In subsequent studies, we will perform as many standard assessments as possible and analyze the therapeutic effect in more detail by comparing initial and end time points. Finally, the follow-up period in this study was relatively short. Thus, further research is warranted to establish the long-term effectiveness of home-based serious games.

Conclusions

In conclusion, after applying a home-based serious game (Smart Speech) to children with articulation disorders, voice parameters showed improvement in MPT, and articulation parameters revealed improvement in all U-TAP, TA, and DDK. Therefore, home-based serious games are considered to be helpful in improving language function.

Acknowledgments

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Authors' Contributions

Conceptualization: MS, MHK, and GWK; Methodology: MHK and GWK; Software: Y Jo; Validation: SYK and Y Jung; Formal analysis: SYK; Investigation: HY and GWK; Resources: MS and GWK; Data curation: SYK and HY; Writing—original draft preparation: SYK and MS; Writing—review and editing: SYK and GWK; Visualization: SYK, MS, and Y Jung; Supervision:

GWK; Project administration: MHK; Funding acquisition: MHK. All authors have read and agreed to the published version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH Checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1167 KB - games_v11i1e49216_app1.pdf]

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Abbreviations

DDK: diadochokinesis
F0: frequency
MPT: maximum phonation time
PCC: percentage of correct consonants
RAP: relative average perturbation
RM-ANOVA: repeated-measures ANOVA
SMR: sequential motion rate
TA: three-position articulation test
U-TAP: Urimal Test of Articulation and Phonology
VOT: voice onset time

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Global Scientific Trends in Virtual Reality for Pain Treatment From 2000 to 2022: Bibliometric Analysis

Xun Yang[1,*], MD; Sen Zhong[2,*], MD; Sheng Yang[2,*], MD; Meng He[1], MD; Xu Xu[1], MD; Shisheng He[2], MD; Guoxin Fan[3], MD; Lijun Liu[1,*], MD

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*these authors contributed equally

Corresponding Author:
Lijun Liu, MD

Abstract

Background: Virtual reality (VR) is a computer simulation technique that has been increasingly applied in pain management over the past 2 decades.

Objective: In this study, we used bibliometrics to explore the literature on VR and pain control, with the aim of identifying research progress and predicting future research hot spots.

Methods: We extracted literature on VR and pain control published between 2000 and 2022 from the Web of Science Core Collections and conducted bibliometric analyses. We analyzed the publication and citation trends in the past 2 decades, as well as publication and citation analyses of different countries, institutions, journals, and authors. For references, we conducted cocitation and burst analyses. For keywords, we conducted co-occurrence, clustering, timeline view, and citation burst analyses.

Results: Based on 1176 publications, we found that there was a continuous increase in publication and citation volumes, especially in the last 5 years. The United States was the most representative country, and the University of Washington was the most representative institution, with both having the most publications and citations. The most popular journal in this field was *Burns*, and Hoffman HG was the most productive author, leading many studies on patients with burn pain. The reference with the most citation burst was a study on the verification of new hardware in pain control. The keywords with the highest citation bursts related to various situations of pain such as “burn pain,” “wound care,” “low back pain,” and “phantom limb.”

Conclusions: VR has been applied in various clinical situations for pain management, among which burns and pediatric surgery have achieved satisfactory results. We infer that VR will be extended to more clinical pain situations in the future, such as pain control in wound care, low back pain, and phantom limb pain. New research hot spots will include the development of software and hardware to improve the immersive experience of VR for pain control. However, our work was based solely on English literature from the Web of Science database. For future studies, we recommend that researchers explore literature from multiple databases to enhance the scope of their research.

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KEYWORDS
virtual reality; pain management; bibliometrics; research trends; CiteSpace; VOSviewer

Introduction

Pain is an unpleasant sensory and emotional experience that can affect patients’ quality of life. Any form of harmful irritation has the potential to cause pain, and various medical procedures, including venipuncture and wound care, can result in temporary discomfort for patients. Moreover, chronic pain can have an even more substantial impact on individuals. It has been reported to affect more than 30% of people worldwide, and epidemiological studies have estimated that the prevalence of chronic pain is between 18% and 34.5% [1-3]. To a certain extent, continuous pain can adversely affect the patients’ family relationships and become the cause of both heavy social burden and economic burden [4-7]. The main clinical treatment for pain is medication, including paracetamol, opioids, etc. In addition, there are other interventions to relieve pain such as psychological interventions, acupuncture, massage, and spinal cord stimulation [8]. Because of the strong influence of psychological factors on pain perception, psychological intervention has become an important means of adjuvant drug treatment [9].

Virtual reality (VR) is an emerging technology in the psychological intervention for pain, which immerses users in a virtual 3D environment through a wearable screen [10]. In recent years, research has demonstrated that VR can effectively control pain by shifting attention [11]. Some researchers believe that VR influences memory, emotion, and attention, which can help alleviate pain [12]. Functional magnetic resonance imaging has provided evidence that VR can effectively reduce the activity of brain regions associated with pain [13], similar to the effects of opioids [14]. Due to its action mechanism, VR has shown significant efficacy in controlling acute pain and has been used in the management of pain during procedures such as burn wound care and acupuncture [15,16]. Additionally, VR has been applied to chronic pain management, where it creates a sense of presence in a new environment, improves mood, and diverts attention, ultimately reducing pain levels [17]. Chronic conditions such as chronic low back pain [18], chronic cervical pain [19], fibromyalgia [20], complex regional pain syndrome [21], and chronic neuropathic pain have also been targeted with VR-based interventions [22,23].

Despite the growing scientific literature on the use of VR in pain management, there is still a lack of studies on its development trends and hot spots, which can provide scientific guidance for researchers in this area. Bibliometrics is an analytical method that can generate a comprehensive view or quantitative parametric analysis of an entire research field or a specific scientific application area [24-26]. This study aimed to analyze the application of VR in the field of pain management in the past 2 decades using bibliometrics, to provide researchers with an overall research development trend and to help guide future research directions.

Methods

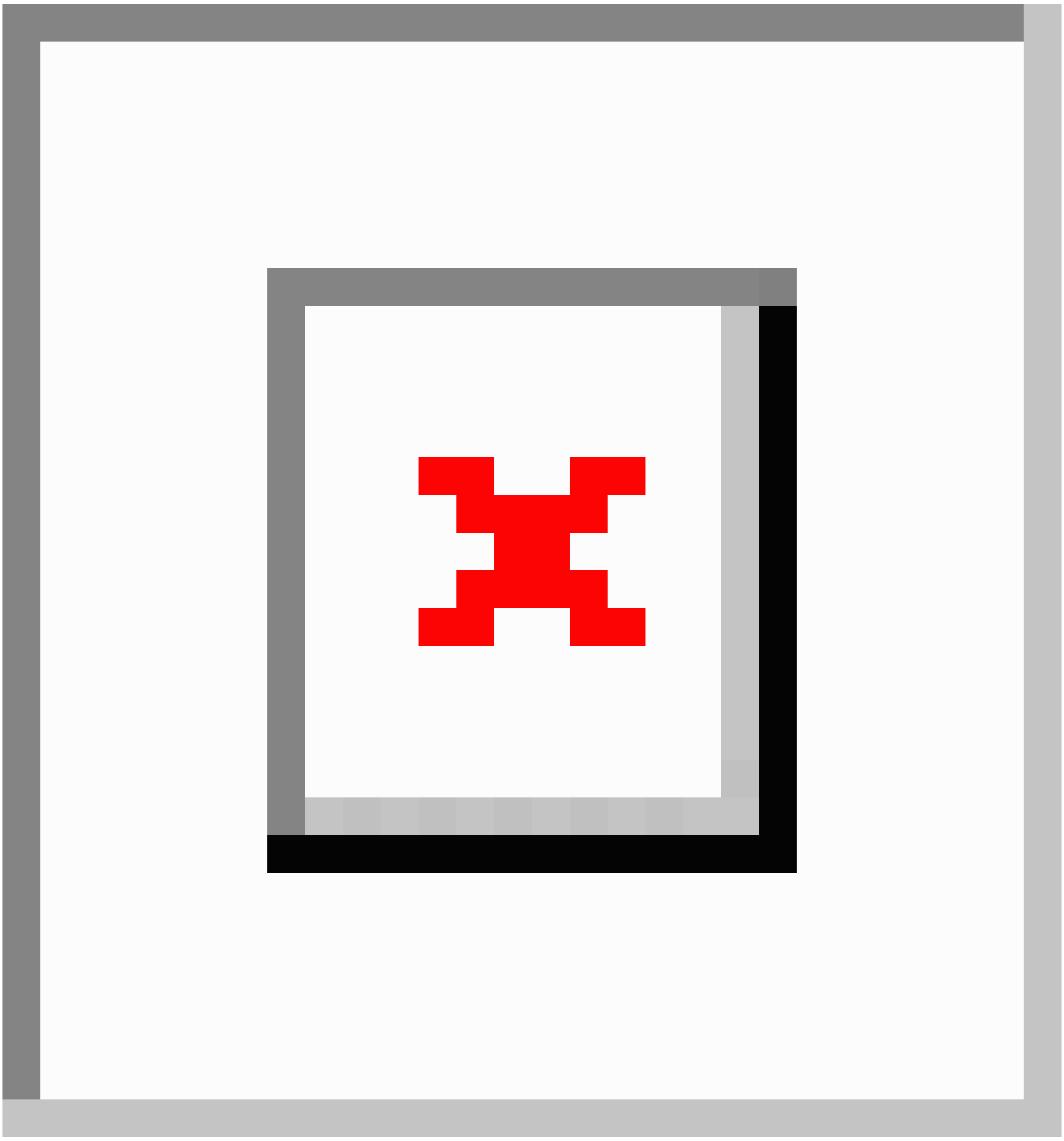
Search Strategy

We searched publications from the Web of Science Core Collection (WoSCC) for analysis. The search strategy was "((TS= (virtual reality)) AND ((TS=(pain)) OR TS= (painful)))." The search was conducted in April 2022.

Included and Excluded Criteria

This study included articles and reviews that were published from 2000 to 2022. The following were excluded: (1) non-English literature and (2) publications that are books, book chapters, meeting abstracts, letters, conference proceedings, editorial materials, etc. The screening process is shown in Figure 1.

Figure 1. The screening process of the selected literature in this study.



Data Export and Analysis

We obtained the information of these publications from the WoSCC through the above search strategy. CiteSpace (version 5.8.R3; Drexel University) and VOSviewer (version 1.6.11.0; Centre for Science and Technology Studies, Leiden University) were used for further data analysis. Quantitative and qualitative analyses were performed and presented in this study, including the following:

1. Annual trends of the publications and citations: these present the general trends in this field.
2. Publication and citation analyses of different countries and institutions: these aim to find the countries or institutions that have contributed more to this field and their partnerships. Researchers may choose to learn from or collaborate with them.
3. Publication and cocitation analyses of different journals: if a study published in journal A and another study published in journal B are both cited by a study published in journal C, then journal A and journal B are considered to have a cocitation relationship and the cocitation count is increased by 1. The definition also extends to the cocitation analysis of authors and references, which is described in further detail below. Journals with a higher number of publications and cocitations are considered as more important journals in the field. Researchers can pay attention to these journals to identify the research progress or publish their study in these journals in the future.

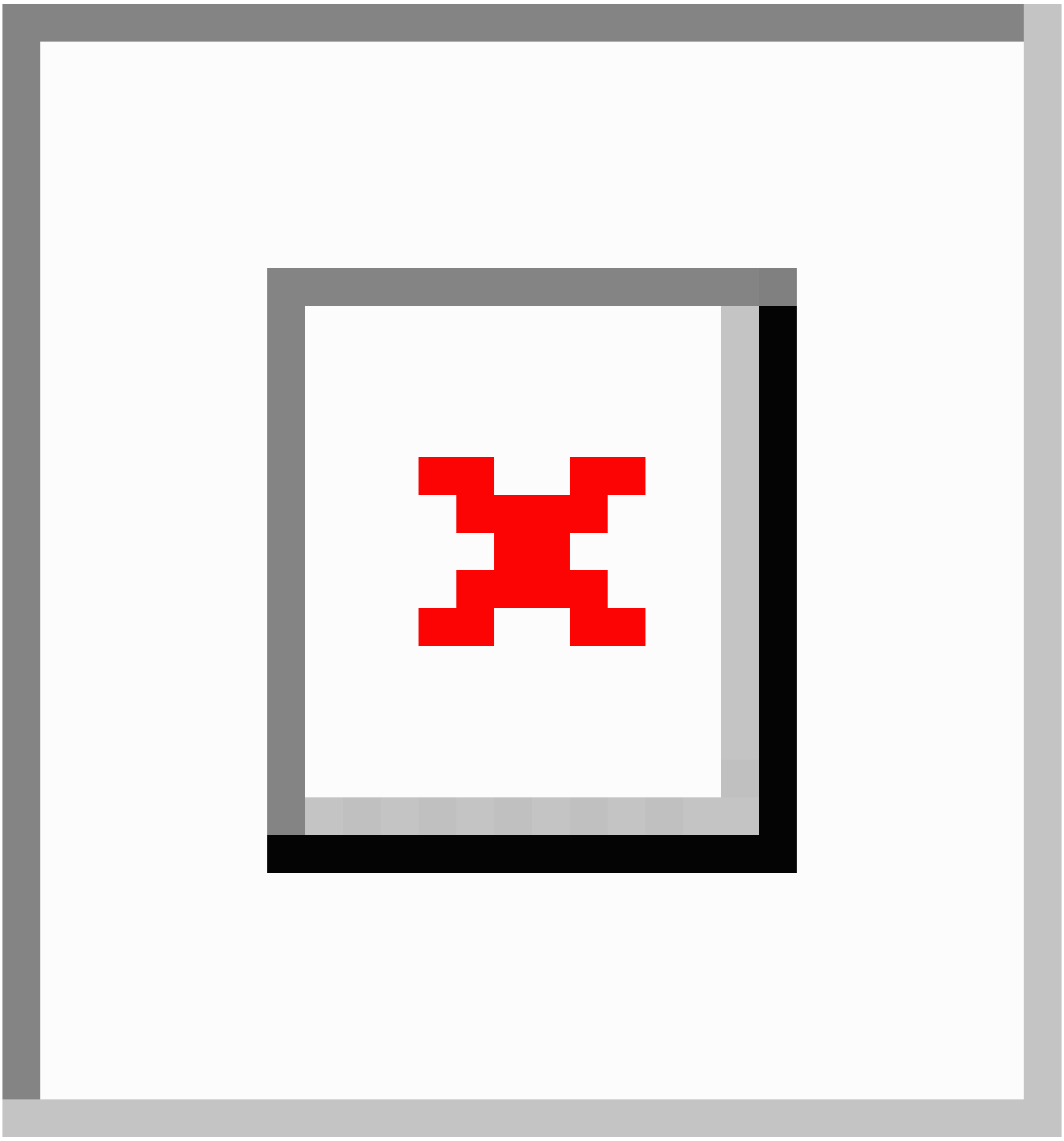
4. Publication and cocitation analyses of different authors: by identifying authors with a high volume of publications or cocitations, researchers can potentially connect with leading experts and stay informed about their research directions and progress.
5. Cocitation and citation burst analyses of references: references with a high number of cocitations can provide insights into the research hot spots of a field. These references are widely recognized and cited by authors in the field, indicating their relevance and significance within the research community. Researchers can use these references to identify key topics and focuses within the field. The citation burst analysis is an indication of the increase regarding researchers' attention to a reference over a given period of time, which is a very important indicator for identifying research hot spot trends.
6. Keywords analysis (co-occurrence, clustering, timeline view, and citation burst): we presented the keywords in the field based on co-occurrence and obtained the research hot spots in the field through the keywords that appear more frequently. Subsequently, those keywords were divided into several clusters, with similar keywords in each cluster, to capture the main research topics. By tracking these keywords through a timeline perspective, we gained a better understanding of the development and evolution in this field over time. Finally, by the analysis of citation bursts, we identified the research hot spots and trends in the field.

Results

Publication and Citation Trends

A total of 1528 publications were retrieved from the WoSCC. In all, 1176 publications were used for further analysis after excluding 41 non-English publications and 311 other publication types. Time trend analysis showed that from 2000 to 2021, the number of published papers increased from 3 to 234, which was statistically significant (2-tailed t_{22}=4.061, *P*=.001; Figure 2). The annual citation frequency had also increased from 3 times in 2000 to 5613 times in 2021, which indicated a similarly significant growth (2-tailed t_{22}=3.565, *P*=.002). In addition, publications and citations in the past 5 years showed a particularly rapidly growth, with an average annual increase of 42.75 papers and 1005.75 citations.

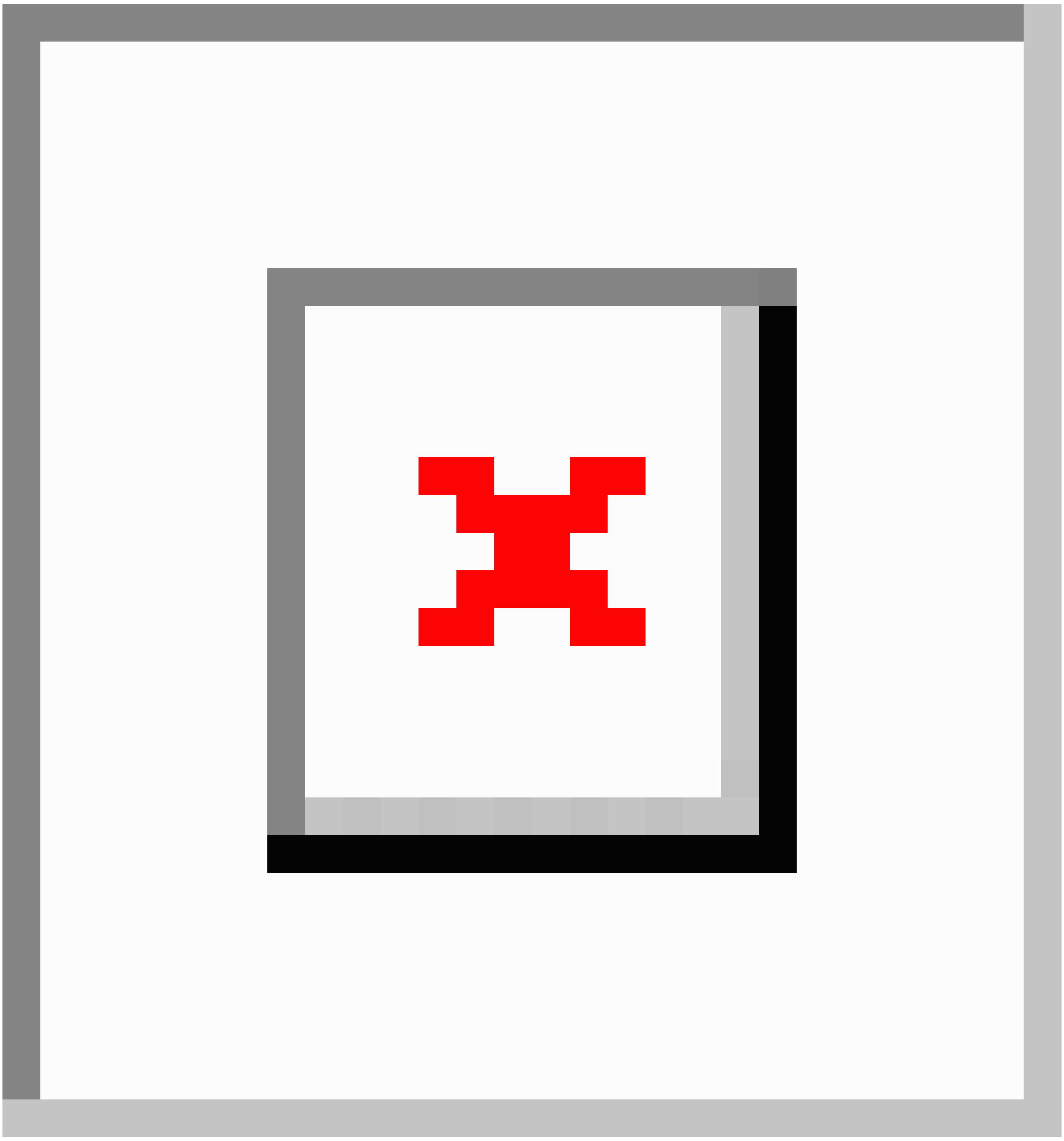
Figure 2. Annual trends of publications and citations.



Distribution of Countries and Institutions

In this study, all the included publications came from 69 countries. The top 11 countries with the most publications are showed in Figure 3A (each node in the figure represents a country). Of these countries, the United States (n=382) had the most publications, followed by England (n=97), Australia (n=89), Canada (n=86), and Spain (n=81). Furthermore, the country citation analysis is shown in Figure 3B. The lines between countries represent the mutual citation relationship between them (Figure 3B); more frequent citations are represented by thicker lines. A total of 1674 institutions participated in this research area, as shown in Figure 3C. In this figure, the institution that generated the most publications was the University of Washington (n=70), followed by the University of Barcelona (n=19), University of Queensland (n=18), University of Haifa (n=14), and University of Sydney (n=14). Similarly, we also analyzed the citation of institutions (Figure 3D). The top 5 countries and institutions with the most citations are summarized in Table S1 in Multimedia Appendix 1. Moreover, clustering analyses of countries and institutions are summarized in Tables S2 and S3 in Multimedia Appendix 1. A total of 5 and 12 clusters were found for countries and institutions, respectively. The top 5 countries and institutions in each cluster are shown in Tables S2 and S3 in Multimedia Appendix 1.

Figure 3. Distribution of countries and institutions. (A) Cooperation mapping of different countries. (B) Citation mapping of different countries. (C) Cooperation mapping of different institutions. (D) Citation mapping of different institutions.



Distribution of Journals

The included 1176 publications on pain and VR research came from 720 academic journals, of which the top 10 journals with the most publications accounted for 15.31% (180/1176) of the total publications, which can be considered as authoritative journals or mainstream journals in this field. Figure 4A shows the visualization results of the publications by different journals. Each node represents a journal, and a larger node indicates greater volume of publications. The cocitation relationship between journals is shown in Figure 4B. The line connecting the nodes indicates that there was a cocitation relationship between the 2 nodes. The top 10 journals with the most publications and cocitations are summarized in Table 1. Among the top 10 journals, 60% (n=6) were from the Q1 quartile and 30% (n=3) were from the Q2 quartile.

Figure 4. Distribution of journals and authors. (A) Publication mapping of different journals. (B) Cocitation mapping of different journals. (C) Cooperation mapping of different authors. (D) Cocitation mapping of different authors.

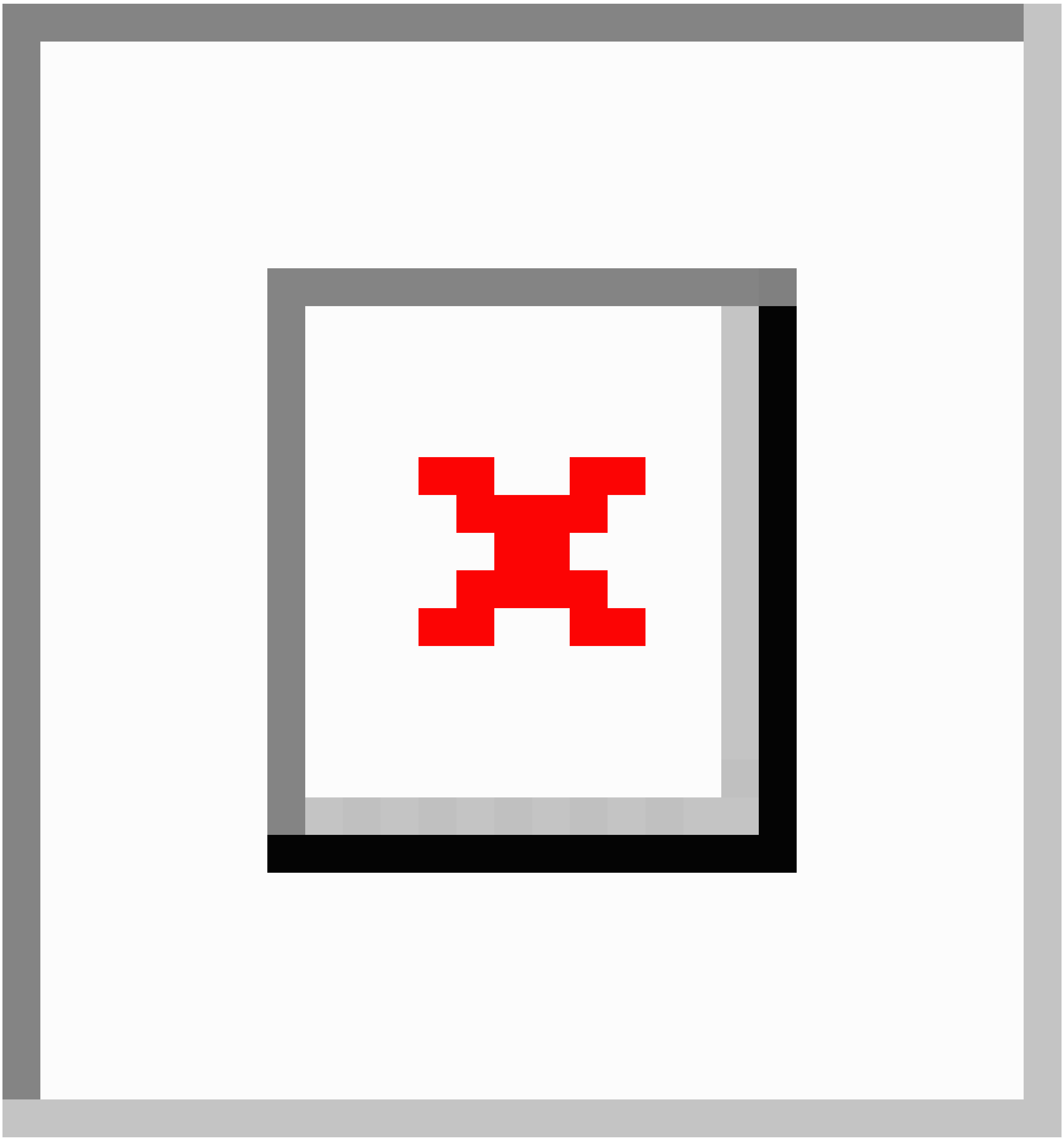


Table . The top 10 journals with the most publications and cocitations.

Ranking	Journal	JCR[a] category	Category rank in 2020	Category quartile in 2020	IF[b] in 2020	Publications or cocitations, n
Publications						
1	*Burns*	• Critical care medicine (SCIE[c]) • Dermatology (SCIE) • Surgery (SCIE)	• 23/36 • 37/69 • 88/211	• Q3 • Q3 • Q2	2.744	23
2	*Journal of Burn Care and Research*	• Critical care medicine (SCIE) • Dermatology (SCIE) • Surgery (SCIE)	• 30/36 • 52/69 • 147/211	• Q4 • Q4 • Q3	1.845	20
3	*Journal of Clinical Medicine*	• Medicine, general & internal (SCIE)	• 39/167	• Q1	4.242	20
4	*Journal of Medical Internet Research*	• Health care sciences & services (SCIE) • Medical informatics (SCIE)	• 10/107 • 5/30	• Q1 • Q1	5.428	19
5	*Frontiers in Psychology*	• Psychology, multidisciplinary (SSCI[d])	• 43/140	• Q2	2.988	18
6	*Pain*	• Anesthesiology (SCIE) • Clinical neurology (SCIE) • Neurosciences (SCIE)	• 4/33 • 23/208 • 39/273	• Q1 • Q1 • Q1	6.961	17
7	*Cyberpsychology Behavior and Social Networking*	• Psychology, social (SSCI)	• 14/65	• Q1	4.157	16
8	*PLoS One*	• Multidisciplinary sciences (SCIE)	• 26/72	• Q2	3.24	16
9	*Scientific Reports*	• Multidisciplinary sciences (SCIE)	• 17/72	• Q1	4.38	16

Ranking	Journal	JCR[a] category	Category rank in 2020	Category quartile in 2020	IF[b] in 2020	Publications or cocitations, n
10	*International Journal of Environment Research and Public Health*	• Environmental sciences (SCIE) • Public, environmental & occupational health (SCIE) • Public, environmental & occupational health (SSCI)	• 118/274 • 68/203 • 42/176	• Q2 • Q2 • Q1	3.39	15
Cocitations						

Ranking	Journal	JCR[a] category	Category rank in 2020	Category quartile in 2020	IF[b] in 2020	Publications or cocitations, n
1	*Pain*	• Anesthesiology (SCIE) • Clinical neurology (SCIE) • Neurosciences (SCIE)	• 4/33 • 23/208 • 39/273	• Q1 • Q1 • Q1	6.961	2341
2	*Cyberpsychology & Behavior*	• Communication (SSCI) • Psychology, applied (SSCI)	• 1/72 • 11/73	• Q1 • Q1	2.71	946
3	*Clinical Journal of Pain*	• Anesthesiology (SCIE) • Clinical neurology (SCIE)	• 16/33 • 99/208	• Q2 • Q2	3.442	930
4	*Burns*	• Critical care medicine (SCIE) • Dermatology (SCIE) • Surgery (SCIE)	• 23/36 • 37/69 • 88/211	• Q3 • Q3 • Q2	2.744	914
5	*PLoS One*	• Multidisciplinary sciences (SCIE)	• 26/72	• Q2	3.24	728
6	*Journal of Pain*	• Clinical neurology (SCIE) • Neurosciences (SCIE)	• 34/208 • 57/273	• Q1 • Q1	5.828	688
7	*Journal of Burn Care & Research*	• Critical care medicine (SCIE) • Dermatology (SCIE) • Surgery (SCIE)	• 30/36 • 52/69 • 147/211	• Q4 • Q4 • Q3	1.845	558
8	*Archives of Physical Medicine and Rehabilitation*	• Rehabilitation (SCIE) • Sport sciences (SCIE)	• 5/68 • 23/88	• Q1 • Q2	3.966	528
9	*Cyberpsychology Behavior and Social Networking*	• Psychology, social (SSCI)	• 14/65	• Q1	4.157	472
10	*European Journal of Pain*				3.934	467

Ranking	Journal	JCR[a] category	Category rank in 2020	Category quartile in 2020	IF[b] in 2020	Publications or cocitations, n
		• Anesthesiology (SCIE) • Clinical neurology (SCIE) • Neurosciences (SCIE)	• 13/33 • 75/208 • 121/273	• Q2 • Q2 • Q2		

[a]JCR: Journal Citation Reports.

[b]IF: impact factor.

[c]SCIE: Science Citation Index Expanded.

[d]SCCI: Social Sciences Citation Index.

Distribution of Authors

The relationships between author and citation are showed in Figure 4C. Each node represents an author and the size of the node indicates the publication counts of the author. The lines between the nodes represent the citation relationship between authors: the thicker the line, the more citations there are between the 2 authors. Table 2 showed the top 10 authors with the most publications and their cocitations. For better visualization, we only included authors with more than 30 cocitations, and a total of 153 authors were included (Figure 4D). The top 10 authors with the most publications came from 4 countries (the United States, Spain, Italy, and Israel), and 7 (70%) out of 10 are American authors.

Table . The top 10 authors with the most publications and cocitations.

Ranking		Author	Publications or cocitations, n	Country
Publications				
	1	Hoffman HG	47	United States
	2	Patterson DR	32	United States
	3	Sharar SR	28	United States
	4	Wiederhold BK	17	United States
	5	Garcia-Palacios A	16	Spain
	6	Riva G	14	Italy
	7	Wiederhold MD	13	United States
	8	Jensen MP	11	United States
	9	Bahat HS	11	Israel
	10	Carrougher GJ	10	United States
Cocitations				
	1	Hoffman HG	1561	United States
	2	Gold JI	275	United States
	3	Patterson DR	270	United States
	4	Moseley GL	253	Australia
	5	Riva G	236	Italy
	6	Ramachandran VS	227	India
	7	Schneider SM	225	United States
	8	Slater M	222	Spain
	9	Melzack R	208	Canada
	10	Dahlquist L	168	United States

Distribution of References

We analyzed a total of 36,224 references from 1176 papers. The most frequently cited and cocited papers are summarized in Table 3. The cocitation relationships are visualized in Figure 5A. It is worth noting that the top 10 cocited references were all from the United States, and 6 of them were from Hoffman HG. We found that all the papers that were cocited the most were about pain control using VR technology.

Table . The top 10 papers with the most citations and cocitations.

Ranking	Citations or cocitations, n	Title	Authors and year	Journal	Country
Citations					
1	435	Virtual Reality in Neuroscience Research and Therapy	Bohil et al [27], 2011	*Nature Reviews Neuroscience*	United States
2	304	Don't Fear 'Fear Conditioning': Methodological Considerations for the Design and Analysis of Studies on Human Fear Acquisition, Extinction, and Return of Fear	Lonsdorf et al [28], 2017	*Neuroscience and Biobehavioral Reviews*	Germany
3	274	Virtual Reality as an Adjunctive Pain Control During Burn Wound Care in Adolescent Patients	Hoffman et al [29], 2000	*Pain*	United States
4	254	Biofeedback in Rehabilitation	Giggins et al [30], 2013	*Journal of Neuroengineering and Rehabilitation*	Ireland
5	253	The Effectiveness of Virtual Reality Distraction for Pain Reduction: A Systematic Review	Malloy and Milling [31], 2010	*Clinical Psychology Review*	United States
6	242	Keeping Pain in Mind: A Motivational Account of Attention to Pain	van Damme et al [32], 2010	*Neuroscience and Biobehavioral Reviews*	Belgium
7	239	Transcontinental Robot-Assisted Remote Telesurgery: Feasibility and Potential Applications	Marescaux et al [33], 2002	*Annals of Surgery*	France
8	220	Use of Virtual Reality for Adjunctive Treatment of Adult Burn Pain During Physical Therapy: A Controlled Study	Hoffman et al [9], 2000	*Clinical Journal of Pain*	United States
9	200	Effectiveness of Virtual Reality-Based Pain Control With Multiple Treatments	Hoffman et al [34], 2001	*Clinical Journal of Pain*	United States
10	199	Virtual Reality as an Adjunctive Non-Pharmacologic Analgesic for Acute Burn Pain During Medical Procedures	Hoffman et al [35], 2011	*Annals of Behavioral Medicine*	United States
Cocitations					

Ranking	Citations or cocitations, n	Title	Authors and year	Journal	Country
1	192	Virtual Reality as an Adjunctive Pain Control During Burn Wound Care in Adolescent Patients	Hoffman et al [29], 2000	*Pain*	United States
2	149	The Effectiveness of Virtual Reality Distraction for Pain Reduction: A Systematic Review	Malloy and Milling [31], 2010	*Clinical Psychology Review*	United States
3	142	Effectiveness of Virtual Reality-Based Pain Control With Multiple Treatments	Hoffman et al [34], 2001	*Clinical Journal of Pain*	United States
4	135	Use of Virtual Reality for Adjunctive Treatment of Adult Burn Pain During Physical Therapy: A Controlled Study	Hoffman et al [9], 2000	*Clinical Journal of Pain*	United States
5	116	Virtual Reality as an Adjunctive Non-Pharmacologic Analgesic for Acute Burn Pain During Medical Procedures	Hoffman et al [35], 2011	*Annals of Behavioral Medicine*	United States
6	114	Effectiveness of Virtual Reality for Pediatric Pain Distraction During IV Placement	Gold et al [36], 2006	*Cyberpsychology & Behavior*	United States
7	112	Virtual Reality and Pain Management: Current Trends and Future Directions	Li et al [37], 2011	*Pain Management*	United States
8	104	A Pilot and Feasibility Study of Virtual Reality as a Distraction for Children With Cancer	Gershon et al [38], 2004	*Journal of the American Academy of Child and Adolescent Psychiatry*	United States
9	102	Modulation of Thermal Pain-Related Brain Activity With Virtual Reality: Evidence From fMRI	Hoffman et al [13], 2004	*Neuroreport*	United States
10	102	Virtual Reality Pain Control During Burn Wound Debridement in the Hydrotank	Hoffman et al [39], 2008	*Clinical Journal of Pain*	United States

Figure 5. Distribution of references. (A) Cocitation mapping of different references. (B) Top 25 references with the strongest citation bursts.

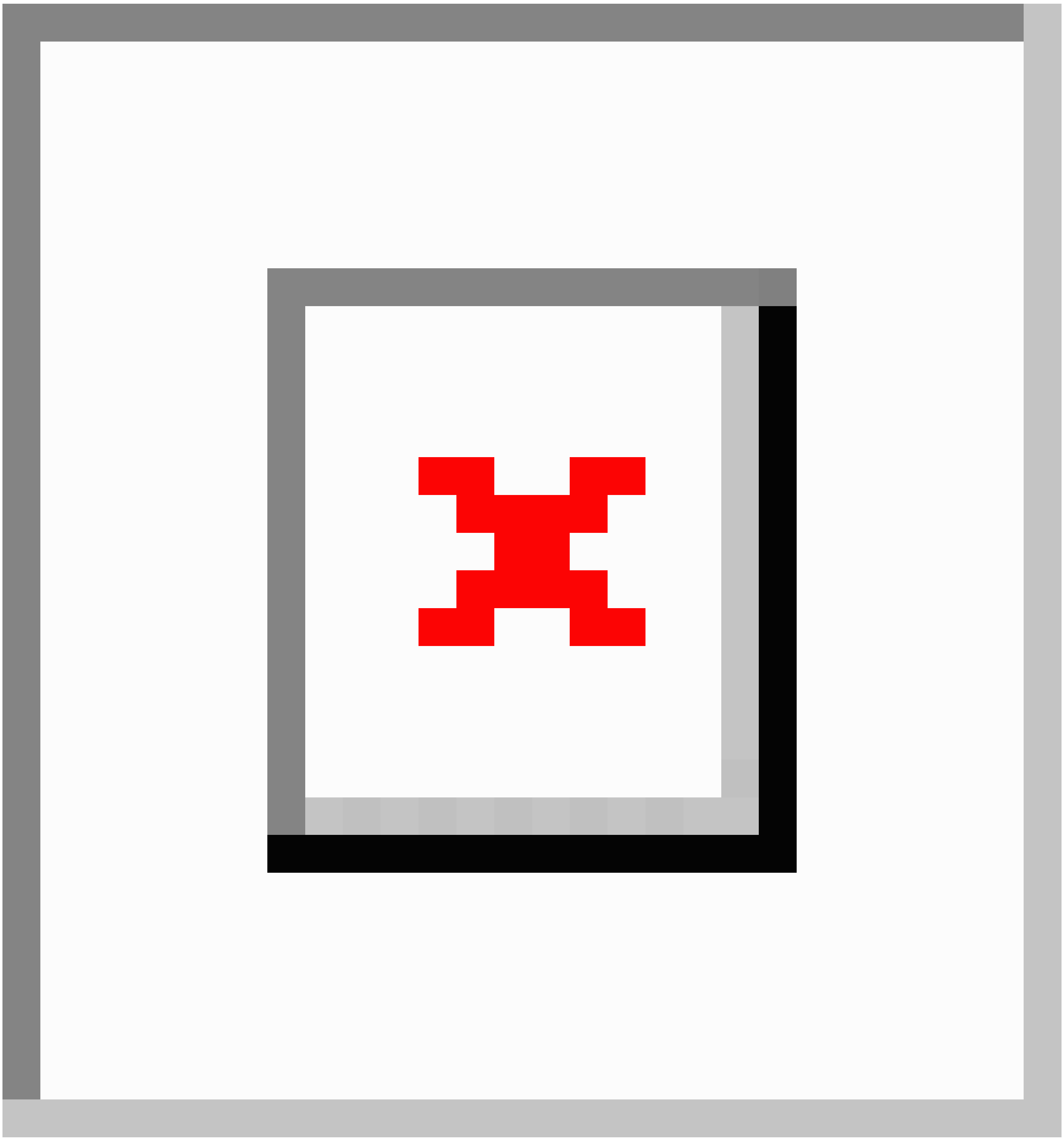
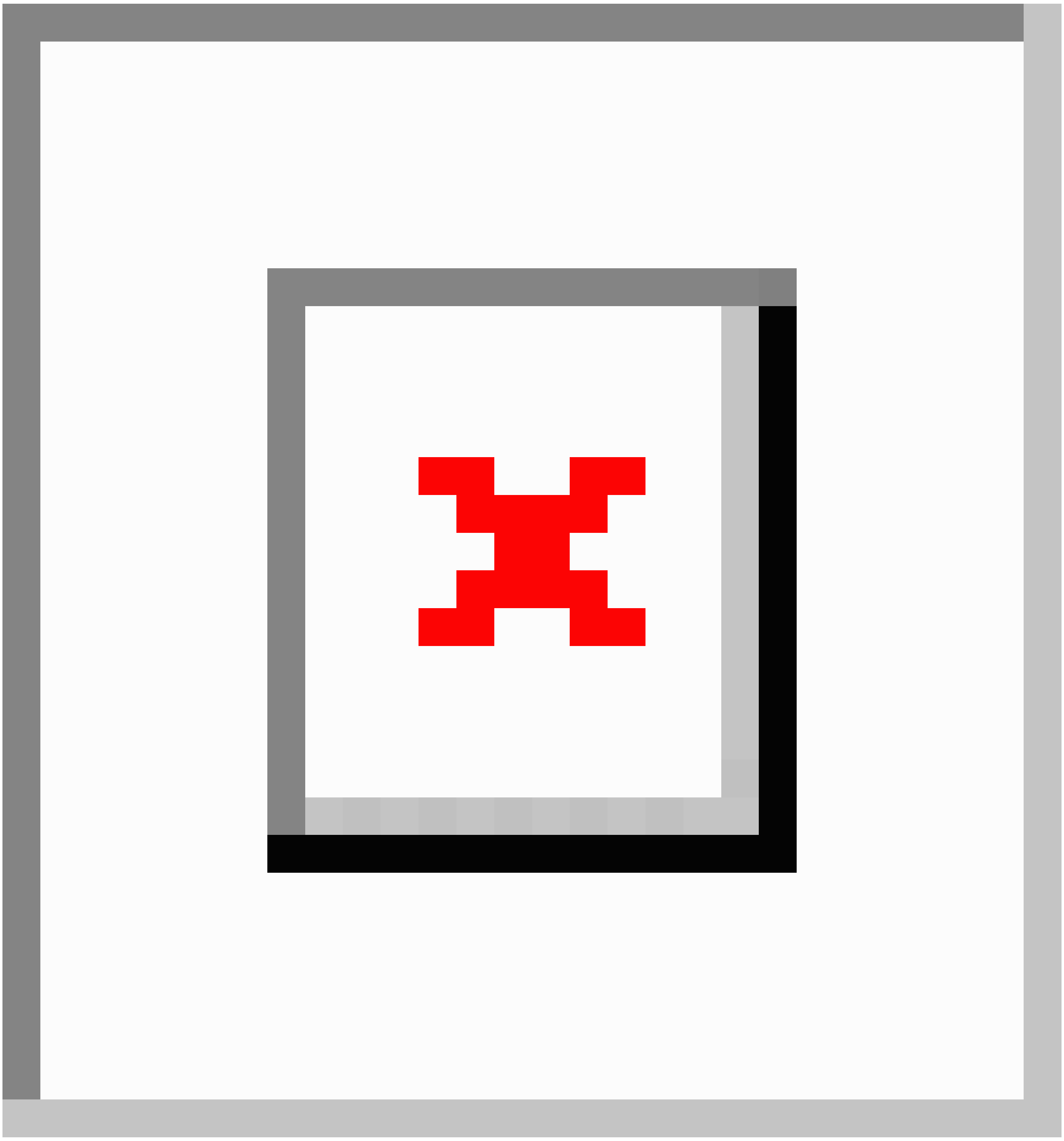


Figure 5B [9,11,13,29,31,34-36,38-54] shows the top 25 strongest citation bursted between 2000 and 200enting more citations and green ones representing fewer citations. A burst of reference means that this paper has been cited more frequently by other papers during this period. From the burst analysis of the references, we found that new directions and new hot spots in this field were constantly emerging and research interest in VR and pain had grown substantially. The burst of reference citations first started from 3 papers written by Hoffman HG in 2001, of which 2 were published in the *Clinical Journal of Pain* and the other in *Pain*. After a lapse of 14 years, the article published by Hoffman HG in *Cyberpsychology Behavior and Social Networking* in 2014 became the most persuasive one. These 3 journals were also among the top 10 journals in the field of VR and pain. Moreover, 8 of the top 25 strongest citation reference were published by Hoffman HG, which was sufficient to justify that Hoffman HG was a pioneer and leader in this field. The latest emerging authors were Mallari B and Arane K, who had published articles in the *Journal of Pain Research* and *Canadian Family Physician*, and these articles had received high citations recently.

Keyword Analysis

The keyword co-occurrence analysis is shown in Figure 6A. The top 10 keywords and their centrality are summarized in Table S4 in Multimedia Appendix 1. The keyword with the highest number of occurrences was “virtual reality” with the highest centrality of 0.09, followed by “pain” with 348 occurrences and a centrality of 0.07.

Figure 6. Keyword analyses. (A) Co-occurrence mapping of different keywords. (B) Clustering mapping of different keywords. (C) Timeline view mapping of different keywords. (D) Top 25 keywords with the strongest citation bursts.



A total of 9 clusters were identified in the clustering analysis, and they are shown in Figure 6B. The *Q* value is 0.412>0.3, and the *S* value is 0.7018>0.7, indicating that the clusters were credible. The top 10 keywords in each cluster are shown in Table S5 in Multimedia Appendix 1. In the cluster, labels were derived from the keywords; a smaller cluster number indicates that the cluster contains more keywords.

The timeline view analysis is shown in Figure 6C. For better visualization, we only showed keywords with more than 18 occurrences. Each node represents a keyword, and only the year that the keyword first appeared was counted. The size of the nodes indicates the frequency of the occurrence. The lines between nodes refer to 2 keywords appearing in the same paper or several papers. For examples, “virtual reality” first appeared in 2000, and the node is the largest, indicating that “virtual reality” had the most occurrences from 2000 to 2022. “Pain” first appeared in 2003, and there is a connection between “virtual reality” and “pain,” indicating that these 2 keywords appeared in 1 or several papers in 2003 at the same time.

The citation burst analysis of the keywords is shown in Figure 6D. The most cited keyword was “wound care,” followed by “visual feedback,” “burn pain,” and “modulation,” indicating that the research on pain relief using VR technology was very popular in the field of burn pain. The latest hot keyword was "preoperative anxiety."

Discussion

Overview

With high incidence and prevalence, chronic pain has become the cause of both heavy social burden and economic burden. VR is a computer simulation technique that has been shown to help patients manage their pain, reducing unnecessary medication use and the numerous side effects. In this study, we analyzed the development process of VR in the field of pain management, as well as research hot spots and future trends. Our results showed that publications in this field grew rapidly, and the United States is now leading in this field. According to our research, the hot spot in this field was burn-related pain, and the representative keywords were "virtual reality," "burn," "surgery" and "pain control." This study provides systematic guidance and potential research directions for researchers in this area.

Principal Findings

VR was first popularized for pain control by Hoffman HG in 2000 [29,55]. Subsequently, publications in this field increased slowly from 2000 to 2017. After 2017, the publications increased rapidly from 63 in 2017 to 234 in 2021, with an average annual increase of 42.75 papers. We infer that there may be 2 reasons for this. First, according to the hype cycle of emerging technologies produced by the Gartner Group in 2015 [56], VR just ended the trough of disillusionment period in 2015 and was in the slope of enlightenment period. At that time, more and more organizations carried out in-depth research on VR technology [57]. The second reason is that as many technology companies such as Facebook, Sony, and other companies made huge investments in the VR field around 2016, VR technology has continued to improve. Additionally, there have been more ways for researchers to obtain VR technology while the cost has also become much lower [58]. In the future, with the continuous innovation of VR technology, we believe that the research on VR technology in medical treatment, including pain control, will become more and more popular. In terms of the global publications, the United States had published a total of 382 articles, accounting for about 32.5% of the 1176 selected articles, which indicates that the United States is the absolute leader in this field. In terms of the number of citations, US researchers topped the list with 12,454 citations, indicating that literature published from the United States are authoritatively reliable in the field of VR pain management, which is inseparable from the leading level of VR technology research. Other countries still have great potential for research in this field on the basis of this citation analysis.

The quality of articles published in this field was also high. Overall, 60% of the top 10 journals were from the Q1 quartile. The top 5 journals with the highest number of publications were *Burns*, *Journal of Burn Care & Research*, *Journal of Clinical Medicine*, *Journal of Medical Internet Research*, and *Frontiers in Psychology*. To sum up, papers in these journals were mostly about burn pain, which is the first application area of VR in pain control [9,29]. Hoffman et al [59,60] have done a lot on the application of VR in burns, and they have confirmed that VR is effective and feasible in pain control of patients with burn pain. However, the mechanism of VR analgesia has not yet been fully elucidated. Whether the analgesic effect can be improved through interaction in the field of burns is a research trend, and there is still a lot of research space in the field of burns [60].

Research Hot Spots

Combined with literature cocitation analysis and keyword co-occurrence analysis, the current research focus in the field revolves around 2 main areas: the control of burn-related pain and pain control during medical operations in children. Two important studies conducted by Hoffman et al [9,29] in 2000 demonstrated that VR can reduce pain perception in patients with burn pain during physical therapy and alleviate pain during burn wound care. Subsequent clinical experiments have consistently confirmed the pain-reducing effects of VR in procedures such as excision and hydrotherapy debridement for patients with burn pain [39,61-63]. Furthermore, Hoffman et al [64] provided additional evidence for VR's pain control capabilities in patients with burn pain by using functional magnetic resonance imaging to demonstrate a reduction in pain-related brain activity while using VR devices. Lee et al [65] used functional near infrared spectroscopy to analyze cerebral blood flow in patients with burn pain during VR experiences. They discovered a significant increase in oxygenated hemoglobin in the prefrontal lobe, suggesting that VR activates the prefrontal lobe to inhibit pain sensations.

Researchers have also been interested in understanding the factors that influence VR's pain control in patients with burn pain. Sharar et al [66] found that VR's analgesic effect remains consistent regardless of factors such as age, gender, race, burn wound size, or duration of treatment. However, a comparison study by Hoffman et al [67] showed that VR headsets with wider viewing angles result in a more immersive experience and better pain control compared to headsets with narrower viewing angles. In summary, the pain-relieving benefits of VR for patients with burn pain have been consistently validated, and future efforts should focus on optimizing the VR experience to further enhance pain control efficacy.

Moreover, VR has shown promising results in pain relief during medical procedures for pediatric patients. Beyond its application in burn-related scenarios, VR has been used for venipuncture, intravenous catheterization [68], lumbar punctures [69], and even preoperative procedures [70] to alleviate anxiety and minimize procedure-related pain in children. Compared to adults, VR is particularly effective in capturing the attention of children and can be applied in various clinical scenarios. Recent research has explored the use of VR for preoperative anxiety relief, postoperative pain management [71], pain control during vaccinations [72], anesthesia and tooth extraction [73], as well as pain management during emergency sutures [73,74]. In the future, VR is poised to play an important role in various pediatric medical operations.

Research Trends and Directions

The role of VR in pain control has been proven, and future research in this field aims to promote the application scenarios of VR pain control and enhance the user experience for patients to improve the analgesic effect. At present, in addition to the application of treating patients with acute burn pain, the analgesic effect of VR has been applied in the first stage of labor analgesia [75], wound care [76], cystoscopy [77], oral surgery [78], and postoperative pain management [79]. However, further studies are needed to confirm its effectiveness in different clinical scenarios such as gastroenteroscopy and puncture surgery. Patients with chronic pain, including chronic cancer pain, chronic neuropathic pain, and chronic low back pain, can also benefit from VR devices, which can provide pain relief and improve mood [80-83]. To manage chronic pain effectively, there is a need to develop more diverse VR software that caters to the needs of patients.

Improving the patient experience will also be a key focus for future research. As an immersive device, VR presents certain challenges. First, hardware equipment needs to be enhanced to provide a more interactive VR experience, as suggested by Yeo et al [84]. Second, the development of high-quality VR software specific to different pain types is crucial for enhancing the patient experience. Additionally, creating appropriate VR scenarios and games tailored to patients' needs will contribute to a better patient experience.

In conclusion, this study conducted a 2-decade bibliometric analysis of research on VR interventions in pain management. Currently, the research of VR in the field of pain has received extensive attention, and satisfactory results have been achieved in a series of fields such as burn pain and pediatrics medical procedure–related pain. It is remarkable that burn pain control is still a research hot spot in this field. The emerging trends include the application of VR in other departments related to pain and improving VR technology to enhance the patient experience. However, the mechanism of pain control with VR is not yet understood, and researchers are constantly working in this field, which will guide the development of more effective VR pain management technology.

Strengths and Limitations

This is the first bibliometric analysis of VR research in the field of pain. We provided scientific information in this field and predicted research hot spots and research trends to summarize the research status in this field and further promote the development of this field.

However, there are multiple limitations in our research. First, we only analyzed publications in the WoSCC and failed to exhaust all the publications on VR and pain control. Second, due to limitations of the analysis tools, we only analyzed the papers published in English and discarded other valuable books as well as non–article and review literature such as conference papers. Last but not least, our retrieval methods also have shortcomings, but they simplified the literature so that it is more in line with our theme, and simplicity was conducive to the development of our analysis and research. However, we still hope that future researchers can use more search terms to include some fringe literature in the analysis scope, which may be a useful recommendation for future treatment in this field.

Conclusions

Through bibliometric analysis and visualization, we provided an overview analysis of the field of VR for pain control. There were more than 60 countries participating in this field, and the relative research had been growing rapidly in recent years. The United States and the University of Washington were the representative country and institution, and Hoffman HG was the pioneer in this field. Through the analysis, we identified the hot spots in this research field, which included burn pain and pediatric surgery pain. More attention will be paid to the application of VR in various pain situations in the future, and more diversified software and hardware will be developed to improve the immersive experience of patients, making VR more distracting and more effective at reducing pain.

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Data Availability

The data sets generated during this study are available from the corresponding author on reasonable request.

Authors' Contributions

XY contributed to project administration, writing–original draft, and writing–reviewing and editing. XY, SZ, and SY share first authorship for their equal contributions to this manuscript. SZ was involved in methodology, software, and writing–reviewing and editing. SY was involved in data curation, investigation, and writing–reviewing and editing. MH and XX contributed to writing–original draft and writing–reviewing and editing. SH, GF, and LL contributed to conceptualization, supervision, and writing–reviewing and editing. SH (tjhss7418@tongji.edu.cn) and GF (fan06309@163.com) are co-corresponding authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The top 5 countries and institutions with the most citations, the top 5 countries in each country cluster, the top 5 institutions in each institution cluster, the top 10 co-occurrence keywords and the centrality, and the top 10 keywords in each keyword cluster.
[DOCX File, 37 KB - games_v11i1e48354_app1.docx]

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Abbreviations

VR: virtual reality
WoSCC: Web of Science Core Collection

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Original Paper

Effects of Exergaming on Musculoskeletal Pain in Older Adults: Systematic Review and Meta-analysis

Nan Mo[1], MSc; Jin yu Feng[1], MSc; Hai xia Liu[1], MSc; Xiao yu Chen[1], MSc; Hui Zhang[1], MSc; Hui Zeng[1], PhD

Xiangya Nursing School, Central South University, Changsha, China

Corresponding Author:
Hui Zeng, PhD
Xiangya Nursing School
Central South University
Xiangya School of Medicine
Number 172, Tong zipo Road
Changsha, 410013
China
Phone: 86 1 378 615 5688
Email: zenghui@csu.edu.cn

Abstract

Background: Exercise is effective for musculoskeletal pain. However, physical, social, and environmental factors make it difficult for older adults to persist in exercising. Exergaming is a new pathway that combines exercise with gameplay and may be helpful for older adults to overcome these difficulties and engage in regular exercise.

Objective: This systematic review aimed to determine the efficacy of exergaming to improve musculoskeletal pain in older adults.

Methods: The search was performed in 5 databases (PubMed, Embase, CINAHL, Web of Science, and Cochrane Library). The risk of bias for randomized controlled studies was assessed using the revised Cochrane Risk of Bias tool in randomized trials (RoB 2), and the methodological quality was assessed using the Physiotherapy Evidence-Based Database scale. Standardized mean difference and 95% CI were calculated using fixed-effects model meta-analyses in the Review Manager version 5.3 (RevMan 5.3).

Results: Seven randomized controlled studies were included, which contained 264 older adults. Three of the 7 studies reported significant improvements in pain after the exergaming intervention, but only 1 reported a significant difference between groups after adjustment for baseline (*P*<.05), and another reported a significant improvement in thermal pain between the 2 groups (*P*<.001). The results of the meta-analysis of the 7 studies showed no statistically significant improvement in pain compared to the control group (standardized mean difference –0.22; 95% CI –0.47 to 0.02; *P*=.07).

Conclusions: Although the effects of exergames on musculoskeletal pain in older adults are unknown, exergame training is generally safe, fun, and appealing to older adults. Unsupervised exercise at home is feasible and cost-effective. However, most of the current studies have used commercial exergames, and it is recommended that there should be more cooperation between industries in the future to develop professional rehabilitation exergames that are more suitable for older adults. The sample sizes of the studies included are small, the risk of bias is high, and the results should be interpreted with caution. Further randomized controlled studies with large sample sizes, high quality, and rigor are needed in the future.

Trial Registration: PROSPERO International Prospective Register of Systematic Reviews CRD42022342325; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=342325

(JMIR Serious Games 2023;11:e42944) doi:10.2196/42944

KEYWORDS

aged; exergaming; pain; review; video game; virtual reality

Introduction

Background

The International Association for the Study of Pain defines pain as an unpleasant sensory and emotional experience associated with or resembling actual or potential tissue damage [1]. Pain is classified as acute, subacute, and chronic. Fewer than 4 weeks is acute pain, and the presence of 4 weeks to 3 months is subacute pain, and chronic pain is a condition that persists or recurs for more than 3 months [2]. The causes of pain in older individuals are often due to osteoarthritis, postherpetic neuralgia, diabetic neuropathy, spondylosis and radiculopathy, poststroke pain, and Parkinson disease [3]. According to data from the 2016 American Health Interview Survey [4], 20.4% of American adults have chronic pain, with 8% of American adults having a high impact on chronic pain [5]. The prevalence of pain increases with age [6]. Individuals aged 60 years and older are classified as older individuals by the World Health Organization [7]. Data from 1999 to 2019 showed that 57%-61% of community-dwelling older individuals reported intermittent or daily musculoskeletal pain [8]. By 2030, approximately 66% of people over the age of 65 years will have chronic pain globally [9]. Pain affects sleep and mood, increases the risk of falls, and reduces the quality of life [9-11]. It imposes a heavy burden on society [12].

Changes in the efficacy of analgesic drugs occur due to aging, such as a possible weakening in analgesic effect and a decrease in the efficiency of drugs acting on peripheral sensitization [13]. It is worth noting that medications may make older individuals more debilitated and adverse reactions occur more frequently [3]. Nonpharmacological treatments have therefore been used for pain relief. The efficacy of exercise in alleviating pain has been demonstrated [14], and exercising in nonpainful areas of the body has an analgesic effect on painful areas [15]. Older adults with poor physical function prefer to exercise at home at no cost [16]. However, the lack of supervision and motivation at home leads to low exercise adherence [17], which further leads to poorer treatment effects [18,19].

Technology can serve as an effective strategy to confront these challenges. Exergames are video games or virtual reality (VR) games that combine gameplay with physical training and are potential tools to make exercises more enjoyable and increase motivation and compliance for physical activity [20-23]. Results of systematic reviews showed that exergames could improve the activities of daily life [24], cognitive [25] and physical function [26], balance [27], walking speed [28], and depression [29,30] among older adults. There was some evidence of randomized controlled trials (RCTs) supporting the benefits of exergames for improving pain in older adults [31,32].

Research Gap and Aim

To our knowledge, 3 reviews have systematically summarized the effects of exergames on pain. A systematic review [33] included thirteen clinical studies, and the mean age of participants ranged from 23.9 (SD 6.8) years to 54.9 (SD 11.8) years. The 6 included controlled trials showed that interactive VR exergames may divert attention from pain and alleviate pain postmastectomy and ankylosing spondylitis, but the results were inconsistent for people with neck pain. The remaining 7 uncontrolled studies showed that interactive VR exergames reduced neuropathic limb pain and phantom limb pain, but did not affect nonspecific chronic back pain. A systematic review and meta-analysis [34] also showed that exergames can improve pain perception in females older than 18 years with fibromyalgia. However, a systematic review and meta-analysis [35] that included 7 RCTs concluded that there was insufficient evidence that exergames can improve musculoskeletal pain in the participants and the mean age ranged from 33.5 (SD 9.5) years to 80 years. The results of these reviews are inconsistent, as well as have some limitations. In the first place, they were not focused on older adults. Secondly, the included studies were not all RCTs. In further, some of them did not perform a meta-analysis and the results were not rigorous enough. Therefore, the purpose of this study is to review the efficacy of exergames for musculoskeletal pain in older adults.

Methods

Overview and Registration

The report of this systematic review and meta-analysis is consistent with the updated guidelines of the PRISMA (Preferred Reporting Items of Systematic Reviews and Meta-Analyses) 2020 Statement (Multimedia Appendix 1) [36]. The registration number is CRD42022342325.

Literature Search

A systematic literature search was carried out in 5 databases, PubMed, CINAHL (through EBSCO), the Cochrane Library, Web of Science, and Embase, from the inception to March 4, 2022. The combinations of Medical Subject Headings and free-text terms were used, and concepts included were exergaming, pain, and aged (see Multimedia Appendix 2).

Eligibility Criteria

The following were the criteria for including the articles: (1) participants' mean age was more than 60 years and they suffered from musculoskeletal pain; (2) game technology was used to enable participants to exercise; (3) the control group was either active control (other interventions but no gameplay) or passive control (eg, usual care, no treatment, or waiting list); (4) the pain was involved in clinical outcomes; (5) the article had been published in a peer-reviewed publication with a RCT; and (6) the articles were written in English.

Exclusion criteria were as follows: (1) reviews, editorials, conference abstracts, and protocols, or full text was not available; (2) incomplete information on the intervention; (3) outcome data for pain were not statistically analyzed; and (4) duplicate publications or no restrictions on the publication date.

Study Selection

A researcher searched the 5 databases according to the search strategies. Duplicates were excluded by EndNote 9X. Two researchers independently reviewed the titles and abstracts of records before reading the entire text for rescreening to identify the included literature based on the eligibility criteria. Any differences were settled through discussion or by consulting a third researcher.

Data Extraction

The data were extracted by 2 independent researchers using the self-developed form in Excel (Microsoft Corp), comprising study characteristics, participant characteristics, intervention details, attrition, supervision, adverse events, experience, measurement tools for the outcome, and the key results. Following that, the 2 researchers subsequently cross-checked. A third investigator was consulted in the event of a dispute.

Risk of Bias and Methodological Quality Assessment

The included studies' quality was evaluated using the revised Cochrane Risk of Bias tool in randomized trials (RoB 2) [37]. The risk of bias in 5 domains, including (1) randomization procedure; (2) deviations from intended interventions; (3) missing outcome data; (4) measurement of the outcome; and (5) selection of the reported result, was appraised using 3 degrees of "low risk," "some concerns," or "high risk." When at least one domain was considered to have "some concerns," but no domain was deemed to have "high risk," the study was labeled as having "some concerns of bias." When at least one domain was deemed "high risk" and many domains were deemed "some concerns," the study was deemed "high risk of bias" [37].

The Physiotherapy Evidence-Based Database scale was used to assess the methodological quality of randomized controlled studies. The scale is a specific instrument for clinical studies of physical therapy interventions [38]. It comprises 11 items related to the selection, detection, performance, information, and attribution bases domains. Research with a score lower than 4 is regarded as bad, 4-5 is considered fair, 6-8 is considered good, and 9-10 is considered excellent [39].

The assessments were conducted independently by 2 independent evaluators. One reviewer resolved the disagreement.

Data Synthesis

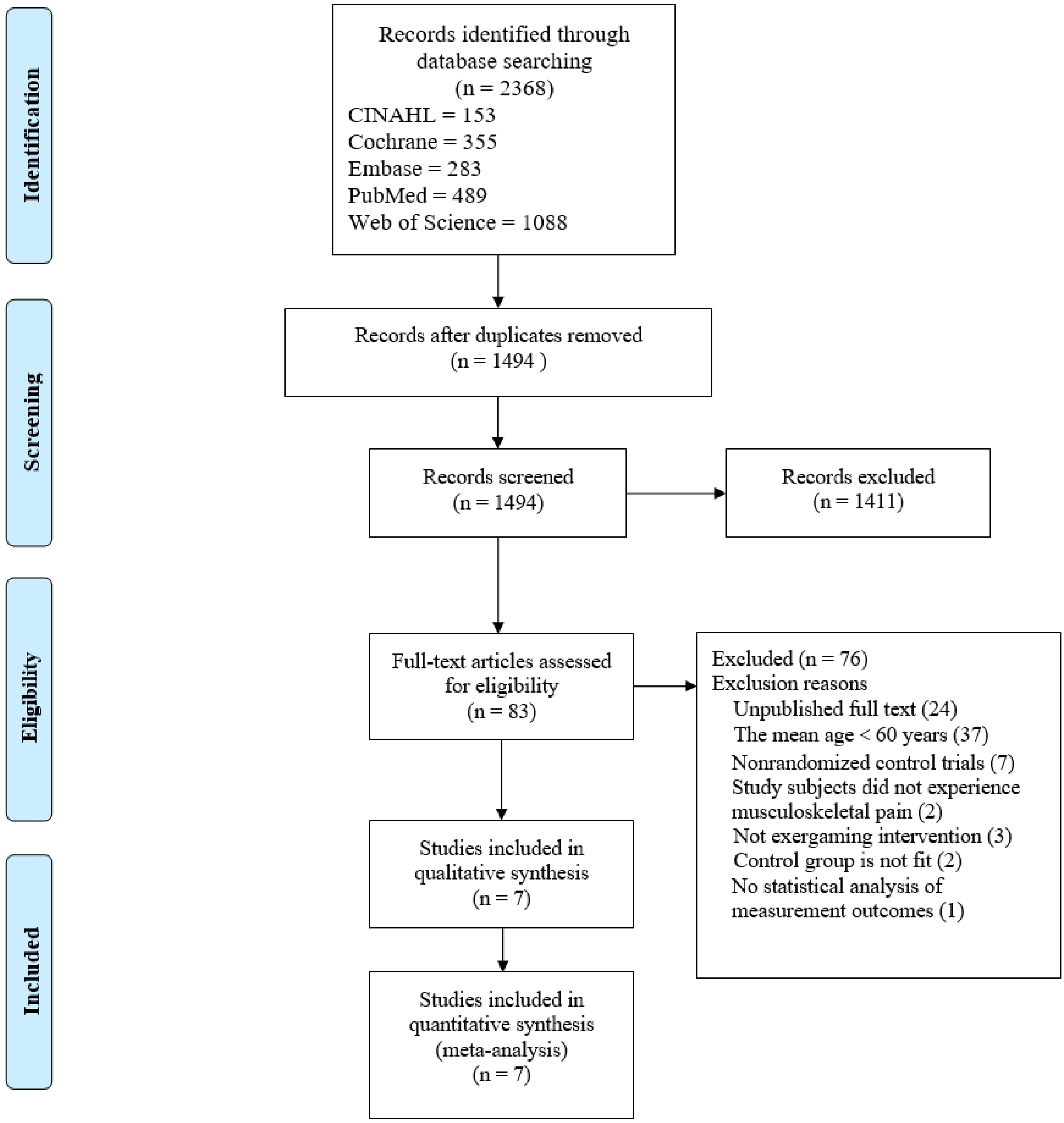
The equation ($Mean_{change}=Mean_{after}–Mean_{baseline}$) and ($SD_{change}=\sqrt{[SD^2_{baseline}+SD^2_{after}–\{2\times correlation\times SD_{baseline}\times SD_{after}\}]}$) were used to calculate the mean change and corresponding SD, and the correlation was set to 0.5. SDs were not given in the study and were obtained by converting the means, sample sizes, and *P* values of the changes in the intervention and control groups [40]. The effect size was measured by the standardized mean difference (SMD) corrected for small sample sizes (Hedges *g*) [40]. Hedges *g* estimates of <0.30, ≥0.30 and <0.60, and ≥0.60 were considered small, moderate, and large, respectively [41]. The heterogeneity among studies was quantified based on the I^2 statistic, with 0%-40% may not be important; 30%-60% may represent moderate heterogeneity; 50%-90% may represent substantial heterogeneity; and 75%-100% may represent considerable heterogeneity [42]. A fixed-effects model was used when I^2≤50%, otherwise a random-effects model was used. We performed subgroup analysis to explore which treatments were more effective or what nature of pain exergaming was more effective for. Meta-analysis was performed using Review Manager version 5.3 (RevMan 5.3). We did not perform a publication bias test because fewer than 10 studies were included [42].

Results

Study Selection

By searching the databases, 2368 records were found. After removing 874 duplicates, 1494 records were evaluated. A total of 1411 records were excluded according to the eligibility criteria. The remaining 7 studies were analyzed. The PRISMA flow diagram depicts the search and screening procedure (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items of Systematic Reviews and Meta-Analyses) flow diagram of study selection according to PRISMA [43].

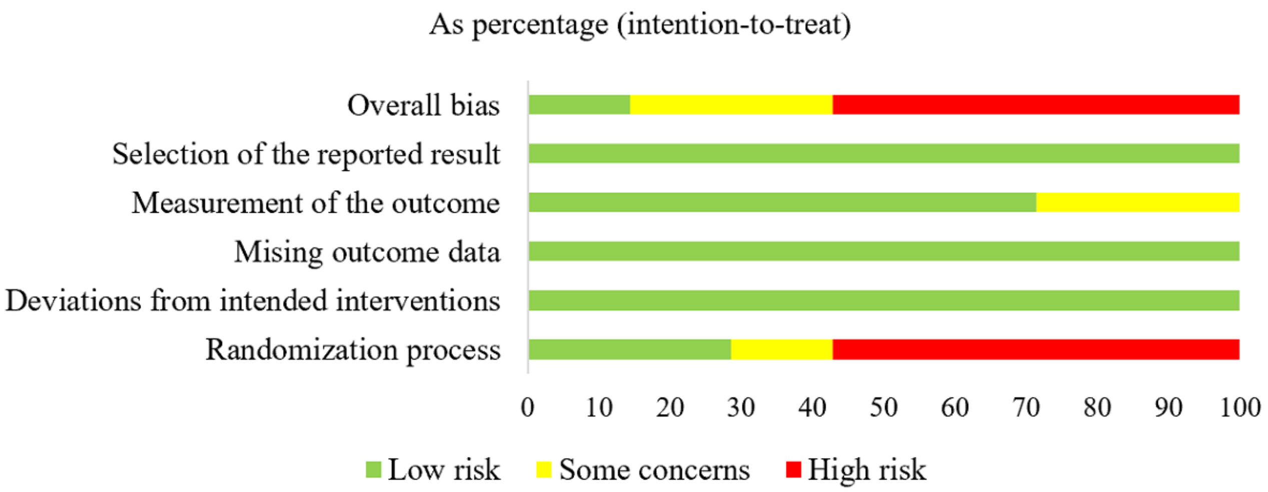


Quality Assessment

Figures 2 and 3 summarized the risk of bias assessment for the 7 studies that were included. One study (14%) was classified as "low risk" [44], 2 studies (29%) as "some concerns" [31,32], and 4 studies (57%) as "high risk" [21,22,45,46]. All studies were judged "low risk" for the domains "Deviations from intended interventions," "Missing outcome data," and "Selection of the reported result." Four studies (57%) were assessed as "high risk" for the domain "Randomization procedure" due to no report allocation concealment approaches, while 1 research (14%) was evaluated as "some concerns" related to baseline imbalance. Due to nonblind assessors, 2 studies (29%) were determined to have "some concerns" in the domain "Measurement of the result."

Figure 2. Risk of bias based on revised Cochrane Risk of Bias tool in randomized trials (RoB 2) [37].

Figure 3. The overall risk of bias in randomized controlled trials.



Physiotherapy Evidence-Based Database scores (mean score approximately 7, range 6-8) demonstrated good overall methodological quality. Monteiro-Junior et al [44] received the highest score of 8, while Stamm et al [46] had the lowest score of 6 (Table 1).

Table 1. Methodological quality as assessed by the Physiotherapy Evidence-Based Database Scale. Item 1 did not count toward the total score.

Study, year	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	8[h]	9[i]	10[j]	11[k]	Total score	Methodological quality
Beltran-Alacreu et al [22], 2022	1	1	0	1	0	0	1	1	1	1	1	7	Good
Ditchburn et al [31], 2020	1	1	1	1	0	0	0	1	1	1	1	7	Good
Fung et al [45], 2012	1	1	0	1	0	0	1	1	1	1	1	7	Good
Hsu et al [21], 2011	1	1	0	1	0	0	1	1	1	1	1	7	Good
Monteiro-Junior et al [44], 2015	1	1	1	1	0	0	1	1	1	1	1	8	Good
Stamm et al [46], 2022	1	1	0	1	0	0	0	1	1	1	1	6	Good
Zadro et al [32], 2019	1	1	1	0	0	0	1	1	1	1	1	7	Good

[a]1: Eligibility criteria.
[b]2: random assignment.
[c]3: allocation concealment.
[d]4: baseline comparability.
[e]5: subject blinding.
[f]6: therapists' blinding.
[g]7: assessor blinding.
[h]8: adequate follow-up.
[i]9: intention-to-treat analysis.
[j]10: comparisons between groups.
[k]11: point estimates and variability.

Characteristics of the Included Studies

Study Characteristics

Seven included studies were published in years from 2011 to 2022. They were conducted in Spain [22], England [31], Canada [21,45], Brazil [44], Germany [46], and Australia [32]. Study designs were RCTs (n=4) [31,32,44,45], pilot RCTs (n=1) [46], and crossover pilot RCTs (n=2) [21,22]. The sample size ranged from 14 to 60, with a total of 264, of which 137 were in the intervention groups and 127 were in the control groups.

Participant Characteristics

All participants had musculoskeletal pain, participants in 5 studies [22,31,32,44,46] had chronic pain, and participants in the 2 studies [21,45] had nonchronic pain. The average age of the participants ranged from 67.8 (SD 6) years [32] to 81.85 (SD 6.82) years [22]. The majority of participants were female, accounting for around 69% of the total.

Intervention Characteristics

Interventions were conducted in the nursing home [22], the university's physiotherapy laboratory [31], the hospital [45], the long-term care center [21], the center of rehabilitation [44], the laboratory [46], and the participant's home [32]. The Nintendo Wii, the Active Airlines serious game, the Interactive Rehabilitation and Exercise System, and the ViRST VR application were the main gaming platforms in the experimental groups. For a period of 4 weeks to 8 weeks, participants exercised for 210 seconds to 90 minutes every session, only once during the intervention to 3 times per week. In 1 study, participants in the control groups carried on with their regular activities. The other studies used traditional physical therapy.

In 4 studies, participants performed exergaming under the supervision of the first author [31], therapist [21,45], and physiotherapist [46]. In 1 study [32], participants performed unsupervised home exergaming, and the remaining 2 studies did not report whether supervision was implemented [22,44]. The number of attrition people ranged from 1 to 9 due to personal commitments and fear of COVID-19 infection. Adherence was reported in only 3 studies [21,32,44].

Most of the participants in the experimental group had a positive experience. The occurrence of adverse events was not reported in 3 studies [31,44,45], while 3 studies reported no adverse events during the intervention [21,32,46]. Two individuals in 1 study experienced unpleasant symptoms such as dizziness, eye pain, or disorientation [22]. Multimedia Appendix 3 depicts an overview of the included study characteristics.

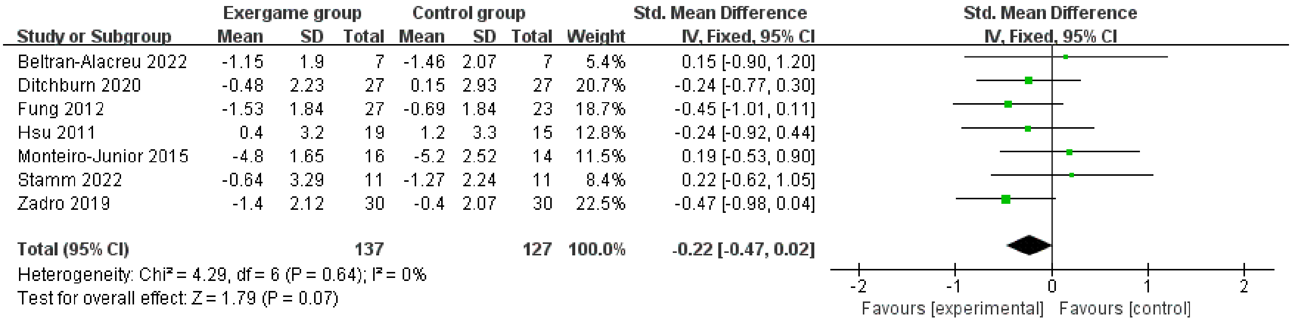
Results of Studies

The Effect of Exergames on Pain

The complete pain data was presented in 7 papers. A study [22] comparing the effects of using Active Airlines serious game and conventional exercise on pain using Visual Analog Scale (VAS) measurements after 4 weeks discovered that both experimental and control groups had significant improvements in chronic neck pain, but exergaming therapy was not superior to conventional exercise. Ditchburn et al [31] compared exercise using the VR rehabilitation system to traditional gym-based exercise, and the results of the study, measured at baseline and after 6 weeks using the VAS, showed a significant improvement in chronic musculoskeletal pain intensity in the experimental group, but no significant change in the control group, and no statistically significant difference between the 2 groups. The difference in improvement in thermal pain, including burning and hot, measured by Multi Affect and Pain Survey, was significant between the 2 groups. In the study by Stamm et al [46], the results measured at baseline versus 6 weeks later on the Numeric Rating Scale (NRS) showed that the improvement in chronic back pain was not significant in the experimental group using the VR system and those in the control group receiving traditional pain therapy, and the difference between the 2 groups was not statistically significant. Fung et al [45] investigated the effect of Nintendo Wii Fit gaming sessions on pain in posttotal knee replacement individuals, finding no significant difference between the 2 groups when compared to a control group receiving lower extremity exercise. Two research investigated the effects of exergaming combined with traditional exercise with regular exercise on pain perception, with Nintendo Wii used. Hsu et al [21] used the NRS and the pain bothersomeness of the upper extremity to measure the improvement of pain in people with upper extremity dysfunction in the experimental and control groups after 4 weeks of treatment and found no significant differences. Another study [44] reported significant improvement in chronic low back pain after 8 weeks of treatment in participants in both the experimental and control groups using the NRS, however, the difference between the 2 groups was not statistically significant. The study by Zadro et al [32] evaluated the effect of home-based exercise via Wii Fit U on chronic low back pain, measured by NRS at baseline versus 8 weeks later, with no statistically significant difference compared to usual activities, however, after adjustment for baseline, the results showed a statistically significant difference between the 2 groups.

A meta-analysis of data provided by VAS and NRS in 7 studies was performed and the overall results of this meta-analysis were inconclusive (SMD –0.22; 95% CI –0.47 to 0.02; P=.07; I^2= 0%; the fixed-effect model; Figure 4).

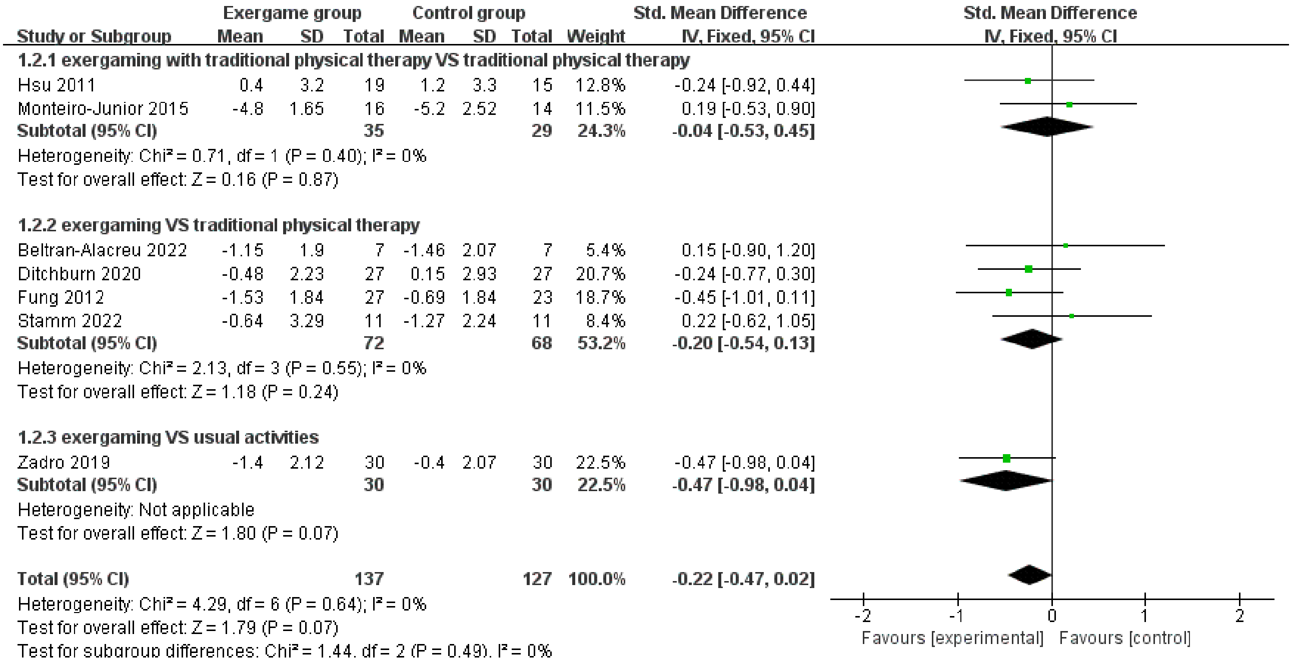
Figure 4. The effects of exergaming on pain perception.



Subgroup Analysis

We investigated the differences in the effects of pain perception on the comparisons. Subgroup analysis showed no significant effect of exergaming in combination with traditional physical therapy (SMD –0.04; 95% CI –0.53 to 0.45; P=.87; I^2= 0%; the fixed-effects model; Figure 5) or exergaming alone (SMD –0.2; 95% CI –0.54 to 0.13; P=.24; I^2= 0%; the fixed-effects model; Figure 5) on pain perception compared to traditional physical therapy. There was no statistically significant difference between exergaming compared to usual activities (SMD –0.47; 95% CI –0.98 to 0.04; P=.07; I^2= 0%; the fixed-effects model; Figure 5). The effect sizes for the 3 comparisons were small (<0.3), small (<0.3), and medium (≥0.3 and <0.6), respectively.

Figure 5. The effect on pain perception in the different the comparisons.



We conducted subgroup analyses to investigate the effects of exergaming on pain perception in participants with chronic pain or nonchronic pain. Subgroup analyses of the 7 studies revealed a nonsignificant difference in the effect of exergaming on chronic pain compared to controls (SMD –0.16; 95% CI –0.45 to 0.14; P=.29; I^2= 0%; the fixed-effects model; Figure 6). Similarly, there was no statistically significant effect of exergaming on nonchronic pain compared to the control group (SMD –0.36; 95% CI –0.80 to 0.07; P=.10; I^2= 0%; the fixed-effects model; Figure 6). Nevertheless, the effect sizes were small for chronic pain (<0.3) and moderate for nonchronic pain (≥0.3 and <0.6). We proceeded to investigate in depth the effect of exercise frequency on pain perception in participants with chronic pain. Subgroup analysis of the 5 studies showed no significant difference in the effect of exercise frequency of twice a week (SMD –0.16; 95% CI –0.64 to 0.32; P=.51; I^2= 0%; the fixed-effects model; Figure 7) and 3 times a week (SMD –0.16; 95% CI –0.53 to 0.22; P=.41; I^2= 35%; the fixed-effects model; Figure 7) on chronic pain compared to the control group, and the effect size was the same for both exercise frequencies (0.16).

Figure 6. The effects of exergaming on chronic pain or nonchronic pain.

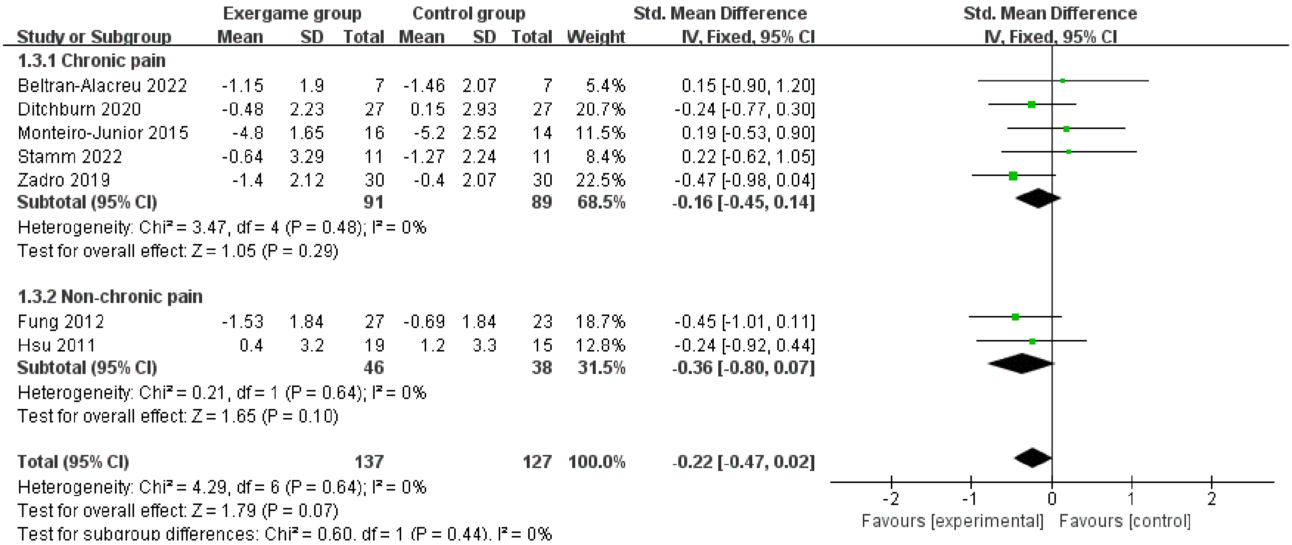
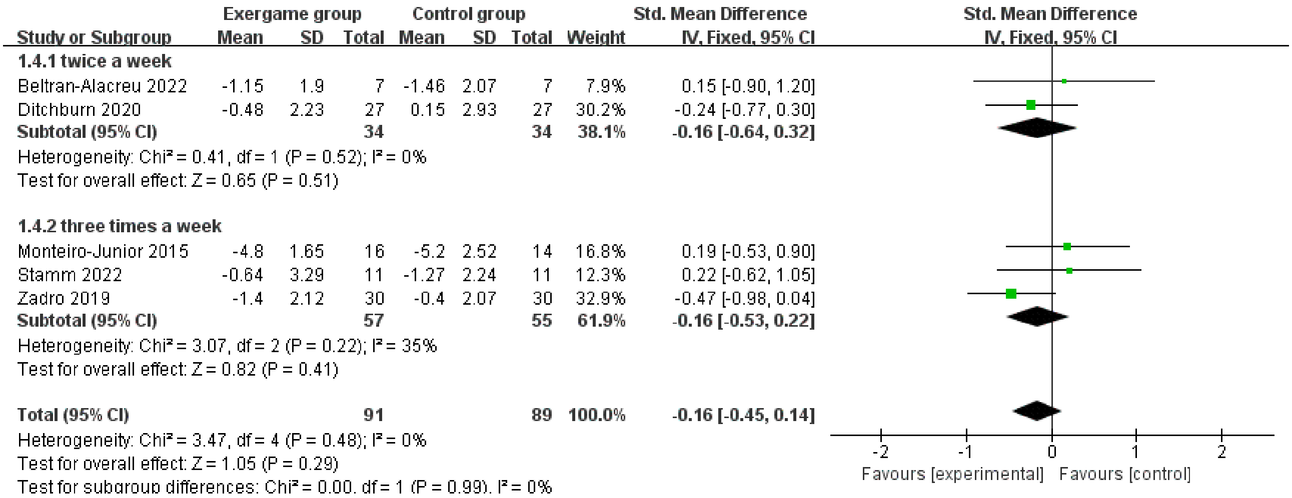


Figure 7. The effect of exercise frequency on chronic pain.



Discussion

Efficacy

This meta-analysis and systematic review focused on the effects of exergaming on musculoskeletal pain in older adults and included 7 randomized controlled studies. The main finding is that the effect of exergaming on musculoskeletal pain in older adults is inconclusive. The results of this study are similar to Collado-Mateo et al [35], and they concluded that exergaming is more difficult to improve musculoskeletal pain in older individuals compared to adults. Of the 7 studies we included, 1 study [32] adjusted for baseline reported a significant improvement between groups. Another study [31] showed significant differences between the experimental and control groups in terms of improvement in thermal pain. Furthermore, the quality of the evidence is low and the sample sizes in the studies were quite small. Further research is needed on the effect of exergames on musculoskeletal pain in older adults.

The highest mean effect size of –0.47 was observed for improvement in pain in the comparison of exergaming versus usual activities, although it was not statistically significant. In this comparison, only 1 study [32] was included and adjusted for baseline, which showed statistical significance. This suggests that exergames have some potential in the treatment of musculoskeletal pain in older adults and that future high-quality studies are needed. Exergaming combined with traditional physiotherapy compared to traditional physiotherapy alone yielded the lowest mean effect size of –0.04, but still favored the experimental group despite the nonsignificant difference between the groups. The results of the 2 included studies were contradictory. Hsu et al [21] examined older adults with upper limb dysfunction, and after 4 weeks, the pain did not improve within either group. In contrast, in the study by Monteiro-Junior et al [44], the pain was significantly improved within both groups after 8 weeks, but the difference between the groups was not significant and showed results in favor of the control group. First, the difference in the results of the 2 studies may be related to the disease experienced by the participants, with different duration of the intervention. Second, the results of the study by Monteiro-Junior et al [44] favored the control group, possibly because participants in the experimental group had to complete not only traditional strength and core training, but also exergame training through the Nintendo Wii, with a total training time of 90 minutes each time, 3 times per week, and higher exercise intensity, which may have made people difficult to obtain optimal results. The results of the network meta-analysis by Fernández-Rodríguez et al [47] suggested that core exercises, strength exercises, or mind-body exercises for less than 60 minutes at a time, at least once to twice a week, with exercise lasting 3 to 9 weeks, are the most beneficial treatment for pain and disability in adults with chronic lower back pain exercise program. Due to older adults tend to have lower endurance levels, they are more susceptible to sports injuries and overexertion and have difficulty tolerating high-intensity training. The sample sizes of the 2 studies were small and the results should be interpreted with caution. In the comparison of exergaming with traditional physical therapy, the mean effect size was –0.2. The results favored the experimental group. Overall, exergaming can be used as adjunctive alternative therapy to traditional physical therapy.

These studies included older adults with a variety of musculoskeletal pain. Most of the participants in the studies suffered from chronic pain (*k*=5) such as back pain (*k*=3), neck pain (*k*=1), musculoskeletal pain (*k*=1), and other nonchronic pain such as upper extremity dysfunction (*k*=1) and post total knee replacement (*k*=1). These can be explained by the results of epidemiological studies, in which the most common pain complaints were osteoarthritic back pain, especially in the low back or neck (65%), musculoskeletal pain (40%), peripheral neuropathic pain (35%), and chronic joint pain (15%-25%) [9]. The results from the subgroup analysis showed that the effect sizes of exergaming on improving nonchronic pain were greater than the effect sizes on improving chronic pain. The results of this study are inconsistent with those of Collado-Mateo et al [35] and the results may be due to age-related group differences, and our study focused only on the group of older individuals. More studies are needed in the future.

The mechanisms by which exercise ameliorates pain are unclear, with 1 suggestion being that exercise leads to an increase in stress pain thresholds and that adaptation of central inhibition occurs over time with exercise training [48]. A meta-analysis showed that increasing the frequency of weekly exercise was most likely to have a positive impact on patients with chronic pain [49]. However, our study results showed that exercise frequency of twice a week and 3 times a week had the same size of effect on chronic pain. There are no standardized criteria for exergaming intervention programs, and it is particularly important to develop an appropriate exercise program. From the RCTs included in this study, 4 weeks of the exercise was sufficient to significantly improve pain, at least twice a week, but not for more than 90 minutes per session.

Exergames Design

Most of the 7 studies tested commercial game platforms, with 1 study using a training rehabilitation-specific platform [31], and participants in the exergaming group experienced significant improvements in pain and for thermal pain, there was a significant difference between the 2 groups, the only 1 of the included studies to show a significant between-group difference for improvement in pain. Therefore, using professional rehabilitation exergames may be more effective than commercial games [23]. Professional exercise rehabilitation games are more specialized because they may be developed with the involvement of professionals in their design and can take into account the type of illness the users have, their needs, etc. Most commercial exergames are not suitable for the group of older individuals, about speed, required movements, amount of information, etc [50]. Therefore, in the future, commercial and medical rehabilitation professions should strengthen their cooperation to develop user-centered exergames for older individuals [51], thus improving the efficacy of exercise [52]. For older individuals, their physiological characteristics [53] and motivations for use should be considered. Older adults are motivated more by perceived health effects, the pleasure of the game, and the improvement of social confidence [20,54]. Wang et al [55] suggested that when designing exergames, first, aging characteristics should be included, paying attention to the decline of cognitive and physiological abilities associated with aging. Second, the game motion recognition should have higher fault tolerance. Third, the feedback should be clear. Fourth, consider the endurance of older individuals, pay attention to fatigue management and control the pace of the game. Fifth, it should have continuous action cues and tutorials. Sixth, it should be connected with reality. Seventh, reasonable use of body parts. Eighth, make good use of repetitive actions and reversible actions. Ninth, design advanced actions for the same game tasks. Lastly, designers should take advice from rehabilitation experts when designing exergames.

Supervision and Adherence

Except for Zadro et al [32], who studied unsupervised home exergame training and found a significant effect of exergaming on pain after adjusting for baseline, the majority of research participants were supervised during exergaming. Compliance among participants was higher but still lower than with supervised exergame training. A prior study indicated that while home exercise training relieved low back pain, supervised training improved pain intensity the greatest [56]. However, to the best of our knowledge, no studies have been conducted to compare unsupervised home exergaming with unsupervised home exercise in pain relief for older individuals. Exergaming, in general, remains a highly promising kind of training that allows participants to undertake unsupervised therapeutic exercises at home, capable of generating a remote rehabilitation environment. Older individuals who are frail or incapacitated can obtain therapy without having to travel vast distances, which may have significant cost-effectiveness benefits [22]. Because just 1 study on home exercise was included in this paper, the results were insufficiently persuasive. As a result, further research might be done in the future, and methods to promote adherence to unsupervised exergame training in older people at home could be pursued.

Security and Experience

Exergames are generally safe for older adults, although a few participants reported feeling uncomfortable, which may be related to the device and form of movement, such as wearing sensors to move the neck making participants feel dizzy, uncomfortable with their eyes, and disoriented [22]. From the reports of coaches and participants, it was found that exergames increased the fun and attraction of physical activity and made the game more enjoyable for the participants [21,45,46]. Previous research has also concluded that participants in the exergaming group had significantly more enjoyment of exercise than the other treatment groups [57]. Participants found exergames highly usable and the game challenging [22]. Exergames can increase participants' satisfaction and compliance [22]. Some studies [20,46] considered socialization as an important factor in improving adherence, as stated in previous studies [58]. However, participants in a control group in 1 study showed a higher acceptance of traditional exercise than exergames [31], possibly because participants in the control group had not experienced exergames. Overall, older adults have positive attitudes toward exergaming.

Limitations

It is the first systematic review of the efficacy of exergaming on musculoskeletal pain in older adults. Several limitations should be in consideration. When searching the literature, publications were limited to those in English and peer-reviewed ones. The small sample sizes of most studies were also a limitation. In addition, the overall risk of bias in the included studies was relatively high.

Conclusions

This paper systematically reviews the efficacy of exergaming on musculoskeletal pain in older adults. The available evidence is limited, and therefore, exergaming cannot yet be considered an effective intervention for improving pain in older adults. Exergames are safe and cost-effective. The playfulness and social components of exergaming may contribute to participant adherence. Increased collaboration between industries to develop specialized exergames for older adults should be considered in the future. Overall, exergaming can be used as a complementary alternative to traditional training. Future larger sample sizes and rigorously designed RCTs are needed to explore the effects of different exergames on older adults with musculoskeletal pain.

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Authors' Contributions

NM contributed in conceptualization, literature search, quality evaluation, data extraction, and writing original draft. JF was involved in literature search, quality evaluation, data extraction, and writing, review, and editing. HL was responsible for literature search, quality evaluation, data extraction, and writing, review, and editing. XC performed literature search, quality evaluation, data extraction, and writing, review, and editing. H Zhang was responsible for writing, review, and editing. H Zeng contributed in writing, review, editing; supervision; and project administration.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.
[DOCX File , 60 KB - games_v11i1e42944_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 33 KB - games_v11i1e42944_app2.docx]

Multimedia Appendix 3
Characteristics of included studies.

[DOCX File , 76 KB - games_v11i1e42944_app3.docx]

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Abbreviations

NRS: Numeric Rating Scale
PRISMA: Preferred Reporting Items of Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
RoB 2: Revised Cochrane Risk of Bias tool in randomized trials
SMD: standardized mean difference

VAS: Visual Analog Scale
VR: virtual reality

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Viewpoint

Time to Think "Meta": A Critical Viewpoint on the Risks and Benefits of Virtual Worlds for Mental Health

Vincent Paquin[1,2,3], MD; Manuela Ferrari[1,3], MHSc, PhD; Harmehr Sekhon[1,2,4], MSc, PhD; Soham Rej[1,2,3], MD, MSc

[1]Department of Psychiatry, McGill University, Montreal, QC, Canada
[2]Lady Davis Research Institute, Jewish General Hospital, Montreal, QC, Canada
[3]Douglas Mental Health University Institute, Montreal, QC, Canada
[4]McLean Hospital, Harvard Medical School, Boston, MA, United States

Corresponding Author:
Vincent Paquin, MD
Department of Psychiatry
McGill University
1033 Avenue des Pins
Montreal, QC, H3A 1A1
Canada
Phone: 1 514 398 4909
Email: vincent.paquin2@mail.mcgill.ca

Abstract

The metaverse is gaining traction in the general population and has become a priority of the technological industry. Defined as persistent virtual worlds that exist in virtual or augmented reality, the metaverse proposes to afford a range of activities of daily life, from socializing and relaxing to gaming, shopping, and working. Because of its scope, its projected popularity, and its immersivity, the metaverse may pose unique opportunities and risks for mental health. In this viewpoint article, we integrate existing evidence on the mental health impacts of video games, social media, and virtual reality to anticipate how the metaverse could influence mental health. We outline 2 categories of mechanisms related to mental health: experiences or behaviors afforded by the metaverse and experiences or behaviors displaced by it. The metaverse may benefit mental health by affording control (over an avatar and its virtual environment), cognitive activation, physical activity, social connections, and a sense of autonomy and competence. However, repetitive rewarding experiences may lead to addiction-like behaviors, and high engagement in virtual worlds may facilitate and perpetuate the avoidance of challenges in the offline environment. Further, time spent in virtual worlds may displace (reduce) other determinants of mental health, such as sleep rhythms and offline social capital. Importantly, individuals will differ in their uses of and psychological responses to the metaverse, resulting in heterogeneous impacts on their mental health. Their technological motivations, developmental stage, sociodemographic context, and prior mental health problems are some of the factors that may modify and frame the positive and negative effects of the metaverse on their mental health. In conclusion, as the metaverse is being scaffolded by the industry and by its users, there is a window of opportunity for researchers, clinicians, and people with lived experience to coproduce knowledge on its possible impacts on mental health and illness, with the hope of influencing policy-making, technological development, and counseling of patients.

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KEYWORDS

metaverse; digital media; virtual reality; mental health; addiction; social functioning; virtual; technology; augmented reality; gaming; social media; cognitive; physical activity; behavior; psychological; development; patient; policy

Introduction

In 2021, Facebook spent US $10 billion on its metaverse division, shipped 10 million virtual reality headsets, and rebranded itself as Meta [1]. The same year, 46 million users were logging onto the game platform Roblox every day, spending a total of 41 billion hours in this virtual world [2]. Concurrently, technology giants Apple, Microsoft, and Google have been developing their own metaverse-related infrastructures. While the idea of a metaverse is not new, the popularity of virtual worlds has boomed in the past few years, particularly during the COVID-19 pandemic [2,3].

The technology magazine *WIRED* defines the metaverse as an extension of "virtual reality—characterized by persistent virtual worlds that continue to exist even when you're not playing—as well as augmented reality that combines aspects of the digital and physical world” [4]. In virtual reality, users wear headsets to see a digital world in 3 dimensions. Through the avatars they embody, they can move in the virtual environment, have life-like interactions with other users, and control digital objects. In augmented reality, users see their real, physical environment, but digital elements are integrated through eyeglasses or a smartphone. Pokémon Go is an example of augmented reality: in this mobile game, the real-world locations of players are captured by their smartphone camera and overlaid with virtual creatures that they can interact with. Other devices combine elements of virtual and augmented reality, allowing users to simultaneously interact with virtual and real objects in “mixed reality” [5].

Although virtual worlds such as Pokémon Go and Roblox are already ubiquitous, the promise of the metaverse is to make these spaces more immersive and interconnected, and to extend their scope of application beyond play unto other aspects of daily life. Of late, there has been an emergence of virtual reality platforms such as VRChat, whose main purpose is to allow users to interact and socialize with others with their self-created 3D avatars. Increasingly, users of virtual worlds trade cryptocurrencies, which are digital currencies that function like money but are independent from states and central banks [6]. With cryptocurrencies, one can buy digital assets (eg, art, avatar apparel, and virtual estates) that are recorded on virtual ledgers as uniquely having one owner, and that are not interchangeable or duplicable; these assets are called nonfungible tokens [7]. Tying together a range of emerging technologies, metaverse platforms thus offer rich and vivid experiences, from games to new ways of socializing, working, learning, and shopping [4,8].

Will the metaverse impact mental health and illness? With every media revolution threatening to infiltrate people’s homes, whether the radio, TV, or the internet, there are concerns for mental health [9]. In line with popular views, a body of research points to potential harmful effects of digital media on depression, anxiety, and addiction-like behaviors [10-12]. However, in truth, cyberpsychology—the study of how humans and computers interact—paints a much more complex picture [13]. The mental health risks of digital media are far from universal and, at least in some cases, the adaptive use of technology may even contribute to improvement in short- and long-term well-being [14]. As interest in the possibilities of the metaverse continues to grow in the general population, we consider in the present viewpoint how this technology may impact mental health. We narratively present a selection of key articles from the literature on digital media to appraise the potential mental health risks and benefits of the metaverse and discuss directions for future research.

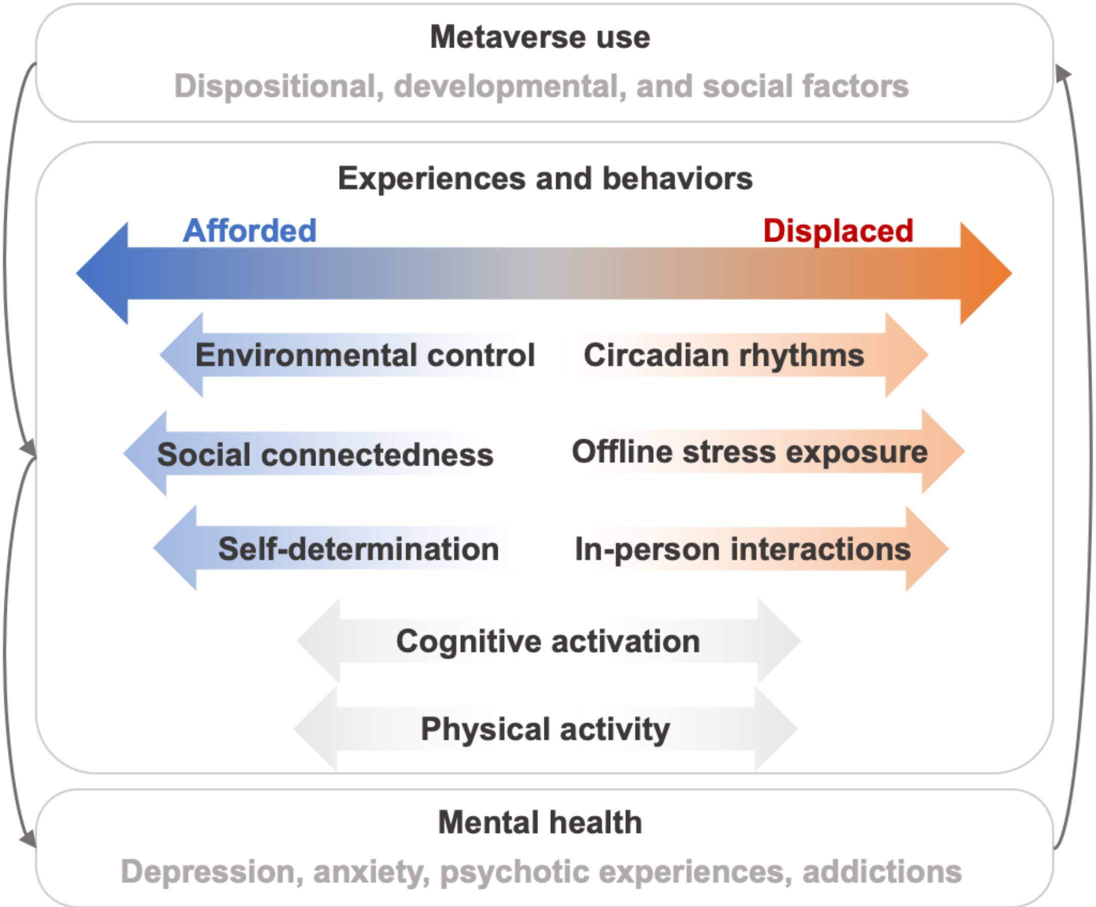
Virtual Worlds and Mental Health

Overview

Most research to date has examined exposure to digital media as a function of screen time, roughly defined as time spent on digital media and other screen devices. This body of literature generally shows that individuals who report greater screen time also report poorer mental health [15]. However, this association is likely to be confounded by other factors, such as preceding mental health conditions, occupational status, and lifestyle, to name a few. When individuals are studied as their own comparators, fluctuations in digital media use over time do not seem to predict changes in mental health [16-19], which goes against the hypothesis that higher screen time causes poorer mental health. However, the utility of screen time as an indicator of digital exposures is likely limited if the amount of time on digital media is not the primary mechanism by which digital media affect mental health. Media researchers have advocated for dropping the concept of screen time and focusing instead on more specific, theory-based measures of digital media exposures [14,16,20]. Limited research has investigated the mental health impacts of the metaverse, but many of the current platforms described as “metaverse” rely on virtual reality and are intended for internet-based gaming or socializing (see the *Introduction* section). The metaverse shares a number of characteristics with social media and video games: these include the possibility of interacting with other individuals in real time regardless of geographical location, the possibility of being anonymous, and the persistence of data over time [21,22]. Video games and virtual reality further afford vivid experiences that can be studied to better understand the potential psychological effects of immersion in the metaverse.

Thus, to anticipate how the metaverse will affect mental health, we can learn from the literature examining the mental health impacts of social media, video games, and virtual reality. From this state of knowledge, 2 broad categories of mechanisms, by which the metaverse may influence mental health, emerge: experiences or behaviors that are *afforded* by its use and experiences or behaviors that are *displaced* by it [9]. Below, we discuss these mechanisms in detail and summarize them in Figure 1.

Figure 1. Interplay among metaverse use, experiences, behaviors, and mental health. Participation in the metaverse may afford certain experiences and behaviors relevant to mental health, while displacing others. The type of use, as well as individual and contextual factors, likely influence these effects. Together, these mechanisms subsequently influence mental health outcomes. In turn, mental states reciprocally influence interactions with the metaverse.



Affordances of the Metaverse

Environmental Control and Self-representation

Virtual worlds of the metaverse have the potential to afford users a number of experiences susceptible of impacting their mental health. This begins with the environment of the person, on which the metaverse affords a unique degree of control: users can easily choose and navigate the environment of their choice, or even self-design the space they are in. Virtual reality relaxation exploits this affordance by bringing the user into restorative, pleasant environments such as lakes, forests, or rivers. According to a recent systematic review, there is preliminary experimental evidence that virtual reality relaxation is effective for improving mood and anxiety, at least in the short term [23]. Conversely, exposure to social stressors in virtual environments is associated with higher levels of subjective distress and paranoia [24], illustrating the potential influence of virtual environmental exposures on mental health.

Virtual worlds also afford users to choose their avatars' appearance and identity, which can influence how they perceive and interact with their surroundings. In an international survey of 142 regular users of video games, greater embodiment over an avatar was associated with lower awareness of bodily sensation during gaming sessions [25]. In a sample of 60 women from the UK general population, reducing avatar height during a virtual reality train ride was associated with increased levels of paranoia and negative social comparison [26]. Experimenting with self-representation in the metaverse may also participate in youth development: some authors have suggested that during adolescence, conducting identity experiments on the internet could help in the development of social competence [27]. However, strong investment in self-representation in virtual spaces could also cause harms, such as dissatisfaction with one's physical body. This risk has been documented in studies of social media usage, showing that people's investment in receiving feedback on their self-portrait photographs, and their comparisons with the photographs of others, may contribute to body dissatisfaction and drive for thinness [28,29].

Cognitive Activation and Physical Activity

The design of metaverse contents may be harnessed toward activating a person's cognitive functions in beneficial ways. Many games have been developed to encourage players to use their cognitive skills to solve problems [30]. In a randomized controlled trial of 72 US adults with major depressive disorder, a video game–based intervention was effective in improving sustained attention and global cognitive functioning compared with an active control [31]. The embodied navigation of virtual worlds, enabled by sensors that capture the user's movement in physical space, can also promote physical activity. This is the case of video games involving physical activity ("exergames"), which can produce significant improvements in cognitive functioning among clinical and nonclinical populations, according to a meta-analysis of randomized controlled trials [32].

Social Connectedness

Interpersonal relationships could be developed and maintained through the metaverse. The capacity to connect with others regardless of physical location enhance individuals' opportunities to join communities with shared interests, values, or identities. Members of marginalized groups and people living with mental health problems may benefit from these platforms for sharing knowledge and obtaining peer support [33-35]. Importantly, internet-based interactions can be experienced as meaningful. In an international survey of people using massively multiplayer online role-playing games (MMORPGs), respondents frequently reported high-quality relationships in their games, which sometimes transformed into friendships or romantic partnerships in the physical world [36,37]. MMORPG users also commonly play with their offline friends or romantic partners [37,38], suggesting that virtual worlds can foster both the formation of new relationships and the enhancement of existing ones. More research is needed to understand the extent to which these social affordances impact mental health, but arguably, they may be beneficial if they decrease a person's loneliness and increase their social capital [39].

Self-determination

Experiences of autonomy and competence in virtual worlds can fulfill the need for self-determination. In a survey of 672 MMORPG players, positive experiences associated with intensive gaming involvement included feelings of achievement, positive anticipation and stress (eg, "adrenaline rush"), enjoyable repetition and routine, positive social obligation, satisfying labor, increased confidence, and positive distraction, to name a few [40]. In samples of college students playing video games in experimental settings, experiences of autonomy and competence while playing were associated with gaming motivation and enjoyment [41]. For people experiencing disability, functional impairments, or social adversity in the context of mental health problems, digital spaces that operate under different parameters than the offline, physical world may thus provide invaluable opportunities for fulfilling the psychological needs related to self-determination.

Addictions

Because they repetitively afford rewarding experiences, virtual worlds can also be the object of addiction-like behaviors. Gaming disorder, which made its entry in the 11th revision of the International Classification of Diseases, captures how this may translate into mental health problems [42]. Gaming disorder is defined by persistent or recurrent gaming behavior, manifesting as impaired control over gaming, increased priority given to gaming (at the expense of other interests and activities), and continuation or escalation of gaming despite the occurrence of negative consequences. A meta-analysis situates the global prevalence of gaming disorder at 2%-3%, with the most common type being internet-based rather than offline gaming [43]. Attributing problematic gaming behaviors as constitutive of a mental disorder is subject to controversy [10,44]. But at the minimum, epidemiological and cross-cultural data show that some players engage in gaming in ways that negatively impact their well-being and functioning [43,45]. In the metaverse, immersive technologies broaden the scope of daily-life activities that can be performed digitally, raising the possibility of even greater absorption into virtual worlds and greater interference with functioning. Addiction is a particular concern considering that companies have a financial incentive to maximize virtual worlds' capacity to captivate users—something that can be facilitated by passively monitoring users' behaviors in the metaverse and by customizing their environment accordingly [46].

Displacement of Offline Activities

Circadian Rhythms

High engagement in the metaverse could be at the expense of other activities in the offline environment. According to the displacement hypothesis [47], excessive use of digital media causes harm to the individual by displacing time spent on other activities that are beneficial for mental health. Notably, participating in virtual worlds in the evening or at night may impair sleep rhythms because of delayed or reduced sleep time. According to a recent narrative review, previous observational studies support an association between greater use of screen-based media and poorer sleep outcomes in adolescents; however, experimental research does not consistently show that screen use has causal effects on sleep [48]. Three mechanisms could be responsible for the putative effects of screen use on sleep: disruption of the neurobiology of sleep due to light emitted by the screen devices, delay of sleep onset or reduction of total sleep time because of time spent on the screen device, and psychological stimulation caused by digital media content [48]. More evidence is needed to determine the causal effects of screens on sleep and whether the degree of immersion afforded by the metaverse will amplify these effects.

Offline Stress Exposure

Individuals may participate in virtual worlds to avoid or escape from anxiety-provoking situations of the offline world. In web-based surveys, avoidance and escapism are relatively commonly reported by video gamers as part of their motivations for gaming [36,45,49]. For example, in an international survey of internet-based gamers, participants endorsed some degree of "gaming to avoid challenges in [their] life rather than deal with them directly" (average item score of 2.46 on a scale of 1 to 5)—a finding that was consistent across North America, Europe, and China [45]. Recurrent avoidance of stressful situations may prevent a person from seeking to solve the problems or from learning to tolerate the stressors they face. However, it has been suggested that escapism through video gaming can also be an adaptive coping strategy that helps regulate or restore mood following exposure to stressful situations [50,51]. A systematic review of surveys conducted among video gamers found that escapism is cross-sectionally associated with both negative outcomes (eg, problematic video gaming, social anxiety, and loneliness) and positive outcomes (eg, social connection, enjoyment, and psychological well-being) [49]. Longitudinal studies are needed to better understand how escapism in the metaverse interacts with and affects a person's mental health problems over time.

In-Person Interactions

A related topic is how the potential displacement of in-person social interactions toward their digital equivalent influences mental health. As highlighted above, there is evidence that internet-based gaming can foster meaningful social interactions both digitally and offline. However, if high social involvement in the metaverse is accompanied by limited social interaction in the offline world, the net result may be an increase in social anxiety and a decrease in social skills in offline contexts [39]. This could explain why internet addiction was associated with a prospective increase in loneliness in a convenience sample of 361 college students in Hong Kong [52]. Potentially, for individuals living with social anxiety or low social skills, achieving connectedness through virtual worlds can simultaneously be a compensatory strategy and a perpetuating factor that constrains exposure to in-person social interactions.

The Importance of Individual and Contextual Factors

Overview

The effects of virtual worlds on mental health likely depend on individual and contextual factors. To begin with, virtual worlds and the technologies that support them differ in their features and affordances, including those discussed above: control of the avatar and environment, cognitive stimulation, social connectedness, and the satisfaction of other psychological needs. Users also have freedom in how they take advantage of virtual worlds' possibilities. Differences in digital media uses, and their relevance for mental health correlates, are frequently observed in the scientific literature. For example, in an experience sampling study of 44 adults with and those without psychosis in the United Kingdom, posting about feelings and venting on social media predicted higher subsequent paranoia, while posting about daily activities predicted lower paranoia [53]. Although such findings are correlational and subject to confounding, they reflect the heterogeneity of uses and mental health correlates for a given technology. This heterogeneity is perhaps best understood in terms of individual or contextual factors. Borrowing on the terminology of Valkenburg and Peter [54], factors that modify and frame the mental health impacts of digital media can be organized in 3 categories: dispositional, developmental, and social.

Dispositional and Developmental Factors

At the dispositional level, individuals' motivations and interests will likely influence how they engage with the metaverse. Among US school-aged children, boys generally report greater use of video games than girls, whereas girls report greater use of social media [55]. In an international longitudinal study of video game players, a person's increase in intrinsic motivation for gaming was associated with a subsequent improvement in their affect and life satisfaction; conversely, an increase in extrinsic motivation (ie, feeling pressured to play) was association with a deterioration of the same outcomes [16]. At the developmental level, age may moderate the mental health outcomes of metaverse usage as a function of the person's developmental needs and sensitivities, as well as age-dependent differences in motivations and profiles of use. To illustrate, early childhood is a crucial period for cognitive development, and there is tentative evidence from a Canadian study that a child's increase in screen time is associated with a decrease in their performance on developmental screening tests between ages of 24 and 60 months [56]. Adolescence is marked by social and identity development, and teens may be particularly sensitive to social acceptance and rejection in virtual worlds [57]. Some authors have also argued that digital experiences have the potential to contribute to agency, connectedness, and storytelling capacities that foster youth's identity development [58].

Social Factors

Social and economic factors are sources of inequalities in the access to metaverse-related technologies. Lower income or economic development is associated with reduced access to internet-connected devices, and in many emerging countries, women have lower access to the internet than men [59]. Given the cost of virtual reality headsets and related technologies, the rise in popularity of metaverse platforms may contribute to widening digital inequalities. Other sources of digital inequalities include older age, as older adults tend to be less autonomous and experienced in the use of new technologies [59], and physical disabilities, which to date have received little attention in the development of virtual reality hardware [60]. Digital inequalities are important to consider in the design of policies and the organization of services relevant to mental health care: these inequalities may translate into unequal access to digital mental health interventions, as well to health information and economic opportunities—all of which are determinants of mental health and recovery.

Virtual worlds are also a space where people can be exposed to bullying and discrimination. Exposure to cyberbullying is relatively common among the youth and has been associated with higher subsequent risk of psychological distress, suicidal ideations, and delinquency [61]. People in virtual worlds may feel emboldened to enact discriminatory and aggressive behaviors, as suggested by reports of sexual harassment, racism, homophobia, and transphobia within some video game communities [59,62,63]. Considering that 3D embodiment over an avatar, and its interactions with a virtual environment, can make internet-based interactions particularly vivid, one question that appears relevant for future research is to consider whether the metaverse risks magnifying the psychological impacts of internet-based bullying and discrimination.

People's offline environment may further influence how they engage with virtual worlds and their propensity for using them in a problematic, addiction-like manner. Socioeconomic disparities and other forms of social adversity could increase people's propensity for problematic metaverse use, for example, by motivating them to escape their stressful environment, or by constraining their access to alternative activities in their neighborhoods. Nagata et al [64] proposed that these effects of social adversity may explain, to some extent, why higher levels of problematic video game use are reported by adolescents in the United States who identify as Native American, Black, or Latinx, and by those with lower parental educational attainment.

Conversely, positive social interactions in the offline environment could be protective against the risk of problematic metaverse use. Illustrating this, a study of 250 MMORPG players found that higher levels of cultural consonance (ie, feeling successful in conventional society) and playing with offline friends were both cross-sectionally associated with lower levels of problematic gaming [38,65]. Similarly, in 2 samples of adult video game players, higher satisfaction of psychological needs in the offline world was cross-sectionally associated with lower levels of internet gaming disorder [66]. Young people's interactions with their parents may be particularly important in shaping how they engage with metaverse technologies. For example, a community-based study of 2974 children and adolescents in Singapore showed that higher parent-child closeness was subsequently associated with a decrease in their levels of pathological video gaming after 1 year [67]. Interactions with friends, family, and society in the offline world are thus relevant to understand individuals' engagement in virtual worlds. Together, these findings illustrate how individual and contextual factors, spanning dispositional, developmental, and social dimensions, may influence the mental health impacts of engagement in the metaverse.

Conclusions: Immersion in the Metaverse

When considered critically, the last 2 decades of research do not demonstrate universal harms of digital media on the mental health of the general population. The state of knowledge reveals many ways in which digital media may benefit or harm a person's well-being, whether as a function of technological, individual, or contextual factors. But popular concerns persist and will almost certainly grow if the metaverse fulfills its commercial and social ambitions. Perhaps what sets the metaverse apart from previous technologies is the greater immersivity it affords, compared with traditional social media and video game devices. Immersion seems to be a factor that could amplify many of the mental health impacts described above: with greater immersion may come greater displacement of bodily awareness, greater embodiment over one's avatar, greater sense of copresence with internet-based friends, and generally more vivid experiences. In turn, these features and experiences are likely to shape the motivations, affordances, and mental health risks associated with metaverse use.

It is too early to indicate whether the metaverse will broadly be a greater risk or benefit to mental health than previous digital media. Undoubtedly, virtual worlds are unprecedented in the scope of experiences and behaviors they can afford, and as such, in their potential to take a greater place in our daily lives. To adequately counsel patients and guide policies around the development and implementation of the metaverse, there is a need for timely and nuanced research on its opportunities and risks for mental health [68,69]. Arguably, previous research on digital media has often failed to achieve timely and nuanced knowledge production, partly due to the lack of clear theoretical frameworks and robust empirical methods [9,20]. Following these lessons, we believe a starting point is to examine the experiences and behaviors that are afforded and displaced by the metaverse, as well as the interplay of these effects with dispositional, developmental, and social factors. Collaboration among clinicians, researchers, individuals with lived experience, technology users, the industry, and other stakeholders will be crucial to successfully generate and translate this new body of knowledge. While metaverse technologies are in the process of being scaffolded and disseminated, psychiatry has a window of opportunity to think through conceptually and to strategically examine their risks and benefits for mental health.

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Conflicts of Interest

SR reports receiving a grant from Mitacs, is a steering committee member for AbbVie and is a shareholder at Aifred Health.

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Abbreviations

MMORPG: massively multiplayer online role-playing game

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Viewpoint

The Development of Game-Based Digital Mental Health Interventions: Bridging the Paradigms of Health Care and Entertainment

Lauri Lukka[1], MA; J Matias Palva[1,2,3], PhD

[1]Department of Neuroscience and Biomedical Engineering, Aalto University, Espoo, Finland
[2]Neuroscience Center, Helsinki Institute of Life Science, University of Helsinki, Helsinki, Finland
[3]Centre for Cognitive Neuroimaging, School of Psychology and Neuroscience, University of Glasgow, Glasgow, United Kingdom

Corresponding Author:
Lauri Lukka, MA
Department of Neuroscience and Biomedical Engineering
Aalto University
Rakentajanaukio 2
Espoo, 02150
Finland
Phone: 358 440375666
Email: lauri.lukka@aalto.fi

Abstract

Game elements are increasingly used to improve user engagement in digital mental health interventions, and specific game mechanics may yield therapeutic effects per se and thereby contribute to digital mental health intervention efficacy. However, only a few commercial game–based interventions are available. We suggest that the key challenge in their development reflects the tension between the 2 underlying paradigms, health care and entertainment, which have disparate goals and processes in digital development. We describe 3 approaches currently used to negotiate the 2 paradigms: the gamification of health care software, designing serious games, and purpose shifting existing entertainment games. We advanced an integrative framework to focus attention on 4 key themes in intervention development: target audience, engagement, mechanisms of action, and health-related effectiveness. On each theme, we show how the 2 paradigms contrast and can complement each other. Finally, we consider the 4 interdependent themes through the new product development phases from concept to production. Our viewpoint provides an integrative synthesis that facilitates the research, design, and development of game-based digital mental health interventions.

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KEYWORDS

digital mental health interventions; development frameworks; gamification; game-based interventions; intervention development; mental health; paradigms; serious games

Introduction

Background

Digital mental health interventions (DMHIs) are actively developed in response to the growing mental health crisis [1]. Some of the new interventions [2-6] use elements from entertainment games to improve user engagement and intervention effectiveness [7,8]. Using a game-based approach to pursue health-related aims requires developers to have competencies in both health care and game development; however, the 2 paradigms have considerable disparity in their goals. In health care, health-related aims are pursued by minimizing user interaction with the intervention, whereas entertainment products, largely oblivious to their health effects, seek to maximize user interaction with the content. This difference has led to specialized practices, institutions, and business models that are not readily compatible and challenge interdisciplinary development, which Mathews et al [9] succinctly describe as follows:

> *The "fail fast, fail often" mantra espoused by technology startups is frustrated by the confusing regulatory landscape of healthcare. This cultural clash is further exacerbated by the cautious, stepwise, and time-consuming process of healthcare innovation*

> *that is grounded in the risk-averse clinical principle of "first, do no harm."*

Existing models of intervention development [10-13], although comprehensive, do not sufficiently address the tension between health care and entertainment in the development of game-based DMHIs (gDMHIs). In this paper, we describe the tension and offer a framework to facilitate new product development and implementation.

The Treatment, Engagement, and Implementation Gaps in Digital Interventions

Mental disorders are common and cause distress and burden to both individuals and society [14]. However, most people with mental disorders remain untreated. The median treatment gap, defined as the difference between the prevalence of a disorder and those treated for it, is >50% for many disorders [15]. For instance, only a fourth of those living with anxiety disorders receive any treatment, with 1 (10%) in 10 receiving possibly adequate treatment [16]. The mental health care system is globally unable to offer sufficient interventions to address patients' needs.

Solutions to the mental health burden are increasingly sought from scalable digital interventions. The evidence of their effectiveness for both depression and anxiety is already substantial [17-19], and their effectiveness compares to that of face-to-face interventions [20]. Moreover, the treatments display a considerable dose-response relationship [17,18,21,22]: greater user interaction with the software-based intervention, that is, engagement, is associated with higher intervention effectiveness. However, digital interventions suffer from an engagement gap. High dropout rates and low user engagement are observed in digital interventions, particularly in self-guided programs [17,23-25], where 40% of the participants may drop out before completing a fourth of the intervention [23], and only 0.5% to 28.6% complete the entire intervention or continue its use [26]. As engagement is related to intervention effectiveness, there is a substantial need to ensure that users find the interventions interesting, motivating, and meaningful.

The engagement gap is also an indication of the implementation gap: researchers and developers struggle to transfer the effectiveness established in clinical settings to real-world environments [27]. The effectiveness of DMHIs in ideal and controlled research settings (efficacy trials) is almost double that in real-world settings (effectiveness trials) [18,28]. The intervention's clinical effectiveness in optimal circumstances does not guarantee real-world impact, which calls for paying more attention to how the interventions are designed and developed with both users and clinicians in mind.

Game-Based Approaches Seek to Increase Intervention Engagement and Effectiveness

Game-based approaches are increasingly developed with the ambition to improve user engagement with and the effectiveness of DMHIs [7,8]. This rationale reflects the immense popularity of digital entertainment games. Playing video games is a hobby for 71% of American youth and 65% of adults [29], and globally, there are >2.7 billion players [30]. Although youth and young adults are the most active players, the average player is aged 38 years, and those in their 30s still play, on average, >6 hours a week [31]. Digital games are a familiar, accessible, attractive, and engaging medium for the general audience.

Game-based interventions are currently developed for numerous psychiatric disorders, including depression [3], anxiety [2], attention-deficit/hyperactivity disorder (ADHD) [5], and autism spectrum disorder [6], and serious mental illnesses, including schizophrenia and bipolar disorder [4]. Fleming et al [8] suggested that game-based interventions can extend treatment reach, thus helping close the treatment gap and improve user engagement and intervention effectiveness. There are numerous game-based interventions in development [32], but only a few are in the market. To support their development, there is a considerable need for frameworks that address the particularities of the game-based medium and facilitate interdisciplinary collaboration.

The Aim of This Paper

There is a substantial need for DMHIs that are engaging, effective, and feasible, and game-based approaches have potential in this regard. In this paper, we offer an interpretive synthesis that integrates and contrasts the literature in 2 fields: health care and entertainment. First, we argue that the 2 fields are in tension, which challenges the development of game-based interventions. Then, we discuss how to negotiate the tension. We focus on 4 themes, namely the target audience, engagement, mechanisms of action, and effectiveness (TEME) framework. We conclude the discussion by reflecting on the themes through new product development phases. Aimed at researchers, developers, and designers working with game-based interventions, our paper facilitates interdisciplinary collaboration and the wise use of game-based elements to ameliorate mental health.

The Tension Between Health Care and Entertainment

The Paradigms Address Different Needs

We suggest that the engagement gap with DMHIs reflects a tension between health care and entertainment, which becomes especially apparent in game-based interventions. Our approach is built on the notion of the differentiation of society into subsystems such as law, economy, politics, religion [33,34], health care, and entertainment. The thorough history of the 2 paradigms is beyond the scope of this paper, but their differences can be summarized in the code that they specialize in. Health care is concerned with the code of health, focusing on identifying and classifying sources of disability and seeking remedies for them [35]. Moreover, health care has legitimized priority over the domain of health, manifesting in the authority of certified clinicians overviewed by regulatory bodies. Meanwhile, entertainment, also described as "audience-centered commercial culture" [36], is a societal subsystem focusing on the code of leisure. The value of entertainment manifests through its ability to attract and captivate the attention of the audience over time in the theater and through literature, music, and games. The freedom of expression prevails in these domains because of the low risk to audiences' health. The subsystem codes are associated with underlying universal human needs. According to the notions proposed by Max-Neef et al [37], health care addresses the existential needs of subsistence and protection by curing and helping, whereas entertainment responds to the needs of idleness, creation, and identity by offering fantasies, relaxation, and opportunities to have fun both alone and together with others.

The organizations catering to the same need differentiate into industries that share a high-level *raison d'être* and have specialized concepts, regulations, structures, competencies, and methodologies to support their work. This specialization both increases the effectiveness in addressing the underlying human needs *and* creates distance from other societal subsystems. Refocusing on game-based mental health interventions, they can be viewed as a combination of 2 domains: the entertainment game industry, which has developed specialized skills in digital art and animation, programming, project management, storytelling, game design, and media business, and mental health care, which focuses on psychiatric diagnoses and their etiology and treatment. To summarize, health care practices are not intended to craft digital entertainment and vice versa. The differences between DMHIs and entertainment games are illustrated in the Table 1.

Table 1. Differences between the paradigms of health care and entertainment are exemplified through digital mental health interventions (DMHIs) and digital entertainment games.

	DMHI	Digital entertainment games
Underlying paradigm	Health care	Entertainment
Paradigm code	Health	Leisure
Underlying need	Alleviating disorders and increasing well-being	Offering enjoyment, relaxation, and social connection
Users	Patients, clients	Consumers, players, fans
Goal	Introducing behavioral change and alleviating symptoms	Captivating and entertaining the player
The scientific base	Extensive research base	Growing research base
Categorized by	Therapeutic modality (eg, CBT[a])	Game genre (eg, FPS[b])
Evaluated by	Efficacy and safety	Game experience, business metrics, and reviews
Initiative to use	Often recommended by a health care professional	Chosen by the player from a wide variety of alternatives
Entry to market	High threshold: clinical evidence, regulations, and gatekeepers	Low threshold: global digital marketplaces
Availability	Growing number of interventions	High number of commercial games
Purchase	Insurance often pays for the service.	The customer pays for the service.
Business model	B2B[c]	B2C[d]

[a]CBT: cognitive behavior therapy.

[b]FPS: first-person shooter.

[c]B2B: business to business.

[d]B2C: business to consumer.

We are not aware whether the tension between health care and entertainment would have been previously framed in this way. However, the disparate goals of health care and entertainment have attracted prior attention. Yardley et al [38] discussed the need for digital interventions to promote "effective engagement" rather than merely pursuing an increase in user interaction. They highlighted the need to establish a causal connection between user interaction with the intervention and the intended behavior change. Exploring gamified information systems, Liu et al [39] described the phenomenon as "meaningful engagement": the intervention needs to reach its experiential outcomes—to be sufficiently enjoyable and feasible—to reach its instrumental outcomes of behavior and symptom changes. Furthermore, Siriaraya et al [40] separated "game value" from "therapeutic value," highlighting the difference between the 2 paradigms. These considerations emphasize how engagement and effectiveness are distinct, and we suggest that this relates to the 2 paradigms and their codes.

Differentiating Among Gamified Interventions, Serious Games, and Purpose-Shifted Entertainment Games

DMHIs with and DMHIs without game elements are actively developed, and the former particularly negotiates the underlying paradigms of health care and entertainment. We classified game-based interventions into the following 3 categories: gamified DMHIs, serious games, and purpose-shifted digital entertainment games. We refer to them collectively as gDMHIs, "game-based interventions" in short. As the intervention adapts more elements from entertainment games, on the one hand, its gameness [41] increases, and, on the other hand, its intentional therapeutic functionality transforms (Figure 1).

Figure 1. Three categories of game-based digital mental health interventions (gDMHIs) are positioned between health care and entertainment. DMHI: digital mental health intervention.

	Health care	gDMHI			Entertainment
Intervention	DMHI	Gamified DMHI	Serious game	Purpose-shifted digital entertainment game	Digital entertainment game
Description	DMHI without game elements	DMHI with game elements	A serious game with a therapeutic intention	A digital entertainment game used for therapeutic ends	A game with the primary purpose to entertain

At one end of the continuum, DMHIs pursue health benefits and use minimal game-based elements. At the other end, there are digital entertainment games that may have incidental health benefits to their primary aim of capturing the interest and attention of the player. The former can be described as functional software that serves a particular purpose, whereas the latter is built to create experiences that are valuable in their own right [42,43]. The design of digital entertainment games is a specialized domain differentiated from traditional, functional software development [44,45], which is also reflected in the concepts used. Functional software has users, and its evaluation focuses on usability and user experience, whereas games are evaluated based on their playability and game experience [46].

Between health care and entertainment lie 3 categories of gDMHI. When game design elements are incorporated into a DMHI, the intervention becomes gamified [47]. The 2 most common rationales for using gamification in health care are improving user engagement and the effectiveness of the intervention, and the most common game elements include levels, progress feedback, points, rewards, narration, and personalization [7]. The incorporated game elements should not be superficial and exogeneous to the designed intervention, but synergistic with the experience the intervention intends to create [48]. In addition, gamification is not limited to the features visible to the user but can include the use of game design principles and methods in design and development [47].

In contrast to gamified applications, serious games are full-fledged games that are used for purposes beyond entertainment [47,49], often in education, health care, and organizational development. Gamified applications and serious games are frequently differentiated in the research literature [50], but in practice, the line between the two is not easy to draw. To distinguish between gamified and full-fledged game interventions, Liu et al [39] suggested that gamification incorporates game elements on top of real-world systems without sacrificing their functionality, whereas serious games are separate from real-world systems. Thus, a gamified intervention may more closely resemble and augment functional applications while retaining the instrumental functions of the system, whereas a full-fledged game often includes a fictional world for the player to immerse in.

To further clarify, we differentiated game-based interventions from "serious games for health" serious games used within the health care system by clinicians and patients for therapeutic and educational purposes [51,52]. Not all game-based approaches within health care are interventions: only those that prevent, assess, and help manage disorders are interventions, in contrast to software with educational and information management aims [53].

Whereas gamified and serious game DMHIs are intentionally designed for therapeutic purposes, purpose-shifted games take an alternative approach. These are games designed for entertainment purposes but used for serious, therapeutic purposes, either with or without modifications [54]. The rationale for this approach lies in the finding that playing digital entertainment games may have a positive impact on well-being regardless of the design and use intention of the games [55,56]. Positive effects arise, for instance, from the users' connection with other people, which that alleviates loneliness and creates meaningful relationships; the games' cognitive demands, which train attention, perception, and executive functions; and the positive, eudaimonic experiences offered by the games [57,58].

The forte of the purpose-shifted approach is that commercially available video games are accessible, affordable, and of high quality compared with many designed gamified interventions and serious games. Consequently, this approach is quite popular. Recent reviews found that 14 of 27 interventions for depression [3] and 13 of 28 interventions for anxiety [2] used a purpose-shifted approach, and the rest of the interventions were designed. However, the approach also comes with a considerable downside: researchers have limited opportunities to continue intervention development because they do not control the intellectual property, code, art assets, or delivery of the game.

Differentiating among gamified games, serious games, and purpose-shifted entertainment games exhibits the variance in gDMHIs. Moreover, it contributes to understanding the developer's approach and position between the 2 underlying paradigms: is the intervention a functional application to which game elements are added, an entertainment game whose purpose is shifted, or a tailor-made serious game? Because game-based interventions draw from both health care and entertainment, there is a need to consider both perspectives in their development.

Bridging the Paradigms of Health Care and Entertainment

The TEME Framework

Overview

Interventions are intended for a particular audience who, by interacting with the interventions, hopefully, achieve positive changes that are explained by the interventions' mechanisms of action [10-13]. To contrast and discuss the paradigms of health care and entertainment, we focus on 4 interrelated themes that are necessary, but not sufficient, for the development of new products (Table 2). We acknowledge that other aspects are also necessary, including privacy [59,60] and integration with existing infrastructure [61]. However, we consciously focus on the 4, as they are illustrative of the differences between and strengths of the 2 paradigms and serve to solve the tension between them.

Table 2. The target audience, engagement, mechanisms of action, and effectiveness (TEME) framework for game-based intervention development.

Theme	Key question	Health care	Entertainment
Target audience	Who is the intervention engaging and effective for?	Health indication and user characteristics frame the target audience.	Differences in game preferences create various audiences.
Engagement	Does the user want to interact with the intervention?	Engagement is associated with effective mechanisms of action.	Subjective and objective engagement are measured.
Mechanisms of action	What explains the intervention effects?	The mechanisms of action are evidence based.	The mechanisms of action are synergistic with their game-based implementation.
Effectiveness	What does the intervention achieve?	The intervention helps achieve behavioral change and symptom reduction.	Interaction is satisfying and fulfills the players' psychological needs.

Target Audience: Who Is the Intervention Engaging and Effective for?

Intervention development begins with the target audience's needs [62]. In mental health, there are 2 main ways in which user needs are conceptualized: a diagnostic approach and transdiagnostic approach [63]. The former frames the need through diagnostic taxonomies, and the latter focuses on a particular symptom or health-related behavior. However, both approaches frame the intervention in terms of a health indication, and it is the health care paradigm that provides the initiative; goal; and, consequently, methods for evaluating the intervention's success.

Health indications, such as ADHD, schizophrenia, and depression, create the initial frame for the target audience. However, the actual target market is a subpopulation of this total addressable market influenced by several implicit factors. Users' age, gender, education, personality, and prior experiences with mental health services and the severity of their symptoms influence user engagement [64]. Knowing these background factors provides an opportunity to target audiences that favor digital interventions and to extend the intervention reach to new and underserved audiences through inclusive and participatory design [65]. Although our discussion emphasizes the end user, the intervention's target audience may also include other stakeholders, such as therapists in case of interventions that blend web-based and face-to-face therapies [66].

Besides the factors influencing DMHI use in general, some aspects influence user engagement with gDMHIs specifically. This reflects the considerable differences in users' game preferences [67]. Appreciating the divergence in player motivations goes back to Bartle [68], who noticed that the players of multiuser dungeons (an obsolete multiplayer game genre) engage with the games for divergent reasons and in different ways. On the basis of "a long, heated discussion," he identified the following 4 motivations to play: *achievers* play to pursue game-related goals, *explorers* seek to understand the fictional game world, *socializers* focus on role playing and interacting with others, and *killers* compete for dominance through conflict. Bartle's [68] insight was that players engage in an apparently similar activity for widely different reasons and use the affordances of the game to serve their preferences. Since his original work, player motivations have been explored further. A review of 12 player typologies found that there is surprising conceptual uniformity in the categorizations, concluding with 5 primary player motivations, adding immersion¸ which is concentration on the story, fantasy, and narrative, to Bartle's original 4 [69]. In addition to affecting *how* games are played, game preferences influence *which* games are played. Using survey data, Mandryk and Birk [70] classified players into 4 categories: those who appreciate single-player games, those who appreciate first-person shooter or action games, those who appreciate casual games, and those who appreciate most genres. Moreover, the researchers found that their categorization was not associated with depression, indicating that people with depression appreciate various genres. Thus, the game genre decision partly defines who finds the genre attractive and engaging.

We advocate an integrative approach to the target audience. The health indication provides a rationale for the intervention and limits the target audience. In addition to the factors influencing engagement with DMHIs, the chosen game genre influences who are drawn to the game-based intervention, continue to engage with it, and hence gain a positive impact from the interaction. Understanding the target audience allows developers to identify and cater to the variance in the users, their needs, play styles, and preferences and to remove frictions that prevent players from enjoying the intervention as much as they expect to.

Engagement: Does the User Want to Interact With the Intervention?

The user's motivation to interact with the gDMHI is to gain certain benefits and enjoy their time while doing so. According to concepts proposed by Siriaraya et al [40], the "therapeutic value" of the intervention is a function of its "game value": the more experientially pleasurable the intervention is, the more likely the player is to continue to interact with it. These 2 concepts are related through the behavioral change that the interaction invites. The capability, opportunity, motivation, and behavior (COM-B) system describes 3 antecedents for behavioral change [12]. To build the user's capabilities, opportunities, and motivation, the intervention can, for instance, educate, persuade, train, and model new behaviors, which we call the mechanisms of action. Behavioral change can lead to symptom change [13], although often after a significant delay of days and weeks, which should motivate attention to the player experience.

Mere interaction with the intervention, however, is not sufficient, which Yardley et al [38] highlighted through the concepts of microlevel and macrolevel engagement. For instance, an exergame delivers its effects when the user trains with it, exhibiting microlevel engagement. This may turn into macrolevel engagement with the broader goals of the intervention when the intervention teaches the user healthy exercise routines and encourages the transfer of new behavior outside the immediate interaction. Thus, unlike commercial entertainment games, whose success is often closely tied to microlevel engagement, gDMHIs are driven by 2-tier engagement, and a successful intervention becomes obsolete once the player has internalized the intended change, which is a considerable digression from the entertainment paradigm. Subjectively, microlevel engagement may be experienced as a reduced effort to interact with the intervention. Subjectively, microlevel engagement may be experienced as a reduced effort to interact with the intervention [71]. This is also what the player may expect from a game-based approach: when the intervention is introduced through the notions of "game" and "play," they allude to interactions that are more pleasurable than those with solutions more strongly associated with a functional approach.

To design for microlevel engagement, the concept needs a clear definition and metrics. Here, we turn to Perski et al [72], who provide a useful definition: "(1) the extent (eg, amount, frequency, duration, depth) of use and (2) a subjective experience characterized by attention, interest and affect." The 2 sides represent complementary aspects of engagement, objective and subjective aspects, which require different approaches in their evaluation [73,74]. The subjective criteria may be pursued through qualitative research, such as user interviews, think-aloud protocols, and focus groups that provide rich and detailed qualitative data on engagement [75], or swiftly through questionnaires [76]. Subjectively, high levels of engagement with gDMHIs may be experienced as immersion, where the player becomes unaware of the mediating technology, perceiving the interaction as unmediated [77]. The phenomenon is also known as presence, a sense of being "in the game." It has many similarities to the notion of flow, where the subject is absorbed in the task and becomes unaware of their surroundings [74,78,79]. This pleasurable mental state is the experiential value players seek from the game and manifests as a sense of "want to" rather than "have to" engage with the game [80].

To complement the evaluation of a subjective sense of engagement, game analytics can provide objective indicators of engagement. Among the strongest and most valuable tools in commercial entertainment game development, game analytics provides proof, also in business terms, that the target audience enjoys spending time with the game [81]. User analytics offers insights into microlevel engagement by measuring the time spent with the intervention, accompanied by metrics of retention, that is, players returning to the intervention.

Entertainment games are a medium focused on building engagement that is experienced as immersion. This provides the developers with a user-centered goal that can be evaluated both subjectively and objectively. The health care paradigm complements the approach by ensuring that evidence-based mechanisms of action are in place so that user interaction contributes to the expected health benefits.

Mechanisms of Action: What Explains the Intervention Effects?

Overview

Mechanisms of action explain how and why the intervention achieves the intended change in the user's behavior and symptoms [10]. They have also been called "mechanisms of change" [13], and "intervention functions" [12], and they include sharing knowledge, building motivation, changing beliefs, modeling new behaviors, and persuading change. In game-based interventions, these rationales are given a digital form through their game-based implementation. Next, we describe and contrast 3 common and distinct approaches to game-based interventions: adapting existing psychotherapies, offering cognitive training, and encouraging physical exercise (Table 3).

Table 3. Three approaches to game-based interventions exhibit the potential synergy between health care rationale and its game-based implementation.

Approach	Mechanisms of action	
	Health care: "what"	Entertainment: "how"
Adapting existing psychotherapies	Behavior change through an increase in mentalization capabilities	Narrative and story-driven implementations
Offering cognitive training	Training cognitive functions such as attention	High-paced action games
Encouraging physical exercise	Increased physical activity	Virtual reality, augmented reality, and fitness games

Adapting Existing Psychotherapies

Numerous existing psychotherapies have been adapted as gDMHIs, the most prominent of which is cognitive behavioral therapy [2,3]. There are numerous benefits to using an existing therapy to guide the development work: it provides a theoretical foundation, a rationale on how and why the intervention should work, credibility with stakeholders, and legitimacy for the work. Despite the differences between psychotherapies, their effects seem curiously similar [82]. It has been suggested that there are common factors that explain their effectiveness [83], although the research is ongoing [84]. Leiman [85] conceptualized that all psychotherapies seek to change the patient's position toward their challenges. When the client begins the therapy process, they are in an object position to their problem. Through therapy, they gain an understanding of their problem and capabilities to control it and, consequently, shift toward a subject position. Thus, the effectiveness of psychotherapy is based on the growth of mentalization capabilities and self-reflection, which then lead to behavioral changes.

Narratively rich game genres, such as role-playing and adventure games, may be particularly suited for adaptations of existing psychotherapies that invite an active reflection on one's thoughts, emotions, and behaviors. The interactions with game characters can be used to, for instance, simulate challenging social situations through role playing, model effective behaviors, and develop emotional regulation. An example of this approach is SPARX, a serious game for adolescents living with depression. The computerized CBT intervention consists of 7 modules, including psychoeducation, building hope, encouraging behavioral activation, and coping with negative emotions [86].

Offering Cognitive Training

Compared with psychotherapeutic approaches, the mechanisms of action of cognitive training games are considerably different. Their rationale lies in the finding that many mental disorders are associated with cognitive deficits [87]. For instance, depression is related to moderate deficits in memory, attention, and executive function, and these deficits may prevail partly even after depression is in remission [88]. Computerized interventions have been designed to address these deficits, and this approach has been found effective in addressing depressive symptoms [89].

Compared with reflective psychotherapeutic games that rely on player interaction with the narrative, characters, and story, the mechanisms of action in cognitive training games are more closely associated with the game mechanics. For instance, fast-paced first-person shooter games, real-time strategy games, and other action games may provide pathways for improving cognitive skills [90] and alleviating cognitive deficits associated with mental health challenges. Furthermore, the mechanisms of action may also be related to game preferences: reflective therapies may be preferred by those with a tendency for immersion and socialization, whereas cognitive training games appeal to achievement, exploration, and domination motives. Bearing in mind that fast-paced games are preferred by younger audiences [31], the interventions may be suited to addressing cognitive deficits associated with mood or neuropsychological disorders in the youth. An example of this approach is EndeavorRx, a gDMHI that seeks to alleviate pediatric ADHD [91].

Encouraging Physical Activity

To further contrast the mechanisms of action of reflective psychotherapeutic games and those of cognitive training games, the effectiveness of exergames is dependent on increasing physical activity. The rationale lies in the finding that physical exercise has significant and large antidepressant effects [92,93]. For instance, the augmented reality game Pokémon Go, which encourages finding, gathering, and collecting digital fantasy pets from various real-life locations, has been found to contribute to a greater number of daily steps and increased social interactions because the locations are frequented by like-minded players [94]. These interactions, in turn, may have positive effects on mood [95]. It appears that the interventions that encourage physical activity often use a purpose-shifted approach facilitated by the availability of exergames [2-4,96]. Currently, however, the quality of evidence on the effectiveness of exergames for mental disorders is low.

We highlight how development efforts need to find the synergy between the health research–based mechanisms of action and their game-based implementation. The 3 described mechanisms of action, built on existing psychotherapies, cognitive training, and physical exercise, exemplify how health care research can intertwine with the game genre implementation.

Effectiveness: What Does the Intervention Achieve?

The effectiveness of gDMHIs is indicated by behavioral and symptom changes [10,13]. Reaching a meaningful reduction in symptom scores indicates a clear benefit expected by clinicians and the players and payers of the intervention alike. To complement the symptom- or disorder-focused approach, the intervention may have other, equally meaningful benefits that occur in parallel or in addition to the symptom change. As the World Health Organization (WHO) [97] states in its constitution, "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." In subjective terms, symptom alleviation may be related to improved quality of life [98]. To illuminate the complexity of the concept, a qualitative synthesis of the experiences of people with mental disorders found that good quality of life was associated with feelings of well-being, positive self-perception, control, autonomy, a sense of belonging, participation in meaningful activities, and a positive future view [99]. In other words, an improved quality of life is not perceived merely as the absence of symptoms.

Expanding from the symptom-based approach, the impact of gDMHIs may be considered through the self-determination theory [100]. It describes the following 3 universal human needs that contribute to intrinsic motivation, self-regulation, and well-being: competence, autonomy, and relatedness. Digital games have a unique possibility to contribute to the 3 needs by fostering a sense of competence by presenting the players with increasingly difficult puzzles as their skill increases, creating a sense of connection with other players enjoying similar activities, and supporting player autonomy by offering choices and various ways to play. As opposed to mediums that are more passively consumed, games are characterized by a sense of agency [101]: the player does not spectate the protagonist but becomes them, controls them, and sees the fiction through them. By answering to the players' needs, game-based interventions can have positive effects across the cognitive, social, and emotional spheres [56].

However, whether the interaction serves the underlying human needs depends on both the game design and the players' mindset. Games that serve the players' needs are associated with continued motivation to play [102,103] and affective well-being [55]. When the players use the game to fulfill their psychological needs, playing can be viewed as adaptive and healthy [104], whereas using the game as an avoidance behavior is associated with mental distress and problematic gaming [105]. Thus, creating designs that answer to the players' deeper psychological needs and encourage healthy playing styles is vital.

User interaction with the gDMHI produces a vast amount of data, including behavioral biomarkers [106], which may contribute toward understanding the psychological needs, mechanisms of action, and mental well-being beyond the disorders. Players' interaction with the game mechanics and puzzles provides indications of their motor and cognitive performances, which are particularly useful in cognitive training interventions. Players' affective states and changes in their social interactions may be derived from their text-based outputs and interactions with other players, which contributes to therapies that use reflective approaches. However, the use of behavioral biomarkers as outcome measurements is only growing. Recently, they have been used, for instance, in the assessment of social anxiety [107], mood disorders [108], and mild cognitive impairment [109].

To summarize, gDMHIs are expected to contribute to a significant reduction in mental health symptoms, which is preceded by player engagement and behavior change [13]. Thus, the overall effects of the intervention may extend beyond the symptom change that the digital medium affords to accurately measure. Leveraging in-game data provides corroboratory insights into why and to what extent the interventions are effective, including in terms of broader psychological needs. This contributes to understanding how the interaction impacts a user's behavior, which is, hopefully, generalized in the broader context of the user's life [110], exhibiting macrolevel engagement.

Translating the TEME Framework to Intervention Development

Overview

New product development is a gradual, evolving process [10,11]. It can be described in phases, bearing in mind that the research, design, and development efforts, particularly in a novel domain, are often characterized by exploration, iteration, looping back to earlier phases, and redesign based on feedback. Therefore, the development phases should be considered nonlinear.

We summarized gDMHI development into 4 phases (Table 4). The design begins with research into the target audience and their needs, which are performed through a high-level concept that outlines the intervention. The intervention, as well as the service concept more broadly, is advanced iteratively during development. The evaluation of the intervention likewise gradually grows more comprehensive, culminating in a randomized controlled trial (RCT) that is valued as a particularly strong proof in health care. Should the results prove favorable, the solution may be implemented, and its development may continue in live production.

Table 4. Throughout the game-based digital mental health intervention development phases, the emphasis shifts among the 4 themes: target audience, engagement, mechanisms of action, and effectiveness. The level of focus on the themes are represented as higher focus (HF) and lower focus (LF).

Theme	Concept design	Development	Evaluation	Production
Target audience: who is the intervention engaging and effective for?	HF	HF	LF	LF
Engagement: do users interact with the intervention?	LF	HF	HF	HF
Mechanisms of action: what explains the intervention effects?	HF	LF	LF	LF
Effectiveness: what does the intervention achieve?	LF	LF	HF	LF

Throughout the 4 phases, the focus of the development team fluctuates between the paradigms of health care and entertainment: designing an effective health care intervention and an engaging video game experience [111], pursuing instrumental and experiential outcomes [39], or, in other words, creating therapeutic value and game value [40]. The 2 complementary perspectives intertwine through the development process.

Concept Design: A Model for Addressing the Target Audience's Needs

The concept provides an overview of *what* the intervention is, which is intimately related to the following question: *who* is it for? Understanding the target audience and their contextual needs and preferences allows defining the characteristics of the intervention [10,11,112]. Interviews, questionnaires, focus groups, desk research, and ethnography can be used to create a rich understanding of the target audience's preferences, media used, and target audience's thoughts about and frictions with the existing solutions and services. However, the tools are secondary to the aim of shifting one's perspective through empathy, which is a cornerstone of design [111]. In fact, several development frameworks, models, and philosophies focus on users. They include participatory design [113]; service design [111]; persuasive design [114]; and user-centered design [115], which is also common in gDMHI design. A study exploring 20 development processes found that 50% of them adopted a user-centered approach in the concept phase, and the rest invited user participation in the development phase [116]. Accentuating the importance of users reflects the threats of overly focusing on the solution instead of the need it addresses, which may lead to users rejecting the intervention, and necessitating costly changes later in the development [4,117]. Starting from the target audience, as well as other necessary stakeholders, facilitates the definition of the intervention objectives, technology, and game genre [51].

It is a common misconception that user research would directly inform the design. Users can describe their experiences with existing solutions, but developers are responsible for integrating the understanding into a model that considers the mechanisms of action, technological possibilities, stakeholder dependencies, commercialization, and regulations. Often, the digital concept aims to challenge the dominant, nonscalable, one-to-one, and in-person model of mental health service delivery [118]. The concept can also include considerations of the business model: how the intervention is priced, purchased, and compensated [119]. In contrast to the entertainment industry, which is dominated by the direct-to-consumer model, where the player chooses, uses, and pays for the game, health care characteristically includes more complicated commercial models. Aitken and Nass [32] described 4 such commercial models: direct-to-consumer model, where the user pays for the service; device-like reimbursement model, where the cost of the intervention is covered by the medical benefit plan when the intervention is prescribed by a physician; drug-like reimbursement model, which relates the intervention to pharmacy benefit; and value-based contracting, where the intervention is provided for an organization and paid per the benefits achieved. Thus, the preliminary documented concept is a user-centered account of whom the team is designing for, a science-based account of how the intervention contributes to the user's health, and a description of the intended commercial model.

Development: Iterating the Design and Planning Its Implementation

During development, the team gradually turns the concept into an actual intervention. The phase is iterative: it oscillates between design and testing, which seeks to ensure that the team is progressing in the right direction [10,112,115]. During development, the team can make use of methods from entertainment, which allow the team to focus specifically on the intervention features, and methods from health care, which focus on establishing and implementing the intervention in the complex health care ecosystem.

The success of games is tied to the experience they create [46]. There are various perspectives on game experience [120]; however, in general, it is built of layers, as the user interacts alone or with other players with the game system, its look and feel, and the underlying systems. The interaction leads to an experience that the player may find immersive, motivating, and pleasurable. Entertainment game design has a wealth of methodologies that can be used to hone the game-user interaction [121-123], which acts as a focus point for the interdisciplinary efforts in visual and audio design, software development, and storytelling [44].

The business-to-consumer digital entertainment industry has established distribution platforms that allow developers to focus on game development. Health care, in contrast, currently lacks such global, or even national, distribution platforms. Therefore, it is important to design for feasibility and consider the implementation of the intervention early [11]. If the intervention is introduced into an organizational context, it needs to fit the existing practices, improve current processes, and integrate with the existing software solutions [124]. In fact, many interventions are expected not only to offer end user benefits but also to be easy to adopt and contribute to organizational efficiency. The Non-adoption and Abandonment of technologies, and the challenges to Scale-up, Spread, and Sustainability of such technologies (NASSS) framework structures the complex health care environment in which the intervention may be implemented [125]. It highlights the interrelations among the health condition, technology, value proposition, stakeholders adopting the solution, and their organizational and wider context over time. In conclusion, the development process gradually builds not only the digital intervention, in the narrow sense of the word, but also the related services and the operating models that sustain it.

Evaluation: Progressive and Comprehensive Intervention Evaluation

The evaluation of the intervention grows gradually more comprehensive. In development, the intervention is tested for its playability and game experience, ensuring that the game-based intervention is found sufficiently favorable by the players in the target audience [46] and is meaningful for other stakeholders. As the development progresses, there is increasing interest in evaluating the intervention's health-related effectiveness. A feasibility study, a higher-order concept than playtesting, focuses on the following question: can the intervention work? [126]. Feasibility studies allow for evaluating whether the intervention can attract the appropriate target audience, understanding how acceptable the participants consider the intervention and its procedures, and understanding how the intervention is to manage in practice and contribute to the development of data collection methodologies. However, a feasibility study provides only initial indications of the intervention's effectiveness. Pilot studies can create stronger, although inconclusive, evidence of intervention effectiveness [126]. Should the intervention pass the preliminary evaluations, an RCT can be conducted. It provides high-quality evidence on the effectiveness and safety of the intervention for regulators, clinical stakeholders, and the scientific community. However, because conducting an RCT is demanding, expensive, and slow, progressing to them without ensuring the overall feasibility of the intervention is not advised [112].

It is important to evaluate the intervention comprehensively beyond the summative results: formative evaluation can provide insights into how and why the intervention is or is not successful in its context [127]. Qualitative research can contribute to understanding the intervention's impact and player experience [128,129], and evaluating engagement creates insights into the intervention's feasibility, acceptability, attractiveness, and dose-response relationship. However, the evaluation of engagement is often lacking, and there is substantial heterogeneity in how it is reported [26,73]. One approach is reporting the following 6 factors: the number of users, their profiles, the number of modules in the intervention, the number of times they are accessed, the percentage of users receiving a therapeutic dose, and the achieved clinical change [26]. Economic evaluation is not to be overlooked either, as it often forms the rationale for adopting a digital approach. Economic evaluation can be performed to understand, for instance, the cost-effectiveness of the intervention and to guide strategic decision-making and investments [130].

We encourage a progressive and comprehensive evaluation of the intervention, that is, considering the subjective user experience and objective engagement alongside the clinical metrics. Complementing summative evaluation with formative and economic evaluations allows for an understanding of the intervention feasibility and whether the benefits justify the costs, which facilitates translating the research to complex real-world environments should the intervention prove both effective and engaging.

Production: Implementing the Intervention in Real Life

When the intervention works in controlled research settings, it may be implemented in more complex, real-life settings. Following the principle of path dependence, the decisions made in the earlier stages regarding, for instance, the health indication, mechanisms of action, game genre, and technical implementation continue to exercise their influence in the production phase. Building on the established foundation, the attention turns to marketing, service production, partnerships, and continuing development.

Implementing the intervention often encounters challenges: the research-to-practice gap [27]. Common barriers include user preference for face-to-face therapies, the perceived complexity of the digital intervention, limited research evidence regarding the intervention, low user engagement, the costs of the intervention, and practitioners' resistance. To overcome these challenges and achieve real-world impacts, developers should prepare for them using numerous models [124,125,131]. The Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) model provides an overview of the components necessary for creating an impact on a population level: the intervention needs to reach a broad audience, be effective, be adopted in numerous settings, be implemented as intended, and be maintained over time [131]. Thus, besides the need for the intervention to be proven effective, the implementation of the intervention demands marketing and organizational support for dissemination. Another useful perspective is the consolidated framework for implementation research, which consists of 5 domains [124]. Intervention implementation is dependent on the intervention characteristics, relationship of the intervention with external stakeholders, organization's internal capabilities to produce the service, individuals within the organization delivering the intervention, and implementation processes. Outside the research setting, the development team needs to consider ways to deliver the intervention to users en masse, which demands changes in organizational structures and service management.

Should the intervention reach a sufficiently considerable population, the developers may begin to view the software as a continuous service. Here, methodologies already in use in game development may prove useful. In contrast to the earlier, linear development process that considered the launch of the game the conclusion to the development, the prevailing game as a service model focuses attention also on postlaunch development [132]. This approach, also called live operations, relies on using business metrics and user feedback to guide the continuous development efforts and add new content [133]. In the future, there is potential in considering gDMHIs as a continuous, evolving service rather than unaltered products [134]. However, it is still unclear to what degree the digital intervention may be developed while retaining the effects and evidence gathered in the previous stages, and there is little research on gDMHI live operations. This reflects the nascent industry that is still waiting for successful interventions to attract a large number of users to fund the continuous research and development of a live product.

Discussion

Summary

gDMHIs use elements of entertainment games to achieve health-related outcomes. We describe how these interventions draw from the health care and entertainment paradigms (Table 1) and categorize them in a continuum between the two (Figure 1). We then introduce 4 themes, the TEME framework (Table 2), to negotiate between the 2 paradigms and facilitate their interdisciplinary development from concept design to production (Table 4).

Contributions to the Development Research

Previous research has discussed the tension of interventions being both engaging and effective [38-40]. By contrast, the existing development frameworks have facilitated the development of behavioral interventions, digital interventions, and serious games for health [10-13]. We expand on the prior literature by elaborating, contrasting, and negotiating the differences between the paradigms of health care and entertainment. The paradigm of health care frames and measures user needs through diagnoses and behavior, has expansive research on mechanisms of action, and is unrelenting in its focus on proving effectiveness, yet it has a shorter history in crafting and implementing engaging experiences in the digital setting. Meanwhile, digital entertainment leads and pioneers in this field. It has expansive practices in iteratively creating immersive experiences in numerous game genres and has advanced development methodologies to measure and design for subjective and objective engagement. However, the entertainment paradigm lacks an understanding of the health indications, mechanisms of action, and health care ecosystem. Thus, the interdisciplinary gDMHI development requires broad competencies in both paradigms and their methods: the digital game–based medium and the health care context.

The TEME framework supports interdisciplinary collaboration by focusing on 4 themes necessary for development: understanding the target audience, ensuring that the intervention is found favorably by them, basing the intervention on proven mechanisms of action, and ensuring its effectiveness. When the 4 themes are reflected in development, developers can seek synergy between health care research and the game-based medium. Common approaches include adapting existing psychotherapies, offering cognitive training, and encouraging physical exercise. However, there are also other developments to be imagined and researched: perhaps the genre of peaceful and serene walking simulators [135] characterized by the ponderous, slow pace could be used to encourage mindfulness practice, or web-based communities could be used to offer peer support, a sense of belonging, and empowerment [136]. We encourage iterative intervention development and evaluation beyond symptom change, considering the behavioral, economic, and organizational impacts.

Earlier, gamification and serious games were considered 2 distinct lines of research [50]. Taking an integrative stance, we suggest that gamified interventions, serious games, and purpose-shifted digital entertainment games can also be viewed as a continuum between health care and entertainment. This distinction contributes a novel perspective to the classification of serious games and serious games in health [51,53,137], allowing an understanding of the developer's position between the 2 approaches.

Earlier, Fleming et al [115] called for a paradigm shift in the development of digital interventions. In particular, they suggested increasing efforts in user-centered design, creating engaging interventions, fostering collaboration, and conducting rapid testing and implementation. Building on these principles, we describe how the development of gDMHIs requires using the strengths of both digital entertainment and health care through an integrative, interdisciplinary framework.

Conclusion: Game-Based Elements Are More Than a Spoonful of Sugar

"In every job that must be done/There is an element of fun/You find the fun and snap!/The job's a game," said supernanny Mary Poppins when instructing unwilling children on how to get their chores done. With the mindset shift, the mislaid items find their place through the magic of motivation. Similarly, the effectiveness of a gDMHI depends on the design's ability to conjure motivation and identification with the change in the users. Engagement and effectiveness depend on the target audience, the underlying mechanisms of action, and their execution as a game. When successful, the game-based approach is more than adding a spoonful of sugar to sweeten an otherwise uninteresting task. Rather, it allows creating interventions that bridge the treatment, engagement, and implementation gaps: they allow expanding intervention reach, inspire effective engagement, and allow viable intervention production.

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Authors' Contributions

LL originated the concept of the paper and wrote the manuscript. JMP revised the manuscript and contributed to the approach and structure of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
COM-B: capability, opportunity, motivation, and behavior
DMHI: digital mental health intervention
gDMHI: game-based digital mental health intervention
NASSS: Non-adoption and Abandonment of technologies, and the challenges to Scale-up, Spread, and Sustainability of such technologies
RCT: randomized controlled trial
RE-AIM: Reach, Efficacy, Adoption, Implementation, and Maintenance
TEME: target audience, engagement, mechanisms of action, and effectiveness
WHO: World Health Organization

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Original Paper

A Conceptual Framework (2D-ME) for Explaining Self–first and Self–third Person Views of Prototyping Dynamics in Serious Games Design: Experimental Case Study

Sofia Hadjileontiadou[1*], PhD; Sofia B Dias[2*], PhD; Leontios Hadjileontiadis[3*], PhD

[1]Department of Primary Education, Democritus University of Thrace, Alexandroupolis, Greece

[2]Interdisciplinary Centre for the Study of Human Performance, Faculdade de Motricidade Humana, Universidade de Lisboa, Lisbon, Portugal

[3]Department of Biomedical Engineering, Khalifa University of Science and Technology, Abu Dhabi, United Arab Emirates

[*]all authors contributed equally

Corresponding Author:
Sofia Hadjileontiadou, PhD
Department of Primary Education
Democritus University of Thrace
Alexandroupolis-Komotini Rd./New Chili
Alexandroupolis, 68131
Greece
Phone: 30 2551030103
Email: schatzil@eled.duth.gr

Abstract

Background: Design dynamics that evolve during a designer's prototyping process encapsulate important insights about the way the designer is using his or her knowledge, creativity, and reflective thinking. Nevertheless, the capturing of such dynamics is not always an easy task, as they are built through alternations between the self–first and self–third person views.

Objective: This study aimed at introducing a conceptual framework, namely 2D-ME, to provide an explainable domain that could express the dynamics across the design timeline during a prototyping process of serious games.

Methods: Within the 2D-ME framework, the Technological-Pedagogical-Content Knowledge (TPACK), its adaptation to the serious games (TPACK-Game), and the activity theory frameworks were combined to produce dynamic constructs that incorporate self–first and self–third person extension of the TPACK-Game to Games TPACK, rules, division of labor, and object. The dynamic interplay between such constructs was used as an adaptation engine within an optimization prototype process, so each sequential version of the latter could converge to the designer's initial idea of the serious game. Moreover, higher-order thinking is scaffolded with the internal Activity Interview Script proposed in this paper.

Results: An experimental case study of the application of the 2D-ME conceptual framework in the design of a light reflection game was showcased, revealing all the designer's dynamics, both from internal (via a diary) and external (via the prototype version) views. The findings of this case study exemplified the convergence of the prototyping process to an optimized output, by minimizing the mean square error between the conceptual (initial and updated) idea of the prototype, following explainable and tangible constructs within the 2D-ME framework.

Conclusions: The generic structure of the proposed 2D-ME framework allows its transferability to various levels of expertise in serious games mastering, and it is used both for the designer's process exploration and training of the novice ones.

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KEYWORDS

2D-ME conceptual framework; Technological-Pedagogical-Content Knowledge; TPACK; activity theory; AT; self–first and self–third person; Games TPACK; GTPACK; internal Activity Interview Script; iAIS; serious games prototyping

Introduction

Background

Serious games are games that focus on learning while entertaining. As their design entails elements from both the game and learning design, it is a process of a rather complicated thread of decisions. Conceptualizations of this process contribute to serious game design modeling frameworks [1]. With regard to serious game designing, the work of Hunicke et al [2] proposed the Mechanics, Dynamics, and Aesthetics (MDA) framework. In particular, their work is fundamental in the area and realizes 3 distinct components that can be viewed from the user's and the designer's perspective. The Mechanics component describe specific options of actions that the user can perform while interacting with a game, and they can be described through verbs (eg, move). On the other hand, the Dynamics component refers to the combined player options toward a system of interactions at a higher level than the Mechanics component, that is, they can be considered the system-behavior of a game. However, the Mechanics component, being more specifically defined at a lower level of abstraction, is more reliable than the Dynamics component. Finally, direct and indirect interactions of the player with the game result in the Aesthetics component that refers to the emotional responses of the player (eg, fun), as they are provoked by the combination of the game Mechanics and Dynamics components, the latter bridging the Mechanics component with the Aesthetics component. Thus, a flow is realized during the game design, that is, an initial selection of the Mechanics component, then the Dynamics component, and finally the Aesthetics component. Although the work of Hunicke et al [2] was criticized as situational [3], it can serve as a direct framework to outline the serious game design. A detailed list of core mechanics was proposed by Järvinen [4] and a list of comprehensive Dynamics was proposed by Pendleton and Okolica [5].

Research in the area of serious game designing resulted in further frameworks that followed the work of Järvinen [4]. Moreover, Ávila-Pesántez at al [6] provided a systematic literature review regarding the methodologies, frameworks, and models applied to game designs in the period from 2008 to 2016, resulting in 11 approaches, whereas Viudes-Carbonell et al [7] provide a state of the art of 6 models in the area. However, the Learning Mechanics–Game Mechanics Framework [8] is worth mentioning, as it was based on the idea that learning occurs while interacting with the game, that is, Learning Mechanics can be mapped to the game's Dynamics component and relevant thinking skills according to the revised Bloom taxonomy [9]. Thus, the learning objectives are diffused in the serious game design [10] to entail the game's educational character. Following this approach, Pendleton and Okolica [5] proposed the Game Design Matrix structure, which reorientates the building block of the MDA framework [2] by first selecting the Dynamics component, according to the expected level of mastery in the Bloom taxonomy, so that the emphasis is initially given to the learning objectives that drive the learning outcome of the serious game. However, the design procedure is an iterative process and Hunicke et al [2] underline the importance of iterative analyses and refinement of the game design results.

In a more detailed approach, Viudes-Carbonell et al [7], following the MDA framework, consider the game design as iterative cycles of design, test, evaluation, and redesign and stress the idea that the iterations would eliminate the risk of failure while designing a serious game. In particular, they focus on the prototyping iterations and consider them as series of small steps toward the enhancement of the quality of the game outcome. Following this path, Fullerton et al [11] consider prototyping an important part of the game design. Prototyping may take place by various means, for example, by pencil and paper, computer, and other artifacts in many disciplines (eg, engineering), to break out a complex problem to subproblems and work on these separately. However, a game is rule based; thus, it is sensitive to changes and/or prediction of possible impacts owing to rule changes. In this perspective, prototyping may resolve unpredictability issues in game design [12]. Moreover, considering games as pieces of art when compared with average software [13], their designing is even unpredictable as the design space may dynamically evolve through the emergence of new ideas and creativity.

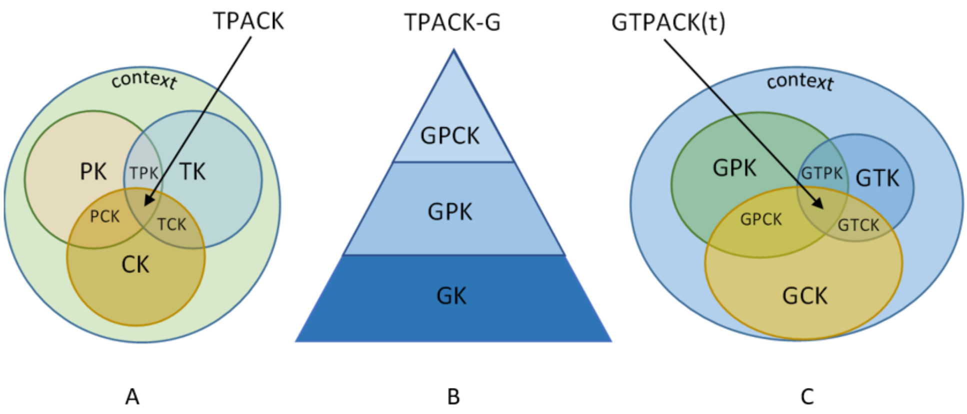
The aforementioned approaches provide the frameworks of designing and establish steps for the enactment of design ideas. However, they do not refer to the knowledge that is needed for the materialization of the game design. With regard to this direction, the frameworks described in subsequent sections have been considered.

Design Frameworks and Serious Games

The Technological-Pedagogical-Content Knowledge Framework

The Technological-Pedagogical-Content Knowledge (TPACK) was proposed as a framework to account for the knowledge needed by the teachers to use information and communications technology in their classrooms [14-16]. In particular, this framework extended the notion of Shulman [17] concerning the pedagogical content knowledge (PCK), by foreseeing the inclusion of knowledge related to technology. Figure 1A depicts the TPACK framework and manifests the interplay between forms of knowledge (content knowledge [CK], pedagogical knowledge [PK], technological knowledge [TK], PCK, technological PK [TPK], and technological CK [TCK]). More specifically, CK refers to the knowledge of the content of the lesson, for example, the concepts that are to be taught; PK refers to the pedagogical considerations as to how to teach the content; TK refers to the knowledge about the technological affordances and their use; TCK and TPK refer to the way the technology could support and materialize the delivery of content and pedagogy; and finally, PCK refers to the pedagogical way in which the content could be delivered to the learners. The contextualized synthesis of all these forms of knowledge constitutes the core TPACK framework. TPACK is usually presented as 3 overlapping equal cycles denoting 3 forms of knowledge (CK, PK, and TK) and their overlaps (TCK, TPK, PCK, and TPACK), all included in a circle that denotes the knowledge that is needed for the integration of technology in a relevant sociocultural context. TPACK has been widely used as a framework to reflect information and communications technology integration in the classroom even under education emergency conditions [18].

Figure 1. Schematic representation of the (A) Technological-Pedagogical-Content-Knowledge (TPACK), (B) Technological-Pedagogical-Content-Knowledge–Game (TPACK-G), and (C) Games Technological-Pedagogical-Content Knowledge (GTPACK; see the GTPACK subsection) frameworks. CK: content knowledge; GCK: game content knowledge; GK: game knowledge; GPCK: game pedagogical content knowledge; GPK: game pedagogical knowledge; GTCK; game technological content knowledge; GTK: game technological knowledge; GTPK: game technological pedagogical knowledge; PCK: pedagogical content knowledge; PK: pedagogical knowledge; t: dynamic; TCK: technological content knowledge; TK: technological knowledge; TPK: technological pedagogical knowledge.



The TPACK-Game Framework

TPACK serves as a theoretical reference framework of necessary knowledge for the technology integration in different contexts; for example, Foster et al [19] proposed TPACK as an aid for the teacher when selecting a game to realize its constraints and affordances for technology, pedagogy, and content. However, Willermark [20] commented on TPACK for its abstract reference to general technology that could be used in the classroom, that is, it lacks the specificity that might contribute to further specification of knowledge that is needed. In this regard, in the specific case of computer game integration in the classroom, Hsu et al [21] proposed TPACK-Game (TPACK-G; Figure 1B) to reflect the knowledge that the teachers need in this case. In particular, they define game knowledge (GK) as the knowledge about the general use of computer games, game PK (GPK) as the pedagogy related to the way a game is used in the classroom, and game PCK (GPCK) as the "knowledge of using games to implement teaching methods for any targeted content" [21]. On the basis of prior work on the developmental pathway of TK and TPK to TPACK, Hsu et al [21] proposed the GPCK as a pyramid, where GK constitutes the basis, followed by the GPK, and finally, at the top, the GPCK. Upon this modeling, they claim that for the development of specific GPCK, the GK and GPK are prerequisites, so a lack of the foundation knowledge of how to play a game, that is, familiarity with gaming environment (GK), leads to a lack of GPK and therefore GPCK [21]. Structural relationships were also detected between the TPACK-G attitudes toward games and actual teaching use [22].

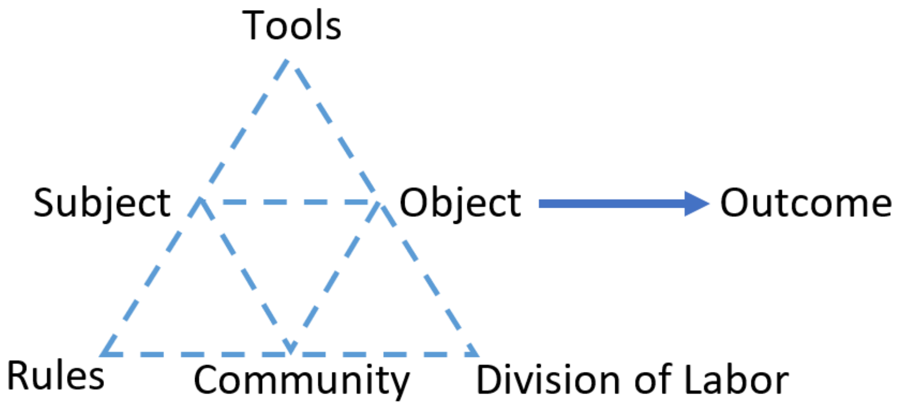
Both the TPACK and TPACK-G frameworks are proposed through a "stationary-like" approach, whereas a more dynamic one might reveal the evolution of types of knowledge over time while an activity takes place, for example, during the iterative approach toward the designer's activities while designing a serious game. The activity theory (AT) framework may provide a lens toward this direction, as explored in the subsequent section.

The AT Framework

Overview

The AT framework has its roots in the 1920s and provides a conceptual framework according to which, the human activity connects the individual world of the subject with the social one (Figure 2). Upon its initial formulation [23,24], the AT framework focused on the activities of the subject, for example, human being. For the subject to meet his/her needs, he/she performes activities by interacting with objects in the world by means of tools that mediate the interaction. Thus, the subject is involved in an activity motivated by an expected outcome (the "why" of the activity), pursues goals that direct the activity (the "what" of the activity), and performs operations (the "how" of the activity) [25]. However, the connection between subjects and activities is bidirectional as they mutually determine one another. Basic principles of AT have evolved through the works of Leontiev [23,24], namely [26] (1) object orientedness, which states that objects differentiate the activities that are directed to them upon motivation toward a need; (2) hierarchical structure of activity, which is a hierarchical system that shows the dynamic relationship among 3 levels of human activity. From a top-down perspective of the activity, at the top, the activity driven by the motive is considered. However, the activity in a lower level is performed through conscious actions that are directed to goals (possibly decomposed to subgoals) that are to be undertaken to fulfill the object. At an even lower level, actions are performed through unconscious operations that are orientated to conditions under which the goal is to be reached; (3) tool mediation, toward a purposeful activity; (4) development, as a context to analyze the activity, for example, from the research respective, this leads to the analysis of the dynamics of the object transformations over time; and (5) internalization externalization.

Figure 2. Schematic representation of the main constructs that form the activity theory framework.



Synergies of AT in Serious Games Prototyping

In the work of Carvalho et al [27], the AT framework was used for the analysis and design of serious games. In particular, they proposed the AT-based conceptual model of serious games, which contributes to the realization of the components of a game and their roles and to the recognition of the educational objectives. In addition, they foresee 3 activities: the gaming, the learning, and the instructional activity and their tensions to describe the contexts in which the game is used. Moreover, for each activity, they propose elements taxonomized into actions, tools, and goals per activity, upon which a game may be analyzed or designed. However, the AT-based model of serious games is restricted only at interactions between the triad, that is, subject, object, and tools. The works of Viudes-Carbonell et al [7] and Manker et al [28] use the AT approach to propose analyses of the prototyping procedure during the design of a serious game. In particular, Viudes-Carbonell et al [7] focus on the iterative character of the serious game design and present an early-stage methodology and a prototype for learning a case-concept. Moreover, Manker at al [28] also focus on the game prototypes and among other, on the role of the prototype to the internalization and externalization of the designer's ideas. The combination of the AT framework with the TPACK framework, namely TPACKtivity, has been proposed by Terpstra [29] as a lens to follow preservice teachers' (PTs') TPACK development through their activities, that is, realizing its dynamic character across the time.

Contradictions, Social and Relational Self-views Within AT

The traditional logic considers contradictions in a system as problems; dialectical logic, however, considers that learning and development are driven by them. Hence, within the AT framework (Figure 2), analysis of the trajectory of the object across time can contribute to the realization of the evolution of its current existence and the expected contradictions that may drive its further development [26]. Thus, a deep assumption is that the activity develops across the time mainly through contradictions that arise, that is, upon resolving 1 contradiction, another may arise. Continuous approach of the activity provides continuity in viewing the driving forces (triggers and resolutions of contradictions) that steer this activity further. Focusing on the subject of the activity system, initial ideas about the dichotomy of the context-free information processing of human functioning as opposed to society were further elaborated, extending the subject approach in the AT. In this direction, Stetsenko and Arievitch [30] proposed a framework to combine the social and relational view of the self. In their approach, the subjectivity that is developed outside and in the activity system of reference, may result from the role according to the social position of the human being (ie, serious game designer), which along with social interactions and collective practices coevolve. On the other hand, the self is considered as an active agentive role that an individual does not only acquire historical cultural norms and experiences but also develops them further through change and novelty. In this sense, the ever-expanding social practices entail human subjectivity, and both social and relational views of the self, coexist, or self-coexist among planes of the activity through the internalization and externalization processes.

The aforementioned design frameworks present either the design of a serious game through the lens of the AT framework or the combination of TPACK with the AT framework. However, they hardly focus on the subject of the activity (ie, the designer), and when they do so, a macrolevel is adopted, referring mostly to the procedures per se, for example, the connection of the subject's internal plane with the world's plane.

Study Aims

In this paper, we introduce the 2D-ME framework, an innovative conceptual framework that adopts a microlevel approach toward the serious game designer's inner world while he/she is prototyping. In particular, we dynamically followed the designer's first- and third-person views (2D-ME) during the prototyping activity under the lens of the AT framework and an extended version of TPACK in the game design area, namely Games TPACK (GTPACK). Under this aim, the following research questions were investigated:

1. Is 2D-ME a useful framework for describing the prototyping dynamics during the design of a serious game?
2. How do the internal (first person) and external (third person) views facilitate the optimization of the prototyping output during a serious game design?

Although we refer to the serious game designer, the 2D-ME framework could easily be transferred to the case of serious game developer (sometimes these 2 roles are undertaken by the same person). Moreover, as it offers new insights in the internal processes during prototyping, the 2D-ME framework could also be used as a research framework for analyzing the research aspects of dynamics during creative prototyping.

Despite the conceptual character of the proposed 2D-ME framework, its practical implementation can easily be realized via a series of steps:

1. Conceptualization of the initial idea target of the serious game
2. Identification of the AT constructs
3. Activation of a metacognitive process (eg, reporting in a diary via a self-interview script), which could facilitate the interplay between the roles of first- and third-person view during the prototyping
4. Enabling and capturing of the dynamics between the AT constructs
5. Adaptation of the AT dynamics for the convergence of prototype successive versions to the initial idea target of the serious game

Methods

The Proposed 2D-ME Conceptual Framework

Main Constructs and Dynamics

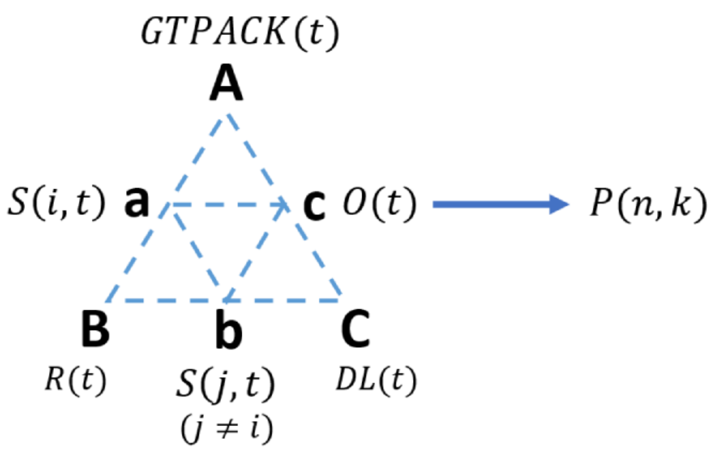
Stemming from the design frameworks presented so far, the proposed 2D-ME conceptual framework is described in this section. Figure 3 depicts the main constructs of the 2D-ME framework. As it is apparent from the comparison between the shapes of Figure 2 (AT) and Figure 3 (2D-ME), a connection of the 2D-ME framework with the TPACK, TPACK-G, and AT is noticeable. This is materialized by the inclusion within the 2D-ME framework of (1) the concept of triangles and interactions as in AT and (2) the combination of TPACK with the TPACK-G as a new entity in the AT triangle, namely GTPACK. However, all constructs of AT (Figure 2) are replaced with new ones (Figure 3), as follows:

- Instruments or mediating artifacts → *GTPACK(t); t=1,2,...*
- Subject → Subject *S(i,t), i* =first-person or third-person view; *t=1,2,...*
- Rules → Rules *R(t); t= 1,2,...*
- Community → Subject *S(j,t), j*=first-person or third-person view; *j≠i*
- Division of Labor → Division of Labor *DL(t)*
- Object → Object *O(t), t*= 1,2,...
- Outcome → prototype *versions P(n,k), n=1,2,...,N; k=1,2,..., M* (last version)

As it is apparent, the 2D-ME framework embeds within its structure a dynamic activity within its constructs that interact and (potentially) are modified across time (*t*). In particular, the prototype designer is considered as the subject *S*(*i*,*t*) and subject *S(j,t), j≠ i*, alternating across time (*t*) between the first-person and the third-person views. The *S*(*i*,*t*), motivated toward the materialization and optimization of the object *O*(*t*), that is, the game prototype *P(n,k), n = 1,2,...,N; k = 1,2,...,M*, at specific time instances *k*, uses their current *GTPAK* (*t*) to produce each prototype version *(P(:,1), P(:,2),...)* toward *P*(:,*M*), which is the final version of the outcome of the activity system. It should be noted that the *n* parameter expresses the different dimensions of prototype (see *The Object Outcome [Prototype]* section). Apparently, the first-person and the third-person view of the subject communicate upon rules *R*(t) and division of labor *DL*(t).

As it can be deduced from the aforementioned 2D-ME structure (Figure 3), the flexibility of the AT framework to project the activity at different levels of analysis is used here to shift from a macro- to a microscale approach. More specifically, at the macroscale approach, the prototyping procedure in the game design provides samples of the evolution of the game design across the time. From a main concept perspective, the 2D-ME framework adopts a microscale approach by following the inner iterative prototyping procedure that follows the game designer across the time. Upon this, an AT triangle is defined, in which the subject, that is, the designer of the serious game, is the focus of the approach. The 2D-ME framework foresees the designer to adopt 2 perspectives while prototyping, that is, the first-person and third-person views. In this way, 2D-ME follows the internalization and externalization actions within the game designer and provides a conceptualization of the prototype design before its externalization to the others (collaborators, users, etc). To further explain the main concept, a description of each entity of 2D-ME is presented in subsequent sections.

Figure 3. Schematic representation of the main constructs that form the 2D-ME framework. DL: division of labor; GTPACK(t): Games Technological-Pedagogical-Content Knowledge (dynamic); O: object; P: prototype; R: rules; S: subject.



The GTPACK

The GTPACK (Figure 1C) is considered in 2D-ME as a tool that extends the TPACK in the area of the necessary knowledge base for the serious game designing. In particular, the Game CK refers to the cognitive content of the game, that is, the subject matter of the discipline of reference. Game Technological Knowledge refers to the knowledge base relevant to the technology related to the games design and its use. Finally, Game PK reflects the knowledge of possible misconceptions, learning theories and how to apply them in games, metacognition, etc. On the basis of this perspective, in a game designing procedure, Game Technological CK might be triggered for the representation of the concept to be learned in the game environment, the GPCK might be triggered for the definition of the game dynamics, and the GTPK might be triggered for the selection of the game mechanics, whereas the GTPACK might be triggered for the whole game design and aesthetics. The GTPACK serves as a tool that mediates the activity of the subject upon the object toward the outcome. It should be noted that the GTPACK is not a stable framework across design time, as the designer might interact with resources (either human and/or material) that may alter its load and dynamics across the time.

The Subject

The 2D-ME framework proposes 2 points of view of the subject, the first-person and the third-person view, considering transitions from the internalization to externalization processes and vice versa, yet both defined within the same person. In particular, the first-person view considers the subjective version of the subject in the activity system that reflects his/her activity following rules of designing a serious game, that is, the social world. The third-person view considers the self-version of the subject that reflects his/her activity according to the object of the activity system that he/she acts upon as the designer. The third-person view is the agentive self who leads the activity as he/she are engaged with the social world. On the basis of this perspective, the first- and third-person views hold a GTPACK and they both coevolve with the activity, yet the third-person view is mainly reflective, to actively introduce possibilities; enhance them by prioritizing other actions; and possibly generate activities that stem from the reality, fantasy, and serendipity.

The Rules

In the AT framework, the rules primarily mediate how the subject acts in relation to the object, including the tools used and the ways they are used [31,32]. This could include specific and/or well-established patterns of behaviors that could be followed because of either cultural norms and/or other reasons (eg, professional and legal mandates). In 2D-ME, the rules refer to the ways of communication between the first- and the third-person views during the subject's communication. Apparently, this interpersonal communication follows some norms (rules) that facilitate the process by which the subject is engaged in unspoken internal dialogue among different and sometimes conflicting attitudes, thoughts, and feelings, all represented by the first- and third-person views. Clearly, these rules are subject dependent and can be imposed, sustained, redefined, modified, or dropped within a dynamic process that could add to the metacognitive skills of the subject.

The Division of Labor

The main responsibilities (what is being done by whom) that are involved toward the object define the division of labor in AT, also taking into consideration the horizontal division, that is, across tasks, and the vertical division, that is, across the power, positions, access to resources, and rewards [31,32]. In 2D-ME, the division of labor refers to the contribution of 2 subject's views, that is, the first- and third-person views, toward the object within the interpersonal communication. The concept of horizontal and vertical division can also be transferred at this inner level by considering the different aspects that could be triggered during the interpersonal communication. For example, the horizontal division could include a systematic definition of a sequence of interpersonal sessions across the prototyping process. Moreover, the vertical division could prioritize the first-person view in the access to and use of technological resources (eg, game developing software), leaving space for the third-person view for reviewing the aesthetics (eg, rewarding and/or corrective feedback on game sensation, fantasy, or challenges).

The Object Outcome (Prototype)

The object in AT can be approached by various views, that is, the object is seen as a thing to be acted upon, an objectified motive, or a desired outcome [33]. The object in 2D-ME is to materialize an idea toward optimizing the outcome, which is a prototype of the game. The prototypes could vary in purpose, as they can refer to a role, an implementation approach, a look, or a sense of feeling. These include interaction with the users (role), the construction of the game (implementation), and users' experience (look and feel) [21]. This multiplicity in roles results in multiple dimensions (denoted with the parameter n, with N being the total number of dimensions). The various versions of the prototype in 2D-ME (ie, $P(n,k)$, $n = 1,2,...,N; k = 1,2,...,M$) are tangible externalizations of the development transformations that the activities undergo between the constructs across the serious game design process.

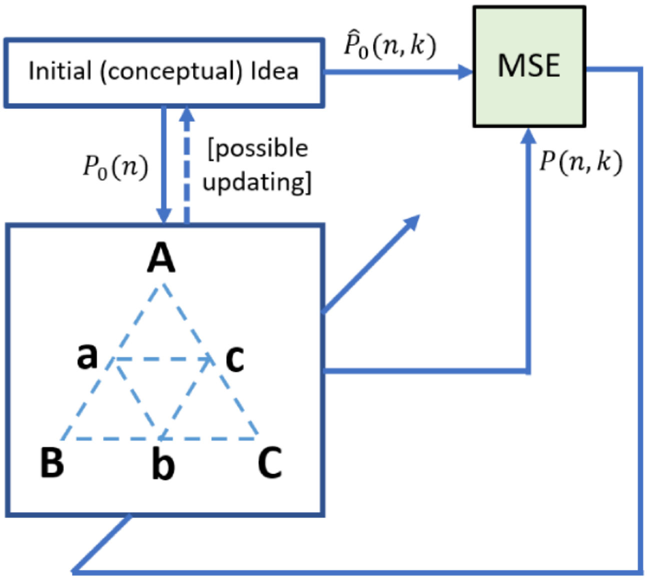
Prototyping Optimization

The proposed 2D-ME conceptual framework considers the prototyping process as an optimization process that converges to the optimal prototype ($P(N,M)$) by minimizing a cost function. This is clearly depicted in Figure 4, where the constructs triangle (Figure 3) is used as an adaptation engine. The cost function per k is the convex function of the mean square error (MSE) between the conceptual (initial and updated) idea of the prototype and its current version ($P(n,k)$) is presented as follows:

The adaptation engine provides the convergence, so the whole activity gradually reaches to the optimized outcome, that is, $P(N,M)$. However, the optimization convergence is not seen within an absolute perspective but rather from the designer's view and experience. This means that the current optimization process could stop at a point that the $P(N,M)$ will not express the full spectrum of the designer's skills and knowledge, but the process will reach at a point where the designer has already concluded for the validity of the final output and the sufficient use of their knowledge and experience, that is, their current level of GTPACK.

Furthermore, as it can be seen from Figure 4, the initial idea ($P_0(n)$; $n = 1,2,...,N$) acts as a trigger to the adaptation engine and, at the beginning of the process, it is considered as static. However, the processes within the adaptation engine (eg, the interpersonal communication), apart from the update of the version of $P(n,k)$, could potentially affect the initial idea, as well. In this vein, its transformation, that is, , is considered at the next stages of the design process. This transformation could alter specific dimensions of the prototype (eg, eliminate some and add new ones) and/or the characteristics of each dimension. Apparently, the frequency of the changes of the is anticipated to be low, considering the level of the designer, that is, how clear and solid is the initial idea in his or her mind. To this end, during the optimization process, some versions of the could be constant across k, for example, . This is, usually, anticipated as the prototype converses to its optimum version, because the designer has already a clear view of its intended and the constructed version.

Figure 4. Schematic representation of the prototyping optimization process in 2D-ME framework. The constructs triangle (Figure 3) is used as the adaptation engine toward the minimization of the difference of the conceptual (initial and updated) idea of the prototype <inline-graphic xlink:href="games_v11i1e41824_fig10.png" mimetype="image" xlink:type="simple"/> and its current version ($P(n,k)$), that is, gradually reaching to the optimization of the prototype (at $k=M$) across its intermediate versions (at $1 \le k \le M$) and across its dimensions. MSE: mean square error.



Capturing of Dynamics

From what it is presented so far, it is clear that 2D-ME entails dynamics among its constructs and in the prototyping optimization process. To capture such dynamics, some sampling tools should be used. Clearly, the interpersonal communication (between the self–first person and the self–third person) that is involved in 2D-ME sets the highest hurdle in the dynamics capturing process. One way to infer for the activation of such communication could be the use of a systematic approach that would include a subject's diary. The latter could be structured on specific contextual factors reflected in a set of statements. A characteristic example of such statements is included in the activity checklist [34,35], which is based on the AT. As the activity checklist provides a "contextual design space" [28], this could be adapted, accordingly, to include statements that could help the designer to describe in his/her diary the dynamics used between the 2D-ME constructs. In this way, the activity checklist itself can serve as a "valuable aide memoir and a tool for reflexivity" [36]. Nevertheless, the activity checklist contains many items (43 for design and 37 for evaluation) [35] that make its full use quite difficult in practice. As a remedy, adaptation of the activity checklist to the form of interview questions, limited in number, was proposed by Duignan et al [37]. Hence, this interview form of activity checklist could trigger reflection and self-talk and could assist in capturing specific dynamics at the various phases of the prototyping process. In this vein, internal questions related with the 2D-ME dynamics that could be self-answered and documented in the diary could be formed, as an internal Activity Interview Script (iAIS), tabulated in Textbox 1.

An additional source of understanding the dynamics is via the exploration of the alterations across the different versions of the prototype. Apparently, this is a lower quality sampling of the dynamics when compared with the aforementioned approach; it provides, however, a way of monitoring the dynamics, especially when exploring the differences across the dimensions (n) of the prototype versions across the design time. A process of deconvolution is then applied to identify the constructs that were more frequently used in a current version of the prototype. Projecting this construct activation across the whole prototyping process, the dynamics per construct can be revealed.

Textbox 1. The internal Activity Interview Script.

Question 1. Goals-related questions

- Question 1.1. What are the different roles that you identify in yourself and are involved in the prototyping?
- Question 1.2. How do you breakdown, in a step-by-step form, your prototyping process?
- Question 1.3. How this fine-graining process can vary?
- Question 1.4. How do you know that you have successfully completed each intermediate goal?
- Question 1.5. How could you evaluate the achievement of your higher-level goals?

Question 2. Contradictions-related questions

- Question 2.1. What contradictions can you identify between your different roles?
- Question 2.2. How do you resolve such contradictions?

Question 3. Tools, transition, internalization, externalization–related questions

- Question 3.1. How does Games Technological-Pedagogical-Content Knowledge support the transition between the first-person and third-person view?
- Question 3.2. How does Games Technological-Pedagogical-Content Knowledge affect the way you think and reason about the prototyping activity?
- Question 3.3. How difficult is to perform the different interpersonal roles?
- Question 3.4. How do you use representations of your work between the different interpersonal roles?
- Question 3.5. How do you internally handle the complexity of the prototyping process?

Question 4. Rules, division of labor–related questions

- Question 4.1. How do explicit or implicit rules, norms, and procedures affect your different interpersonal roles?
- Question 4.2. How do you organize the different interpersonal roles across the prototyping process?

Experimental Case Study Setup

An experimental case study was set up as a running example of the realization of 2D-ME in practice. In particular, the case refers to a PT as the designer of a serious game for kindergarten through grade 12 students. The motivation for the latter was drawn from the physics student's exercise textbook (page 63) for the fifth grade for primary school in Greece. In the latter, an exercise related to the light reflection on mirrors presents a situation in which a series of mirrors are fixed at different positions in a box. At the perimeter of the box there are 4 openings where specific objects (compass, scissor, and pencil) and a boy's eye are positioned. The student is asked to identify and draw the paths of the light reflections on mirrors so as the boy can see the 3 objects (see $P_o(n)$ in Figure 6). This exercise was presented to the PT as a stimulus for the design of a related serious game on light reflection. The PT was at his final semester of his studies at the Department of Primary Education, Democritus University of Thrace, Greece, and he already had attended 1 semester concerning serious game design using Scratch [38]. In particular, concerning his GTPACK, the PT had Game CK about the light mirror refection, which was the concept to be practiced by the serious game. Moreover, he had extended GPK because of his studies and good Game Technological Knowledge based on the familiarity with the game prototyping, design, and implementation in Scratch. Thus, his current GTPACK was considered adequate for this experimental study. It should be noted that the PT was already aware about the GTPACK framework.

The research design foresaw controlled experimental situation that took place at the Democritus University of Thrace computing laboratory within 1 month. The PT willingly participated in this experiment and was informed about the experimental process before embarking on it. More specifically, he was asked to express in a diary the conceptualization of his initial idea $P_0(n)$ of the serious game and then to proceed to his prototyping activity and optimization (Figures 4 and 5). Moreover, he was addressed with the aforementioned iAIS and was advised to document his relevant thoughts in the diary during the prototyping procedure. It was made clear to the PT that the use of the diary should be spontaneous and in no way should hamper his creative impetus. Furthermore, he was informed and consented that an observation documentation would be made by a researcher (first author, SH) to capture the explicit prototyping performance of the PT. At the end of the experiment, the PT consented to openly share the diary; a thematic analysis of the diary was manually conducted and combined with the data from the observations along with the outcome of the whole activity.

Figure 5. Schematic representation of the dynamics across the prototyping optimization for *k=1,2,...,5*. At the top, the Games Technological-Pedagogical-Content Knowledge (GTPACK) alteration across are displayed, where the dynamics affect its internal set (at *k=1,4*). The constructs dynamics are denoted with arrows, accompanied with the related internal Activity Interview Script (iAIS) questions (Textbox 1). The optimization process is depicted for each outputted prototype, whereas the estimated mean square error (MSE) is depicted at the bottom, showcasing its reduction as the game design evolves.

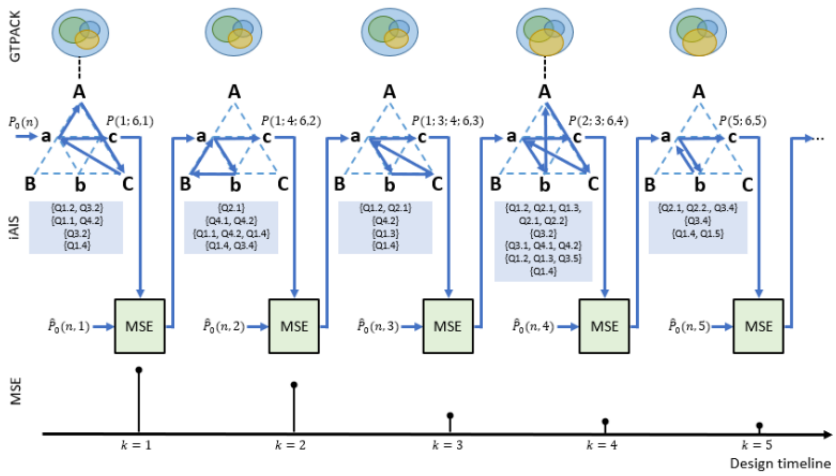
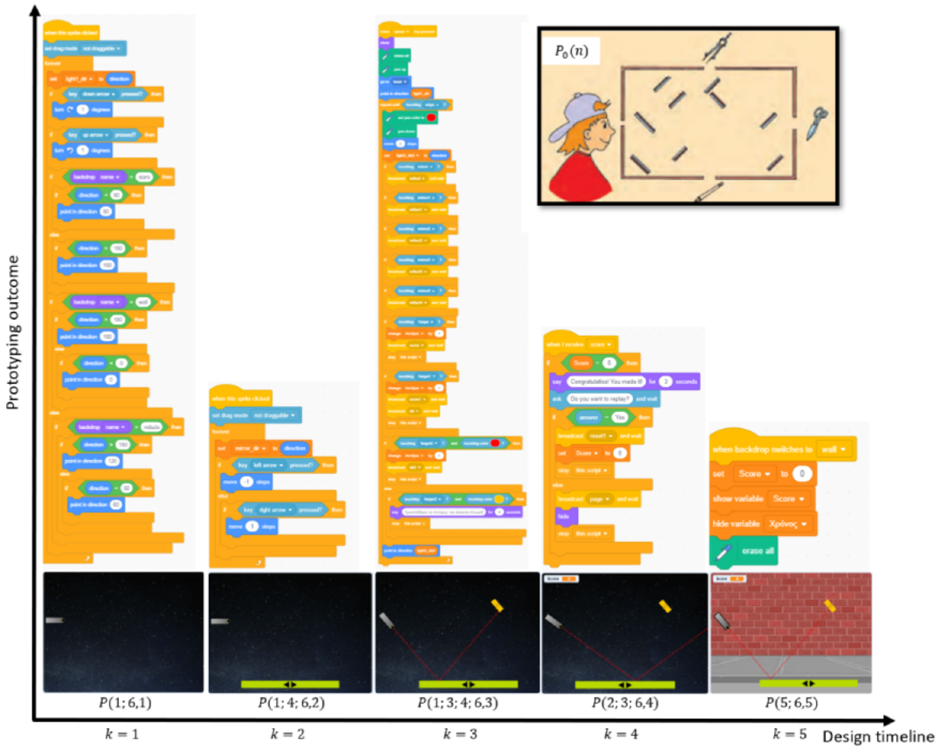


Figure 6. Illustration of the produced game prototype scenes, along with the addition of the Scratch programming code at each *k*, *k=1,2,...,5*. The initial idea, $P_0(n)$, that acts as the stimulus for the creation of the light reflection game is also depicted.



Results

Conceptualization of the Initial Idea

The PT formulated his/her initial idea $P_0(n)$ of the serious game, based upon his/her GTPACK. Textbox 2 shows what he wrote in the diary.

From the excerpts mentioned in Textbox 2, it can be inferred that the PT conceptualized his initial idea $P_0(n)$ of the serious game. He also defined the *N*=6 dimensions, where *n*=1 corresponds to the space (sprites: a source of the light ray, one mirror and one target), *n*=2 denotes the dynamics (hidden objective, player autonomy, limited actions, and feedback), *n*=3 refers to mechanics (move, rotate, aiming and shooting, and allocating), *n*=4 corresponds to the sprite costumes (a torch, a line, a top view of a mirror, and a top view of a brick), *n*=5 refers to the aesthetics, and *n*=6 is for the programing dimension.

Textbox 2. Initial idea formulation-Diary excerpt

I can extend the image in the school textbook where there is a source that produces the light ray and mirrors at stable positions to reflect it so as through successive reflections it can reach a specific point. The students are asked to hypothesize the reflections and then draw a line to depict the path of the light ray as it reflects in this labyrinth of mirrors. Thus, if the student realizes this path once, then there is no interest to resolve it. So, I need to extend this activity towards a more interactive and interesting situation through my serious game. Keeping the analogy with the textbook activity, where it is presupposed that the student already has been taught the light mirror reflection, my educational aim is to involve the students in a serious game, in order to further elaborate the light reflection concept in more dynamic situations than the textbook, eg, the student can try the mirror reflection towards different lines of the ray and not in a specific labyrinth. Thus, my objective is to move the cognitive effort from the applying level and beyond according to the Bloom's taxonomy. Moreover, I can use depictions from the textbook that the students are acquainted of, i.e., a torch as a source for the light ray, a line for the light ray, top view of a mirror and a top view of a brick as target.

I will elaborate on the well-known K-12 students' misconceptions about the light reflection, concerning the equality of the angles of the light ray as it lands on and reflects from the mirror surface. I will assume that the students had already been taught the light mirror reflection; thus, they have conquered the first two levels of the Bloom's taxonomy, so my serious game will not provide relevant information.

My objective is to move the cognitive effort concerning the aforementioned concept at the applying level of in the Bloom's taxonomy.

As a tool I will use Scratch.

I will follow the GDM design framework and I will choose dynamics and mechanics from those presented in the work of [5], combined with additional important elements, namely:

- *Space and Dynamics: The student should manage to apply the idea of the equal angles that are employed in the mirror reflection, but I do not want to show this; they must hypothesize the light line in a space arrangement that with include three sprites, ie, a source of the light ray, one mirror to reflect upon and one target where the reflected ray should hit, respectively. Thus, I choose the hidden objective dynamic. I also want the student to arrange in a way the game space, so I choose the player autonomy dynamic; yet, with limited actions so as not to be confused. Finally, I will provide feedback to his/her efforts, eg, a score counting the successive efforts toward the shooting the target with the reflected light ray.*
- *Mechanics: The torch will be at a stable position, but the student could rotate it. The mirror would be horizontally positioned in the bottom of the scene and could be moved in both directions on the x axis and the target will be at a stable position. Thus, I choose move, rotate, for the objects, aiming and shooting for the light ray, allocating for the hypothesized path of the light ray.*
- *Sprite costumes: I will use depictions from the textbook that the students are acquainted with, ie, a torch as a source for the light ray, a line for the light ray, top view of a mirror and a top view of a brick as target.*
- *Aesthetics: I think that the acquaintance of the students with the sprite costumes, the appealing scene, the explicit roles of the sprites and the challenge to target the brick will motivate the students to have fun and keep playing it toward higher scores. All these will contribute to the esthetics dimensions of my serious game, ie, its sensation (sense of pleasure), fantasy (make-believe), challenge (obstacle course), discovery (uncharted territory), and expression (self-discovery).*
- *Programming: I need to program all the needful with Scratch.*

Dynamics in Adaptation Engine and Prototype Optimization

Overview

During the activity, the PT followed iteration paths through which a series of enhancement of the prototypes that were developed in Scratch resulted in the final output (the game). Here, indicative versions of the prototype are presented to reflect the dynamics and realization of the adopted optimization procedure within the 2D-ME framework. In particular, we followed the $P(n,k)$, $n = 1,2,...,6$, $k = 1,2,...,5$, prototypes in the sequential order that they were developed, cumulatively constructing the serious game aspects. It should be noted that not all dimensions are simultaneously activated across the prototyping, because the PT placed the effort according to his temporal preferences and focus on specific dimensions.

Diary-Based Sampling

As a first means of dynamics acquisition, excerpts from the PT's diary were used for each version of the prototype. Figure 5 facilitates the presentation at multiple levels that are used during the application of the 2D-ME framework, showcasing the activity system that the PT was involved in, its dynamics across the triangles' vertices (Figures 3 and 5: {A,B,C},{a,b,c}), and the optimization procedure that took place. The corresponding activated dimensions (separated by semicolon) are described below; researcher SH's external view based on the iAIS is also noted within brackets and included in Figure 5:

- Initial idea: , Prototype: P (1;6,1)
  - a→A: "From the first person view, I will start by setting the main scene and creating the first sprite; however, my GTPACK is not adequate to achieve this" (Question 1.2). "I need to enhance my GTK on how to program the reflection of the light ray on a moving mirror" (Question 3.2).
  - A→C: "I need to incorporate multiple roles within myself to activate a reflective path for my design decisions" (Question 1.1 and Question 4.2).
  - C→a: "From the first person view, I now feel more confident to start materializing my $P_0(n)$ idea" (Question 3.2).
  - a→c: "From the first person view, I managed to write the Scratch code for the main scene and the first sprite and produce the first version of my object, ie, $P(1;6,1)$" (Question 1.4).

- Initial idea: , Prototype: P (1; 4; 6, 2)
  - a→b: "From the first person view, I will next put the mirror in the scene" (Question 1.2). "From the third person view, I realized that I need to revise my initial idea for the size and the way the mirror should look like, to avoid trivial game options" (Question 2.1).
  - b→B: "The third person view helps me to identify design pitfalls and use one rule, i.e., to be on the shoes of the user, in order to better understand the game" (Question 4.1 and Question 4.2).
  - B→a: "From the first person view, I keep as a rule to really play the prototype, in order to feel the pitfall that I conceived as such from the third person view" (Question 1.1 and Question 4.2). "I also follow the rule to distinguish between what remains the same and what should be changed towards optimization" (Question 1.4).
  - a→c: "From the first person view, I understand that the third person view scaffolds my thoughts for the next step towards the implementation of my initial idea and I managed to write the Scratch code for the mirror, selecting the analogous size and view, producing the second version of my object, i.e., *P(1; 4; 6,2)*" (Question 1.4 and Question 3.4).

- Initial idea: , Prototype: P (1; 3; 4; 6,3)
  - a→b: "From the first person view, I will next put the brick and the light ray in the scene and adopt the sprite costumes of a line and top view of a brick, respectively" (Question 1.2). "From the third person view, I realized that I need to revise my initial idea for the fixed angle of the light source to avoid trivial game options" (Question 2.1).
  - b→C: "I realized that I need to have a more organized sequence of reflections; hence, I have decided to adopt more frequent alternation between the first and third person view during my design process" (Question 4.2).
  - C→a: "From the first person view, I now feel more excited to put more degrees of freedom to the torch" (Question 1.3).
  - a→c: "From the 1st person view, I managed to write the Scratch code for the addition of the brick, the light ray and the rotation of the torch, producing the third version of my object, i.e., *P(1; 3; 4; 6,3)*" (Question 1.4).

- Initial idea: , Prototype: P (2; 3; 6,4)
  - a→b: "From the first person view, I will next include the feedback to the student via a score display; however, I feel that something is missing..." (Question 1.2 and Question 2.1). "From the third person view, I had the idea of inserting randomness in the game. I find myself a bit strange when I have ideas that I do not know how to implement. It is a contradiction to my general attitude to proceed safely. However, when I follow them, I believe that new possibilities are revealed." (Question 1.3, Question 2.1, and Question 2.2).
  - b→A: "I feel that I need to expand my GTPK towards the motivational and engaging role of the surprises in the game through randomness and its relevant programming" (Question 3.2).
  - A→C: "I can use my enhanced GTPACK and identify better the involvement of my different roles in myself for the technology- and aesthetics-related aspects of the prototyping" (Question 3.1, Question 4.1, and Question 4.2).
  - C→a: "From the first person view, I broke down the move mechanic across my prototyping procedure, in order to realize which objects it should refer to, and materialize the decided randomness" (Question 1.2, Question 1.3, and Question 3.5).
  - a→c: "From the first person view, I managed to write the Scratch code for the addition of the score and incorporate movement of the sprites, producing the fourth version of my object, i.e., *P(2; 3; 6,4)*" (Question 1.4).

- Initial idea: , Prototype: P (5; 6,5)
  - a→b: "From the first person view, I feel that, most probably, I have reached the point of satisfaction with the structure of the game so far; but I am not 100% sure..." (Question 2.1). "From the third person view, I visualized a more interesting approach, focusing on the game aesthetics, that incorporated the sense of depth in the main scene" (Question 2.2 and Question 3.4).
  - b→a: "From the 1st person view, I understood that this reflection provides me with many options to increase the sensation and fantasy of the game, using different 3D scene backgrounds" (Question 3.4).
  - a→c: "From the first person view, I managed to write the Scratch code for the addition of a 3D background in the scene, producing the fifth version of my object, i.e., *P(5; 6,5)*" (Question 1.4). "I believe that, at this point, I have achieved my first higher goal to construct a good prototype of these functionalities and aesthetics of the game, converging to the initial idea conceptualized in the form of $P_0(n)$" (Question 1.4 and Question 1.5).

It should be noted that in the excerpt of the optimization process presented earlier, the initial idea was kept constant across k, as the level of the game designing was of low complexity, trying to conceive and materialize the basic environment and functionalities of the game. As the game advanced, updates of the $P_0(n)$ took place, for example, through the insertion of >1 mirrors spreading randomly in the scene space and introduction of various game levels with different degrees of difficulty (eg, random distribution of nonreflecting obstacles and time limitation per level). Moreover, the GTPACK of the PT was enriched during the prototyping process, showcasing the internal dynamics that are developed across the design time at the GTPACK level, depicted as expanded overlapping spaces in Figure 5 (top). The estimation of the MSE (Figure 5, bottom) was based on the comparison (equation 1) between the current and the $P(n,k)$ across the n dimensions. As the dimension of programing (n=6) is not included in the , this was excluded from the MSE calculation, involving the dimensions of n=1,2,...,5 in equation 1. As at each k, not all dimensions are involved in $P(n,k)$, the highest drop in the MSE is expected when many dimensions of $P(n,k)$ are activated, as it can be seen at k=3 (P(1; 3; 4; 6,3)).

Prototype-Based Sampling

At a second sampling of the dynamics, with lower resolution, the materialization of the prototypes per optimization version were also analyzed. Figure 6 depicts the sequence of the produced prototypes for k=1,2,...,5, reflecting the specific dimensions that were examined at each k, visualized at the scene level and the corresponding Scratch code; the stimulus from the exercise textbook used as $P_0(n)$ is also presented. From Figure 6, at k=1, there is a very simple output at the scene level (one sprite); however, there is more extended structure at the programing level. This reflects the activation of the GTPACK as a means for extending the gaming programing background. At k=2, the work at the programing level is simplified and the scene is extended with the inclusion of the second sprite. The complexity of the programing is increased at k=3, because there is the addition of the third sprite and the light ray. This shows higher convergence to the initial idea, revealing that the PT follows an optimization process. In addition, at k=4, the experimentation with the light ray and the rotation of the sources (already seen at k=3), along with the addition of the user feedback (score) reveal an activation of the GTPACK (to enhance the game programing skills) and of the third-person view (also seen in Figure 5). In this way, the PT sees his prototype from the eyes of the user and tries to accommodate the issues of trivial solutions and lack of feedback, thus increasing the game options and esthetics. The interpersonal interaction about esthetics continues at k=5, in which the scene becomes 3D, providing more immersive impression to the user. Here, it seems that the dynamics between first- and third-person views are the ones that dominate (also seen in Figure 5), as the enhancement of the external (user's) view of the game is the focus at this stage of prototyping.

Discussion

Principal Findings

The proposed 2D-ME conceptual framework surfaces the roles of the first- and third-person views that challenge the designer to realize aspects of his/her self in this iterative procedure. Being more reflective, the designer may realize that the self may be both a subject influenced by the society norms, for example, in the aforementioned case, the programing rules, but also a driving self that may influence the society through the output of their game design. These roles were reflected in the case study presented, which served as a showcase of the 2D-ME framework to reveal the dynamics within the iterative process of the prototype optimization, seen both from the designer's space (diary) and the game design outcome (prototype). This may contribute to more knowledgeable game designers, as it provokes reflection in a fine-grained way of thinking at different levels. It should be noted that the case study presented did not entail the hierarchy of the AT framework and was kept mostly at the activity system level, focusing on the optimization procedure.

In the case study presented, the user is a PT, who had already acquired a basic knowledge of the GTPACK framework because he works in the education sector. Nevertheless, there is no requirement for someone to have any specific level of prior knowledge to use the 2D-ME framework; simply, someone who undertakes a prototype design process (in the specific case of game design) will most probably have a basic level of the TPACK in the field. Even if he/she is not an expert, during the prototyping process, he/she will interact with the knowledge base and would acquire extra knowledge in the area. This is schematically shown in both Figure 1C and Figure 5 (GTPACK), where the context of the GTPACK is not split in equal sections but there are different levels of knowledge within it (Figure 3, c), which are dynamically expanded during the interaction with the knowledge base (Figure 5; increased GTPACK for k=3→4). In addition, the knowledge of the iAIS is not provided as a constrain but as a guide to help the user formulate the internal reflection on the activities during the prototyping; someone could follow their own pathway of metacognitive process stimulation. However, we believe that the proposed iAIS targets all the reflective aspects that could be helpful to serve as a tool of memoir and reflexivity during prototyping.

Apart from focusing on the monitoring of the internal dynamics during the prototype optimization process, 2D-ME can also be used as a means of structure for the designer's skills development in the reflection and creativity. Diary writing itself requires the designer to rethink events and processes, along with thoughts, contradictions, decisions, outcomes, which have all taken place at the various stages of the prototyping process, and "relive" it, as many times they want, even after its end. This strategy promotes their critical thinking and reasoning skills, that is, their higher-order thinking skills [39]. In addition, the stimulus from the iAIS (Textbox 1) sets an organized pathway of reflection steps that span across the triangle constructs involved in the 2D-ME framework. In this way, the activity dynamics are scaffolded by the iAIS stimulus and gradually become more imprinted in the game designer's reflection strategy and higher-order thinking. When the narrative information of the diary is transformed into dynamics within the 2D-ME framework (Figure 5), a more externalized representation is achieved that could be visible, apart from the designer themselves, to others, as well. This can provide information for some characteristics of the designer's personal way of thinking and creating, increasing their explainability, especially when they are not tangible at the prototype level and/or cannot be easily inferred from the final output (eg, the $P(n,M)$). In this way, the 2D-ME framework could provide more objectified basis for the analysis and comprehension of the expert designer's process, from idea conception to the final output, which can be used for teaching the novice designers, help them to better understand their internal processes, and improve their designing skills and outcomes.

In the case study that was presented here, the prototyping process was optimized by taking into consideration the relation between 2 adjacent versions of the prototype, that is, for the creation of $P(n,k)$, $P(n,k–1)$, $(k>1)$ was considered as input to the AT triangle (Figure 5). Nevertheless, additional views could also be adopted, and a higher (>1) order of memory could be used, for example, for the creation of $P(n,k)$, $\{P(n,k – 3), P(n,k – 2), P(n,k – 1)\}, (k >3)$ can be used as a sequence of inputs. Moreover, this sequence could also vary across the whole process, both in the number of the previous versions used and in their continuity, for example, $\{P(n,k – 3), P(n,k –1)\}, (k >3)$. This depends on the scale of the focus that is used at each k, providing the opportunity to the designer to shift from the micro- to the macroscale of the prototyping process [40,41]. This influence of previous prototype versions within the creation of the new one materializes the convolution of the dynamics adopted in the past with the dynamics shaped in the current version, in an effort to create a new, more enhanced prototype. This blending of dynamics in a macrostructural approach showcases the causalities that are created across the prototyping process that, in a way, contribute to the personal characteristics of the designer's style. For example, sequential use of the prototyping versions (eg, as in Figures 5 and 6) could reveal steadier design style, in which each step is cumulatively constructed from the previous one. A more discontinued use of past prototyping versions could express more diffusion of the design ideas at various time instances of $k – l$ $(l = 1,2,…| k – l >0)$, revealing a distributed way of materializing the design ideas, in which different parts of them gradually are synthesized and construct a more integrated prototype version at the kth time instance.

The adopted bilateral sampling of the dynamics in the 2D-ME framework, that is, via the analysis of the diary notes and the prototype versions, provides both the internal and external views of the prototyping dynamics and outcome, respectively. Additional means of dynamics sampling could also be foreseen by incorporating other sources of relevant information, such as biosignals. In fact, the biological-signal data from multiple biological-signal sources, for example, electroencephalography, electrocardiography, electromyography, electrooculography, and electrodermal activity, can be combined with artificial intelligence or machine learning or deep learning to provide additional queues of the developer's state (eg, stress, relaxation, or hyper or hypoactivity) during the design of the game and the creation of a series of prototypes [42-44]. In this way, the projection of the creative thinking onto the physiological signals and testing of the same protocol to game users could reveal the transferability of the designer's intentions to the gamers via the similarity of the related acquired signals. This could be used as a measure to optimize the game design and create a dynamic cocreation process [45-48], which could adapt to the specific characteristics of the designer and the target group of the serious game users [49-53].

Limitations and Further Research

The proposed 2D-ME conceptual framework provides new insights into the internal dynamics of the game designer's prototyping process. Clearly, the presentation here of 1 case study with 5 prototype versions cannot express the whole range and magnitude of such dynamics. However, it serves as a good example of the potentialities the 2D-ME framework could provide, both to the game designers and educators and researchers. In addition, the adoption of MSE (equation 1), as a cost function for the optimization process (Figure 4), could also be further explored, as alternative and a combination of metrics could be involved. The selection of such cost functions should consider the acceptable variation that relates with the context of a particular applied game design problem and should clearly express, as much as possible, the gains from its minimization under the game design problem's particular circumstances [54]. Extensive experimental application of the 2D-ME framework (eg, in educational settings of game design) could further validate its efficiency to monitor the dynamics evolved within the game design prototyping process, not only under the controlled settings, as presented here, but also at more naturalistic environments, for example, at designers' workplaces or laboratories.

The 2D-ME conceptual framework attempts to explain the self–first and self–third person views of prototyping dynamics in serious games design. Nevertheless, as it combines the TPACK and AT frameworks in a dynamic way, it shows many potentialities to be extended further to various design problems, additionally to the area of game design. In this regard, in our future plans, we foresee 2D-ME to be applied in the areas of arts, where the game design is replaced by art design. In many areas of art, such as painting, sculpture, literature, architecture, cinema, music, and theater, the design dynamics is the driving force for the creativity and the development of the artwork through prototyping. Clearly, the 2D-ME framework can easily embrace and explain such dynamics. Furthermore, sharing of the prototype version at specific k time instances to an external group (eg, experts, colleagues, mentors, and educators) could provide an additional level of external input to the internal world of the designer, extending the role of the community. In this vein, the current 2D-ME framework can be extended to the 2D-ME-ALL one, embracing external inputs and dynamics during the prototyping process—thus, enhancing the social and collaborative aspects in the use of the AT objects and extending to runaway ones with even broad societal ramifications [55]. Clearly, during the development of the prototype versions, externalization and projection from the "inner" to the "outer" world is possible and, under a cocreation perspective, wishful, to arrive at an optimized version. Moreover, this externalization does not have to be for the whole prototype but could be associated with specific parts (processes) of the prototyping, where external feedback is needed, upon the personal decision of the designer. In addition, it could happen during 1 or many iterations, providing a dynamic interplay between the inner and outer worlds. Approaching this as interconnected AT systems (constellations) [56] mainly shifts the locus of attention to the multitude of such internal activities, as externalized via their relationships, rather than the interplay between the self–first and self–third person views within the game designer's mind. In this sense, the selection of the scale is important, and the inclusion of interconnected AT systems could explain a concept of collective contribution (ie, transition from the person to the group and, further, to society). Apparently, this can happen in the case of complementary contributions by different experts participating in the game prototyping, for example, directors, graphic designers, composers, light experts, and character creators. It also can be expanded to an interdisciplinary context in which the experts come from distant backgrounds (eg, health and technology). However, even in such cases, the 2D-ME framework could be adopted by each expert to describe the steps that they undertook to arrive at their final contribution to the game design. Finally, there are some creative processes that are performed alone by nature, for example, music composition and painting. In such cases, it is important to focus on the internal dynamics that take place in the artist, as, in this way, we can identify personal traits and idioms that finally characterize the personal artistic style. In this kind of cases, the constellation of AT systems could, probably, be adopted if we want to model the audience interaction with the artistic outcome, especially in cases where there is an interactive part in it, for example, music installations or interactive spaces (eg, Xenakis polytopes). These views and extensions of 2D-ME, along with the addition of biosignals' input by incorporating artificial intelligence, machine learning, or deep learning tools, set the forthcoming research goals; work has already embarked toward such endeavor.

Conclusions

A new conceptual framework, namely 2D-ME, that provides insights upon the dynamics that evolve during a serious game designer's prototyping process has been presented here. Combining information from both the games space, TPACK, and AT, the 2D-ME framework provides explainable representation of, somehow, intangible processes; most of them not easily identifiable in the externalization of the prototyping process, that is, the prototype itself. Using dynamic constructs, the 2D-ME framework incorporates the alternations from first-person to third-person views and vice versa, stimulated by an organized way of internal self-interview (iAIS), providing dynamics monitoring that drive the prototype optimization process. A paradigm of the practical implementation of the 2D-ME framework in the case of a game design on light reflection exemplifies its potentialities and efficiency to capture the fine-grained dynamics involved during the production of the prototype version across the design timeline. Owing to its generic structure, the 2D-ME framework has high transferability to other areas of designing, for example, arts, and could be used both as a means of exploration of the expert designer's creative process and training of the novice ones, providing explainable representations of the underlined higher-order thinking.

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Conflicts of Interest

None declared.

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Abbreviations

AT: activity theory
CK: content knowledge
GK: game knowledge
GPCK: game pedagogical content knowledge
GPK: game pedagogical knowledge
GTPACK: Games Technological-Pedagogical-Content Knowledge
iAIS: internal Activity Interview Script
MDA: Mechanics, Dynamics, and Aesthetics
MSE: mean square error
PCK: pedagogical content knowledge
PK: pedagogical knowledge
PT: preservice teacher
TCK: technological content knowledge
TK: technological knowledge
TPACK: Technological-Pedagogical-Content Knowledge
TPACK-G: Technological-Pedagogical-Content Knowledge–Game
TPK: technological pedagogical knowledge

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The Relationship Between Cognitive Resource Consumption During Gameplay and Postgame Aggressive Behaviors: Between-Subjects Experiment

Huina Teng[1], BS; Lixin Zhu[1], BS; Xuanyu Zhang[2], BS; Boyu Qiu[1], PhD

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Corresponding Author:
Boyu Qiu, PhD

Abstract

Background: The question of how video games can shape aggressive behaviors has been a focus for many researchers. Previous research has focused on how violent video game content leads to postgame aggressive behaviors. However, video games not only convey violence or prosocial content to players but also require cognitive effort from individuals. Since human cognitive resources are limited, consuming more cognitive resources in a game leads to less cognitive resources to suppress aggressive impulses. Therefore, the depletion of cognitive resources from playing video games may also lead to changes in postgame aggressive behaviors.

Objective: This study aimed to examine the relationship between cognitive resources consumed in video games and postgame aggressive behaviors.

Methods: A total of 60 participants (age: mean 20.22; range 18-24 y) were randomly assigned to either the high-load group or the low-load group. Participants from both groups played a video game centered around college life. In the low-load group, participants followed the gameplay instructions to complete it. In the high-load group, participants were given an extra digital memory task to complete while playing the game. Participants in both groups played the video game for about 25 minutes. A maze selection task was then conducted to measure the participants' helping and hurting behaviors.

Results: The independent samples 2-tailed *t* tests showed that the high-load group had significantly higher hurting scores (mean 3.13, SD 2.47) than the low-load group (mean 1.90, SD 2.12; t_{58}=−2.07, *P*=.04; Cohen *d*=−0.535), whereas helping behaviors were not significantly affected (t_{58}=1.52, *P*=.13; Cohen *d*=0.393).

Conclusions: As more cognitive resources are consumed in a video game, more hurting behaviors are exhibited after the game. This finding proposes an alternative route by which video games impact aggressive behaviors, adding to previous theories and raising concerns about the popularity of cognitive training games.

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KEYWORDS

video games; hurting; helping; cognitive resources; aggressive behaviors

Introduction

Video games have become popular as a form of entertainment [1]. The General Aggression Model [2] and the General Learning Model [3] suggest that violent content in video games influences aggressive cognition [4,5] and negative emotions [6,7], leading to aggressive behaviors [8,9]. However, individuals passively receive content delivered by the game and actively invest cognitive resources while playing video games, potentially affecting social behaviors in the short term.

Two possible explanations were initially used to study honest behaviors [10,11], which help us understand the relationship between cognitive resource consumption and social behavior. The "Will" hypothesis [12] suggests that individuals have a natural tendency to engage in negative behaviors (eg, cheating) and therefore need to expend cognitive resources to overcome the impulse to engage in negative behaviors. The "Grace" hypothesis [13] assumes that individuals are naturally inclined to engage in positive behaviors (eg, honesty) and that individuals need to expend cognitive resources to overcome the original impulse so that they can behave negatively to gain benefits (eg, cheating).

Both aggressive (eg, hurting) and prosocial (eg, helping) behaviors are regulated by human cognitive processes [2,3] and are closely linked to cognitive load. According to social learning theory [14], both aggressive and prosocial behaviors are acquired by observing and imitating others. This position suggests that cognitive elements such as attention [15], executive function

[16], and working memory [17] impact aggressive and prosocial behaviors and are hindered by cognitive load. Therefore, these 2 hypotheses (the "Will" and "Grace" hypotheses) concerning honest behavior based on decreased cognitive resources may be equally beneficial in elucidating both hurting and helping behaviors.

Based on the aforementioned reasoning, the "Will" hypothesis suggests that when individuals use excessive cognitive resources while gaming, they may lack sufficient cognitive resources to control the impulse and therefore may display more hurting behaviors. Conversely, the "Grace" hypothesis posits that if cognitive effort is extended in the video game, the individual may lack sufficient cognitive resources to restrain the initial impulse and subsequently display more helping and less hurting behaviors. At present, it remains unclear as to which outcome transpires from expending cognitive resources in gaming.

This study examines the relationship between cognitive resource consumption in video games and postgame aggressive behaviors. If the "Will" hypothesis is met, consuming more cognitive resources during video gaming will lead individuals to show more aggressive behaviors after the game. If the "Grace" hypothesis is met, consuming more cognitive resources during gaming will lead individuals to show less postgame aggressive behaviors.

Methods

Participants

Participants were recruited through a college social media platform (ie, WeChat groups for college students). The participants were screened based on the following criteria: (1) no history of mental disorders, (2) normal or corrected-to-normal vision, and (3) no prior experience with the task used in this study. A total of 63 participants were recruited, and 3 of them did not show up, resulting in a final sample of 60 college students.

An a priori power analysis using G*Power (version 3.1.9.7; Heinrich-Heine-Universität Düsseldorf) was conducted to estimate the sample size. Based on data from Yin et al [18] (n=40), which compared 2 independent groups on the same task, the minimum effect size in that study was 0.77. With a significance level of α=.05, Cohen *d*=0.77, and power=.80, the minimum sample size needed with this effect size was 56 for the independent samples 2-tailed *t* tests used in this study. Therefore, the obtained sample size of 60 was more than adequate to test the hypothesis.

The 60 participants were randomly assigned to the high-load group (n=30, 50%; 11/30, 37% female; age: mean 20.47, range 18-24 y) and the low-load group (n=30, 50%; 12/30, 40% female; age: mean 19.97, range 18-24 y). Informed consent was obtained from each participant before the experiment.

Measures

Video Games

The study used a video game adapted from the one used by Yin et al [18], where participants played the role of a first-year college student facing diverse situations based on college life. The content that the participants encountered in the scenarios was neutral (ie, not including hurting or helping behavior, to avoid in-game hurting or helping content from affecting postgame maze choices) and related to daily life at college, such as choosing which clubs to join, what they chose to wear out, and what sports they were involved in after class. In the low-load group, participants followed the game instructions to complete it. In the high-load group, participants had an additional digital memory task while playing the game. They had to memorize a 4-digit "password" and enter it after completing 5 situations. Subsequently, they received a new password and had to enter it after 5 further situations. In 60 situations, they were given the "password" 12 times, and throughout the game, they had to keep a 4-digit number in their memory. In the high-load group, participants could not take notes while trying to remember the password. Thus, they had to memorize it internally and update the numbers after every 5 situations. They were told to prioritize remembering the password correctly and follow the game instructions to finish it, thus requiring more cognitive effort and resources than the low-load group. On average, the participants completed the game in approximately 25 minutes.

Maze Selection Task

The maze selection task used in the study was modified from the Tangram Task, which is commonly used in psychological research on video games [8,19,20]. Notably, the results of the Tangram Task have been found to correlate significantly with aggression and prosocial behaviors measured through scales and laboratory tasks [21]. In some countries, students may be unfamiliar with tangrams, so Yin et al [18] suggested using mazes instead to measure helping and hurting behaviors.

In the maze selection task, participants were required to choose 11 mazes for the next participant (who is fictional) from 30 given mazes. The fictional participant would walk the maze using paper and pencil, and if they could walk at least 10 mazes in 10 minutes, the fictional participant would be paid an additional ¥30 (US $4.12). There were 10 mazes based on 5 × 5 cells (small and easy), 10 based on 10 × 10 cells (medium), and 10 based on 20 × 20 cells (large and challenging). Participants could help the following participant by selecting easier mazes or hurt them by selecting difficult mazes. The helping score was the total number of easy mazes chosen, and the hurting score was the total number of difficult mazes chosen. Notably, higher scores indicated more helping or hurting behaviors.

Analyses

Only 1 of the 30 participants in the high-load group misremembered the "password" in 1 response, whereas a total of 360 responses (30 participants in the high-load group × 12 responses per participant) were recorded during the experiment. The incorrect response accounted for 0.3% (1/360) of the total responses in the high-load group. Therefore, it was concluded that having only 1 incorrect response was acceptable and that the participants in the high-load group retained their memory for the 4-digit number throughout the experiment. The analysis of the data then included all 30 participants in the high-load group, including the 1 who incorrectly remembered once.

After completing the data collection, we conducted independent samples 2-tailed *t* tests using the helping and hurting scores from the maze selection task as dependent variables and groups (high-load and low-load groups) as independent variables. In the pretests for equality of variances, the samples passed the Levene test for homogeneity of variances (helping scores: $F_{1,58}$=0.03, *P*=.87; hurting scores: $F_{1,58}$=0.52, *P*=.48). Therefore, the Student *t* test was used to calculate the statistical probability (*P* value), and Cohen *d* was used to indicate the effect size.

Ethical Considerations

The study was approved by the Research Ethics Committee of South China Normal University (#SCNU-2021-275). Written informed consent was obtained from each participant. Our data underwent deidentification processes. Participants received ¥30 (US $4.12) as compensation.

Results

Descriptive statistics for the helping and hurting scores from the maze selection task are shown in Table 1. The independent samples 2-tailed *t* tests showed a significant difference between the 2 groups in hurting scores (t_{58}=−2.07, *P*=.04; Cohen *d*=−0.535) but not helping scores (t_{58}=1.52, *P*=.13; Cohen *d*=0.393). The high-load group had significantly higher hurting scores (mean 3.13, SD 2.47) than the low-load group (mean 1.90, SD 2.12; *P*=.04).

Table . Descriptive statistics for the helping and hurting scores from the maze selection task. The helping score was the total number of easy mazes (based on a 5 × 5 cell) participants chose in the maze selection task, and the hurting score was the total number of difficult mazes (based on a 20 × 20 cell) they chose, with higher scores indicating more helping or hurting behaviors.

Score	High-load group, mean (SD)	Low-load group, mean (SD)
Helping	2.07 (2.41)	2.97 (2.17)
Hurting	3.13 (2.47)	1.90 (2.12)

Discussion

Principal Findings

The main finding of this study is that investing more cognitive resources in video gaming led to significantly more postgame hurting behaviors (*P*=.04), whereas helping behaviors were not significantly affected (*P*=.13). Consistent with the "Will" hypothesis [12], individuals in this study may be more inclined to exhibit aggressive behaviors, and inhibiting aggressive behaviors requires a drain on cognitive resources. When cognitive resources are consumed during play, individuals may not have sufficient cognitive resources to inhibit aggressive behaviors and therefore tend to exhibit more aggressive behaviors after gaming.

Comparison to Prior Work

Over the past 2 decades, research on the influence of video games on aggressive behavior has relied heavily on the General Aggression Model [2], suggesting that the violent content in video games is a key factor in causing individuals to exhibit more aggressive behavior. The results of this study complement this model by suggesting another possible cause of more aggressive behavior, namely, the consumption of excessive cognitive resources in games. In actual play, these 2 processes may alter aggressive behaviors simultaneously. The violent content of the game shapes individuals' aggressive scripts and schemas [2]. In contrast, a large amount of cognitive input in the game leaves individuals without sufficient cognitive resources to suppress their impulses to hurt.

This result also raises concerns about cognitive training in video games. In recent years, the use of video games for cognitive training has become increasingly popular [22]. Video games are easy to access and fun, and participants are more willing to participate regularly in video game–based cognitive training [23,24]. Numerous studies have shown that video game training improves individuals' visual attention [25,26] and executive functions [27-29]. However, the results of this study suggest that excessive cognitive resources spent on games may harm individuals' social behaviors. Therefore, further research is urgently needed to assess how cognitive training games affect individuals' aggressive behaviors.

It is important to state that this study provides evidence solely for the potential effect of cognitive load in gameplay on postgame hurting behaviors, and one must not infer directly from this outcome that cognitively training games inevitably result in long-lasting aggression. In most laboratory studies of video games [4,15,18-20], measures of social behavior are typically completed within 20-30 minutes after the game. Changes in social behavior observed under such conditions are generally transient and can be recovered after a period of time. This is also true in high-load games, where participants may feel cognitively exhausted for a short period of time after the game and are more likely to display aggression, but not irreversibly.

However, models of aggression and learning have been proposed specifically for this scenario. Anderson et al [2] note that while the temporary nature of the postgame effect is acknowledged, prolonged and repeated exposure to this state through extended gameplay can permanently alter an individual's levels of aggression or prosocial tendencies. Therefore, although the laboratory findings indicate a short-term aftereffect of playing video games, it still warrants careful consideration and attention.

In addition to the duration of aftereffects and long-term effects, several factors were not tested in a single experiment. For example, it is unclear whether all highly cognitively demanding games induce aggression or only certain types of games. It is also uncertain whether the effect of cognitive load differs from the effect of violent game content and whether these effects interact. Further research is needed to investigate these aspects.

Limitations

This study has certain shortcomings. First, it has been suggested that some cognitive factors such as attentional bias to different information also influence social behaviors [15], and it is still unknown whether these factors interact with the cognitive resources consumed in video games. The interaction of these factors with the consumption of cognitive resources during gameplay could be further tested, which would help to deepen our understanding of the mechanisms by which cognitive resources influence postgame social behaviors.

Second, only 1 task, the maze selection task, was used to measure helping and hurting behaviors, and multiple tasks measuring aggression and prosocial behaviors are needed to test this effect. The maze selection task is founded on a localized adjustment of the Tangram Task, which has undergone extensive use in numerous studies. Furthermore, the modified task has obtained validation through research that establishes its efficacy in measuring helping and hurting behaviors. Therefore, we believed that the results in this study are reliable. However, if multiple tasks measuring aggression and prosocial behaviors were used, it is possible to compare whether different types of social behaviors can all be affected by the in-game consumption of cognitive resources.

Third, the manipulation of cognitive resources in the game was achieved by increasing the working memory load. Therefore, it remains to be tested whether the same results can be obtained by depleting cognitive resources in other ways (eg, inhibition or switching ability). Investigating different manipulation of cognitive resources in future studies will aid in determining whether different types of cognitive depletion affect postgame social behaviors equally.

Conclusion

This study highlights the negative impact of excessive cognitive resources spent on video games, potentially related to increased postgame aggressive behavior due to insufficient cognitive resources for inhibiting aggressive impulses. This finding proposes an alternative route by which video games impact aggressive behaviors, adding to previous theories and raising concerns about the popularity of cognitive training games.

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Data Availability

The data sets used in this study are available from the corresponding author on reasonable request.

Authors' Contributions

BQ, HT, LZ, and XZ contributed to conceptualization. BQ contributed to methodology, supervision, and funding acquisition. BQ and HT contributed to formal analysis and data curation. HT contributed to writing—original draft preparation. BQ, HT, LZ, and XZ contributed to writing—review and editing.

Conflicts of Interest

None declared.

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Original Paper

Role of Gaming Devices Associated With Internet Gaming Disorder in China: Cross-sectional Study

Yifan Li[1*], MSc; Ying Tang[1*], MSc; Shucai Huang[2], PhD; Linxiang Tan[3], PhD; Qiuping Huang[4], PhD; Xinxin Chen[1], PhD; Shuhong Lin[1], PhD; Jingyue Hao[1], PhD; Zhenjiang Liao[1], PhD; Hongxian Shen[1], PhD

[1]Department of Psychiatry, National Clinical Research Center for Mental Disorders, The Second Xiangya Hospital of Central South University, Changsha, China

[2]Department of Psychiatry, The Fourth People's Hospital of Wuhu, Wuhu, China

[3]Education Center for Mental Health, Central South University, Changsha, China

[4]Department of Applied Psychology, School of Humanities and Management, Hunan University of Chinese Medicine, Changsha, China

[*]these authors contributed equally

Corresponding Author:
Hongxian Shen, PhD
Department of Psychiatry
National Clinical Research Center for Mental Disorders
The Second Xiangya Hospital of Central South University
139 Renmin Road
Changsha, 410011
China
Phone: 86 13875970393
Email: shenhx2018@csu.edu.cn

Abstract

Background: Chinese gamers use computer and mobile phone games widely. Consequently, concerns regarding the development of internet gaming disorder (IGD) in adolescents have been raised. However, only a few studies have focused on the influence of gaming devices on IGD.

Objective: This study aims to compare sociodemographic information, gaming use characteristics, personality traits, and gaming motivations between computer game users (CGUs) and mobile phone game users (MGUs), as well as identifying IGD predictors.

Methods: This was a cross-sectional study. A total of 3593 internet game players took part in an online survey, which included sociodemographic information, gaming patterns, gaming motivations, the Chinese version of the Video Game Dependency Scale, and the Chinese Big Five Personality Inventory brief version. The population was divided into 2 groups for comparison by mobile phone or computer use, and the IGD population was also compared within the 2 groups.

Results: There were significant differences between the 2 gaming device groups in the time (t_{2994}=7.75, *P*<.001) and money (t_{2994}=5.11, *P*<.001) spent on gaming and in internet game addiction scores (t_{2994}=3.68, *P*<.001). Individuals using different gaming devices had different game motivations and personality traits and preferred different genres of games. Results showed that IGD predictors were different for the 2 groups, for example, strategy (odds ratio [OR] 4.452, 95% CI 1.938-10.227; *P*<.001) and action shooter (OR 3.725, 95% CI 1.465-9.474; *P*=.01) games increased the risk for MGUs.

Conclusions: Gaming devices should be considered during early identification, such as long daily gaming time, much money spent on gaming, neuroticism, and conscientiousness. In addition, more research should be conducted on new gaming devices and IGD treatment.

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KEYWORDS

internet gaming disorder; gaming device; gaming motivation; personality traits; gaming use characteristics

Introduction

Over the past few decades, internet games have been firmly integrated into people's daily routines, especially among children and adolescents. According to the China Internet Network Information Center (CNNIC) latest report, by the end of December 2021, the number of internet users in China had reached 1.032 billion, and over 517.93 million netizens play games, accounting for 52.4% of the total number of internet users [1]. It is considered that video game activities improve basic attentional functions [2]. However, its inappropriate use has been considered a serious public health issue. Playing games for long periods can increase the incidence of dry-eye disease, obesity, and mental health problems [3,4]. Previous studies have found a positive association between digital device use and poor sleep quality and psychological distress, such as depression or internet gaming disorder (IGD) [5-8].

The American Psychiatric Association [9] first included IGD in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) in 2013 as a disease that needs further exploration, and in 2019, the World Health Organization (WHO) officially included it as a psychiatric disorder in the *International Classification of Diseases 11th Revision* (ICD-11) [10]. The reported prevalence of IGD varies due to differences in the measurement and sampling methods. Thus, the worldwide prevalence of gaming disorder is 3.05% [11]. In China, the prevalence of problematic gaming among adolescents is 5%-17% [6]. Furthermore, many studies have investigated the risk factors for IGD, but few studies have considered the influence of gaming devices; today, a large proportion of gamers use mobile phones, which allows them to play games limitlessly, which may increase the IGD risk.

Steam, the largest digital platform for gaming on a personal computer (PC), announced that 20,313,451 users registered on it during the coronavirus pandemic [12]. The same year, according to Google, mobile phone gamers across 10 countries increased their duration and frequency of gaming by two-thirds [13]. According to a 2020 survey, 62.5% of underage internet users in China regularly play online games. Among them, 28.9% play computer games and 56.4% play mobile phone games [14]. Owing to advances in technology, people's entertainment has been gradually replaced by computers and video games, and many scenarios that would not happen in the real world are implemented in the virtual world, making digital games more attractive to people [15]. Games have become an increasingly popular pastime, especially during the coronavirus pandemic [16]. In today's developed visual media, in addition to computers, mobile phones are another popular terminal for internet games. Different devices can meet different needs [17]. Computer games often feature high-quality sound and visual effects and usually require more time to play; therefore, they have the potential to provide immersion, fulfillment, and competitiveness. In addition, mobile phone games are not only easier to access than computer games but they also increase feelings of social connection and reduce feelings of isolation and negative emotions. One study found that texting games are easily associated with social networking service applications [18]. In addition, recent advances in smartphone gaming platforms have made it easier to access a wide variety of game genres [17]. Furthermore, recently, the number of mobile phone game users (MGUs) has increased dramatically, and the mobile phone gaming market has flourished, leading to a gradual shift in the traditional gaming model from desktop PC– to mobile device–based gaming models [19]. Therefore, this study aims to explore the differences between computer game users (CGUs) and MGUs to gain a deeper understanding of IGD.

In addition, exploring internet gaming use characteristics is important to better understand IGD. Internet gaming characteristics can be used as IGD predictors, including weekday/weekend game time and money spent on games, which can provide information for clinical diagnosis and treatment [20,21]. The influence of the game genre on IGD is worth mentioning. Analysis of variance reveals that internet gaming addiction varies according to the game genre [22]. A noteworthy finding was that IGD might be more prevalent in users of specific genres, especially real-time strategy and first-person shooter games [23]. Gaming motivation is another important factor for predicting IGD. Escapism motivation has demonstrated a significantly strong association with IGD [24]. Other types of motivation may also be used to predict disease [25]. Thus, the theory, assessment, and treatment of IGD can be improved by examining the association between specific types of motivation [26].

Previous studies have indicated that personality traits may also play a necessary role in the development of IGD [27]. Personality traits are characterized by high stability, reflecting thoughts, attitudes, emotions, and behavioral patterns. Despite some controversy, the 5-factor model has become a widely accepted framework of personality traits, which includes 5 dimensions: conscientiousness, extraversion, agreeableness, neuroticism, and openness [28]. Personality traits can affect an individual's experience of games, causing players to show different degrees of pathological game use disorder [29]. Gamers with IGD show high levels of neuroticism [30]. Individuals high in neuroticism tended to experience negative emotions. The act of playing games, especially in immersive environments, provides gamers with alternative virtual reality to relieve negative moods [5]. In addition, gamers with low conscientiousness have a higher risk of developing IGD because they are less persistent in pursuing goals and focusing on responsibilities in their daily lives [31]. Individuals with IGD tend to overplay games, which can affect their relationships, work, or education. Conscientious people are less likely to allow important aspects of their lives to be negatively affected by games [32]. However, results for other personality traits have been inconsistent.

Although previous studies have reported features associated with IGD, most have focused on computer games. Given that each gaming device has unique interface characteristics, we hypothesize that there are some differences in the psychometric properties and development of IGD between CGUs and MGUs. This study aims to compare internet gaming use characteristics and personality traits between different gaming devices and to explore potential specific predictors for IGD according to different gaming devices (mobile phone or computer).

Methods

Study Design and Subjects

This was a cross-sectional study that collected the internet addiction scores, game time, money, game type, game motivation, and personality traits of different gaming device users through an online survey. Differences in these indicators across users of gaming devices or gaming addicts were compared to infer the characteristics of these different populations playing games and the association between devices and gaming addiction.

This study was conducted between October and November 2019 in China. We issued online questionnaires through WeChat (a cross-platform instant messaging tool), based on a network survey. For better understanding, we used the Chinese version of the scale and the Chinese questionnaire. Participants could fill in the questionnaire anonymously by scanning the quick response (QR) code of the survey program Questionnaire Star (a free online questionnaire, survey, and voting tool). On the first page of the questionnaire, we briefly introduced the purpose of this study and some matters that needed attention when filling in the questionnaire. We also demonstrated the voluntary nature, anonymity, and confidentiality of the survey. Individuals could choose the "accept" or "reject" options. Participants could choose "reject" to exit the survey page, and those who chose "accept" would skip to the next page and continue to complete the questionnaire.

The participants were recruited online through WeChat, Weibo, or other social apps. In this study, the inclusion criteria were (1) aged 15-25 years, (2) played online games in the past 12 months, and (3) understood the questionnaire content and agreed to participate. The survey initially recruited 4012 participants. Those who had never played online games or only played offline games were excluded (n=103, 2.6%). Individuals who had severe physical or mental disorders (n=87, 2.2%) were also excluded. To be specific, the following individuals were excluded: (1) current or previous history of psychiatric disorders, including but not limited to schizophrenia, bipolar disorder, or depression, and (2) current or history of medical disorder, including but not limited to neurological and endocrinological disorders. Diagnoses of schizophrenia, affective disorders, and other disorders were obtained by experienced clinicians through the DSM-5 interview [9]. For example, if a subject presented with cognitive, affective, and behavioral disturbances and severe dissonance in clear consciousness (eg, paradoxical thinking or commentary hallucinations), schizophrenia was likely to be diagnosed; if a subject presented with significant and persistent high or low mood, depressive disorder or bipolar disorder was likely to be diagnosed. Other psychiatric disorders were also diagnosed according to the criteria in the DSM-5. In addition, we recommended that these excluded individuals seek professional medical advice. Questionnaires that lacked authenticity were deleted (eg, multiple replies from the same IP address; n=55, 1.4%). In addition, we removed responses in which the gaming device was neither a computer nor a mobile phone (eg, Nintendo Switch, Sony PlayStation, or virtual reality headsets) and individuals who played computer and mobile phone games evenly (n=174, 4.3%). Finally, a total of 3593 (89.6%) internet game users were included.

Ethical Considerations

The study protocol was approved by the Institutional Review Board. All participants were fully informed about the purpose of this investigation and signed an online informed consent form. The study was conducted in accordance with the Declaration of Helsinki, and it was approved by the Research Ethics Committee of Second Xiangya Hospital of Central South University (protocol code 2020004, date March 1, 2020).

Procedures and Measures

Self-administered questionnaires were used to collect sociodemographic information, gaming use characteristics, IGD, and personality traits. Before starting the study, the questionnaire was tested with a small sample of adolescents to improve readability and intelligibility, and it was finalized after the preliminary study.

Sociodemographic data included gender, age, education level, marital status (married or unmarried), and structure of the family (either a sibling or an only child).

In terms of gaming use characteristics, participants were asked which gaming device they used most often (mobile phone, computer, or others).Three groups were divided by reports from the responders based on the gaming time spent on either a computer or a mobile phone: (1) computer game: individuals who played only computer games or played more computer games than mobile phone games; (2) mobile phone game: individuals who played only mobile phone games or played more mobile phone games than computer games; (3) others: individuals who played computer and mobile phone games evenly or the gaming device was neither a computer nor a mobile phone. Participants were also asked about their motivation for playing games, the game genre (role-playing games [RPGs], strategy games, action shooter games, and brain and skill games), and the time (hours/day) and money (yuan/month) spent on gaming in the past 12 months. Specifically, gaming motivation included sensation seeking, escaping reality, coping with negative emotions, passing time, and making friends.

IGD was assessed using the Chinese version of the Video Game Dependency Scale (VGD-S). The scale is a revision of the English version developed by Rehbein et al [33,34] and covers the description of IGD in the DSM-5, published by the American Psychiatric Association (Cronbach α=.92). The scale developed by Rehbein et al [34] is a 4-point Likert-type scale (strongly disagree to strongly agree) consisting of 18 items, with 2 items for each criterion. Participants were asked to choose an experience during the past 12 months from the list of 18 descriptive items. At least 1 of the 2 items must be answered with "strongly agree" to meet the diagnostic criterion. Participants who met 5 or more of the 9 criteria were placed in the IGD group (Cronbach α=.90).

We used the brief version of the Chinese Big Five Personality Inventory to measure personality traits [35-37]. The scale consists of 8 items for each subtype, and there are 40 items in total. In addition, it is scored on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree) and demonstrates high construct validity and reliability (Cronbach α=.85).

Statistical Analysis

First, to reduce bias and confounding variables, we used propensity score matching (PSM) to match CGUs and MGUs based on demographic information. Chi-square tests and *t*-tests(two tails) were used to compare demographic information, IGD scores, internet gaming use characteristics, and personality traits between CGUs and MGUs. Logistic regression analysis was performed to identify IGD predictors in different game device groups. A 2-sided statistical significance level was set at $P<.05$. SPSS Statistics version 26.0 (IBM Corp) was used in this study.

Results

Sociodemographic Data

A total of 3593 subjects were included in the analysis. Of these participants, 1511 (42.1%) were CGUs and 2032 (57.9%) were MGUs. Considering the huge number of differences, PSM was used to match the age, gender, education, marital status, and family structure (only child in the family or not). Next, we acquired 1:1-matched samples, and 1498 (99.1%) CGUs and 1498 (73.7%) MGUs were included. The mean age for each group was 19-20 years (CGU: mean 19.6, SD 1.7 years; MGU: mean 19.6, SD 1.7 years), and most of them were male (CGU: 1259/1498, 84.0%; MGU: 1270/1498, 84.8%). Almost all subjects were unmarried (CGU: 1447/1498, 96.6%; MGU: 1456/1498, 97.2%), and over half of them were an only child (CGU: 886/1498, 59.1%; MGU: 839/1498, 56.0%), which did not present a significant difference. The results of the χ^2 test indicated a significant difference regarding the education level (χ^2_1=38.3, $P<.001$) of the 2 device-specific groups: the percentage of people who earned a bachelor's degree or higher was greater in the CGU group (886/1498, 59.1%) than in the MGU group (717/1498, 47.9%); see Table 1.

Table 1. Sociodemographic data of the 2 different gaming device groups.

Characteristics	MGUs[a] (n=1498)	CGUs[b] (n=1498)
Age (years), mean (SD); *t* (*df*)/χ2 (*df*)=0.16 (2994), *P*=.87	19.58 (1.67)	19.59 (1.70)
Gender, n (%); *t*(*df*)/χ2 (*df*)=0.31 (1), *P*=.58		
Male	1270 (84.8)	1259 (84.0)
Female	228 (15.2)	239 (16.0)
Marital status, n (%); *t*(*df*)/χ2 (*df*)=0.90 (1), *P*=.34		
Unmarried	1456 (97.2)	1447 (96.6)
Married	42 (2.8)	51 (3.4)
Education, n (%); *t*(*df*)/χ2 (*df*)=38.32 (1), *P*<.001		
Lower than undergraduate	781 (52.1)	612 (40.9)
Undergraduate or higher	717 (47.9)	886 (59.1)
Only child, n (%); *t*(*df*)/χ2 (*df*)=1.14 (1), *P*=.28		
Yes	839 (56.0)	868 (57.9)
No	659 (44.0)	630 (42.1)

[a]MGU: mobile phone game user.

[b]CGU: computer game user.

Comparisons of Gaming Pattern IGD Score and Game Genre Between CGUs and MGUs

Participants with IGD and the overall population were compared separately between the 2 groups (Table 2). For the overall population in the CGU group, the mean IGD score was 2.95 (SD 2.67) and the mean time and money spent were 2.21 (SD 1.56) hours/day and 111.31 (SD 189.80) yuan/month (mean US $15.95, SD US $27.20), respectively, while in the MGU group, the mean IGD score was 2.60 (SD 2.57) and the mean time and money spent were 1.95 (SD 1.26) hours/day and 63.00 (SD 149.05) yuan/month (mean US $9.03, SD US$21.36), respectively. IGD scores (t_{2994}=3.68, $P<.001$), time (t_{2994}=7.75, $P<.001$), and money (t_{2994}=5.11, $P<.001$) in the MGU group were all significantly lower than those in the CGU group. The 2 most popular game genres in the CGU group were strategy (1048/1498, 70.0%) and action shooter (205/1498, 13.7%), whereas in the MGU group, the 2 most popular game genres were strategy (981/1498, 65.5%) and RPGs (200/1498, 13.4%). For subjects with IGD in the CGU group, the mean IGD score was 6.86 (SD 1.48) and the mean time and money spent were 3.08 (SD 2.00) hours/day and 228.34 (SD 238.15) yuan/month (mean US $32.73, SD US $34.13), respectively. In the MGU group, the mean IGD score was 6.74 (SD 1.46) and the mean time and money spent were 2.75 (SD 1.63) hours/day and 160.78 (SD 261.41) yuan/month (mean US $23.04, SD US $37.47), respectively. The time (t_{681}=2.37, P=.02) and money (t_{681}=3.53, $P<.001$) spent in the MGU group were significantly lower than those in the CGU group. In addition, the 2 most popular game genres in both groups were strategy (CGU: 246/369, 6.7%; MGU: 222/314, 70.7%) and RPGs (CGU: 69/369, 18.7%; MGU: 47/314 15.0%).

Table 2. Within-group comparisons of IGD[a] scores, gaming patterns, personality traits, gaming motivations, and game genres.

Characteristics	MGUs[b]		CGUs[c]		Total statistics		IGD statistics	
	Total (n=1498)	IGD (n=314)	Total (n=1498)	IGD (n=369)	*t* (*df*)/χ2 (*df*)	*P* value	*t* (*df*)/χ2 (*df*)	*P* value
IGD score, mean (SD)	2.60 (2.57)	6.74 (1.46)	2.95 (2.67)	6.86 (1.48)	3.68 (2994)	<.001	1.02 (681)	.31
Gaming patterns, mean (SD)								
Gaming time	1.95 (1.26)	2.75 (1.63)	2.21 (1.56)	3.08 (2.00)	7.75 (2994)	<.001	2.33 (681)	.02
Money spent gaming (yuan/US $)	63.00 (149.05)/9.03 (21.36)	160.78 (261.41)/23.04 (37.47)	111.31 (189.80)/15.95 (27.20)	228.34 (238.15)/32.73 (34.13)	5.11 (2994)	<.001	3.53 (681)	<.001
Personality traits, mean (SD)								
Neuroticism	25.43 (8.07)	29.68 (6.94)	25.22 (8.10)	29.18 (6.25)	–0.70 (2994)	.48	–0.98 (681)	.33
Conscientiousness	33.07 (6.33)	30.65 (5.26)	33.29 (6.57)	30.42 (5.65)	0.91 (2994)	.36	–0.55 (681)	.59
Agreeableness	34.79 (5.98)	33.02 (5.59)	34.41 (6.56)	31.80 (5.86)	–1.64 (2994)	.10	–2.76 (681)	.01
Extraversion	29.65 (7.04)	28.53 (6.28)	30.02 (7.49)	28.91 (6.94)	1.40 (2994)	.16	0.76 (681)	.48
Openness	32.96 (7.14)	31.90 (6.37)	34.01 (7.24)	32.45 (6.38)	3.98 (2994)	<.001	1.12 (681)	.26
Gaming motivations, n (%)								
Sensation seeking	517 (34.5)	177 (56.4)	620 (41.4)	211 (57.2)	15.04 (1)	<.001	0.05 (1)	.83
Escaping reality	163 (10.9)	86 (27.4)	221 (13.8)	14 (3.8)	10.05 (1)	.002	9.83 (1)	.002
Coping with negative emotions	673 (44.9)	181 (57.6)	711 (47.5)	212 (57.5)	1.94 (1)	.16	<0.01 (1)	.96
Passing time	1008 (67.3)	193 (61.5)	854 (57.0)	204 (55.3)	33.65 (1)	<.001	2.66 (1)	.10
Making friends	298 (19.9)	73 (23.2)	384 (25.6)	107 (29.0)	14.04 (1)	<.001	2.89 (1)	.09
Gaming genres, n (%)								
RPGs[d]	200 (13.4)	47 (15.0)	179 (11.9)	69 (18.7)	1.33 (1)	.25	1.68 (1)	.20
Strategy	981 (65.5)	222 (70.7)	1048 (70.0)	246 (66.7)	6.85 (1)	.01	1.28 (1)	.26
Brian and skill	149 (9.9)	8 (2.5)	66 (4.4)	7 (1.8)	34.52 (1)	<.001	0.33 (1)	.56
Action shooter	168 (11.2)	37 (11.8)	205 (13.7)	47 (12.7)	4.19 (1)	.04	0.14 (1)	.70

[a]IGD: internet gaming disorder.

[b]MGU: mobile phone game user.

[c]CGU: computer game user.

[d]RPG: role-playing game.

Comparisons of Personality Traits and Gaming Motivations Between CGUs and MGUs

Table 2 outlines the significant differences between device-specific groups regarding gaming motivations and personality traits. For the overall population in both groups, CGU participants presented higher openness than MGU participants (t_{2994}=3.98, *P*<.001), and for subjects with IGD, CGU participants presented lower agreeableness than MGU participants (t_{681}=−2.76, *P*=.006). Referring to gaming motivations, including sensation seeking, escaping reality, coping with negative emotions, passing time, and making friends, the two most important game motivations were passing time (CGU: 854/1498, 57.0%; MGU:1008/1498, 67.3%) and coping with negative emotions (CGU: 711/1498, 47.5%; MGU: 673/1498, 44.9%) in the two groups among the overall population. For the subjects with IGD, the most two important motivations in the CGU group were coping with negative emotions (212/369, 57.5%) and seeking sensations (211/369, 57.2%), while in the MGU group, those were passing time (193/314, 61.5%) and coping with negative emotions (181/314, 57.6%).

Identifying IGD Predictors by Game Device Group

After controlling for sociodemographic factors, multivariate logistic regression was conducted to identify IGD predictors in the different game device groups (see Table 3). In the CGU group, a higher daily gaming time (odds ratio [OR] 1.301, 95% CI 1.182-1.432; *P*<.001), more money spent monthly on gaming (OR 1.002, 95% CI 1.001-1.003; *P*<.001), higher neuroticism (OR 1.060, 95% CI 1.038-1.083; *P*<.001), and lower conscientiousness (OR 0.922, 95% CI 0.894-0.951; *P*<.001) were associated with IGD, in addition to motivation for sensation seeking (OR 2.387, 95% CI 1.781-3.200; *P*<.001), escaping reality (OR 3.407, 95% CI 2.347-4.945; *P*<.001), and coping with negative emotions (OR 1.456, 95% CI 1.085-1.955; *P*=.01). In the MGU group, a higher daily gaming time (OR 1.377, 95% CI 1.226-1.547; *P*<.001), more money spent monthly on gaming (OR 1.004, 95% CI 1.003-1.006; *P*<.001), higher neuroticism (OR 1.087, 95% CI 1.063-1.112; *P*<.001), and lower conscientiousness (OR 0.928, 95% CI 0.898-0.960; *P*<.001) were associated with IGD, in addition to motivation for sensation seeking (OR 2.244, 95% CI 1.651-3.050; *P*<.001), escaping reality (OR 2.271, 95% CI 1.496-3.447; *P*<.001), and coping with negative emotions (OR 1.493, 95% CI 1.099-2.029; *P*=.01). Compared to brain and skill games, strategy (OR 4.452, 95% CI 1.938-10.227; *P*<.001) and action shooter games (OR 3.725, 95% CI 1.465-9.474; *P*=.01) increased the risk for the occurrence of IGD in this group, which was different from the CGU group.

Table 3. After adjusting for sociodemographic data[a], binary logistic regression analyses of factors predicting IGD[b] in device-specific groups.

Characteristics	CGUs[c]		MGUs[d]	
	OR[e] (95% CI)	*P* value	OR (95% CI)	*P* value
Gaming patterns				
Gaming time	1.301 (1.182-1.432)	<.001	1.377 (1.226-1.547)	<.001
Money spent	1.002 (1.001-1.003)	<.001	1.004 (1.003-1.006)	<.001
Gaming motivations				
Sensation seeking	2.387 (1.781-3.200)	<.001	2.244 (1.651-3.050)	<.001
Escaping reality	3.407 (2.347-4.945)	<.001	2.271 (1.496-3.447)	<.001
Coping with negative emotions	1.456 (1.085-1.955)	.01	1.493 (1.099-2.029)	.01
Passing time	1.113 (0.832-1.490)	.47	0.906 (0.656-1.251)	.55
Making friends	1.026 (0.742-1.419)	.88	0.891 (0.614-1.294)	.54
Personality traits				
Neuroticism	1.060 (1.038-1.083)	<.001	1.087 (1.063-1.112)	<.001
Conscientiousness	0.922 (0.894-0.951)	<.001	0.928 (0.898-0.960)	<.001
Openness	0.983 (0.958-1.009)	.19	1.003 (0.971-1.031)	.98
Agreeableness	0.990 (0.910-1.021)	.53	0.991 (0.959-1.025)	.60
Extraversion	1.003 (0.980-1.027)	.78	1.001 (0.973-1.031)	.92
Game genres				
Brain and skill	N/A[f]	N/A	N/A	N/A
Strategy	1.486 (0.612-3.607)	.38	4.452 (1.938-10.227)	<.001
Action shooter	1.500 (0.577-3.901)	.40	3.725 (1.465-9.474)	.01
RPGs[g]	1.557 (0.583-4.159)	.38	2.434 (0.963-6.150)	.06

[a]Sociodemographic data included gender, age, education, marital status, and family structure (only child or note).

[b]IGD: internet gaming disorder.

[c]CGU: computer game user.

[d]MGU: mobile phone game user.

[e]OR=odds ratio.

[f]N/A: not applicable.

[g]RPG: role-playing game.

Discussion

Principal Findings

To the best of our knowledge, this is the first study to compare internet gaming usage characteristics and personality traits among people using different gaming devices. The main research findings are as follows: First, the game time, money spent, and IGD scores in the CGU group were higher than those in the MGU group. Second, subjects in different groups preferred different game genres and had different game motivations and personality traits; for example, subjects in the CGU group preformed lower openness than those in the MGU group. Third, the time and money spent on games, neuroticism, conscientiousness, motivation to seek sensations, escaping reality, and coping with negative feelings were associated with the occurrence and development of IGD in both groups in multivariate logistic regression; for MGUs, comparing the brain and skill, strategy, and action shooter games may bring more risks for IGD.

Several researchers have reported that time and money are dominant factors for IGD, and our study found that these 2 factors take effect in each group [20,33,38,39]. In this way, it seems that some developers of highly profitable games become whipping boys. However, in fact, most developers are just enthusiasts who want to create the most enjoyable gaming experience for their players, while game publishers are more concerned about monetization and drive developers in this way, due to which the game comes with paid content to attract players to invest as much time and money in the game as possible. Moreover, to maximize profits, the classical gaming operation pattern usually does not have fixed endpoints, which can easily cause gaming addiction [40]. The playing time, game currency input, and addiction value of the CGU group were higher than those of the MGU group. Some possible explanations are that mobile phones are currently more adapted to some medium-quality or online games with social attributes, while some computer games have higher quality, more immersive experiences, and higher prices, and high-quality games cause greater addiction problems. However, furthermore, as technology advances, the technological differences between mobile phones or other mobile devices and computers will become increasingly smaller. We can assume that mobile phone game addiction may replace computer game addiction as a larger social health issue within a few years because mobile devices are more accessible and often free to play.

The game genre plays an important role in the development of IGD, and it is important to explore its impact on IGD [41]. Our study showed that the 2 groups had different gaming preferences. For the addicted population, both groups preferred strategy and adventure games, and for MGUs, the strategy and action shooter games may bring more risks. Previous research has found that strategy games and action shooter games are popular among teenagers with high IGD risks [42]. Action shooter games have been reported to be associated with high impulsivity, disinhibition, and inattention [42]. Therefore, teenagers' liking strategies or action shooter games need the necessary acquaintances and encouragement to engage in healthy behaviors.

Although many studies have reported the relationship between RPGs and addiction, this study did not find meaningful differences, possibly due to the heterogeneity of the subjects. The reason for the different game preferences between the 2 groups may be that the number of popular games varies on different devices, particularly when the Chinese government tightens restrictions on game distribution, which requires further research.

Certain personality traits can make individuals more prone to addiction. This study found that neuroticism and conscientiousness were both identifying factors for IGD in each group, which is consistent with previous findings [33,43,44]. Highly neurotic individuals are more likely to feel stimuli from the external environment. Online gaming is often one of the choices to gain a sense of security [31]. In addition, it is difficult for those with low levels of conscientiousness to assume appropriate responsibilities or obligations, and the online world offers an environment of less oversight and responsibility, which is tempting for them [33]. Because the 2 personality traits are significantly associated with several addiction disorders, parents and educators should not only value highly neurotic and conscientious adolescents but also help them overcome personality disorders [45,46].

We also found that the openness of the MGU group was higher than that of the CGU group. This means that people in the MGU group preferred to maintain their own gaming habits and did not easily change their game types and modes. In the IGD subgroup, the agreeableness of the CGU group was lower than that of the MGU group. Agreeableness is an assessment of the degree to which an individual likes to appear with others, and it reflects their attitude toward others. Low agreeableness can display a hostile, cynical, and ruthless attitude [47]. The finding indicates that computer game players prefer to enjoy the game alone and may encounter more social problems.

Motivations to seek sensations, escape reality, and cope with negative feelings were seen as factors strongly related to game addiction in our research, which is consistent with previous research findings [24]. In the total population, 34.5% of MGU subjects and 41.4% of CGU subjects played games because of sensation seeking, while in the IGD population, the number of people was >50%. People get pleasure from completing objectives, and developers have designed many large and small objectives in their games (eg, beating an opponent or just checking in online). Some of these in-game objectives are easy to complete, while others seem hardcore (especially those in competitive online games that require expert skills, coping, and long-term patience). These different difficulty levels allow all types of people to find their own goals in the game and earn pleasure by completing them. Some research has found that dealing with negative emotions, such as fear of failure, by imitating game characters against the real world under performance can be seen as a negative reinforcement for gaming disorder [48].

The CGU group was more motivated to look for sensations, possibly because computer games are more immersive. Players interact more with the digital world and have more fun after completing their objectives. There were >40% MGUs and CGUs whose gaming motivation was discomfort, similar to seeking sensations, among the IGD population; the 2 groups also exceeded 50%. As mentioned before, the online world offers an environment with less oversight and accountability, where players can vent their emotions unscrupulously and take less responsibility; in addition, it is noteworthy that negative emotions are often associated with high neuroticism and low conscientiousness. More than half of the participants played games to pass the time; however, interestingly, passing time did not become an IGD predictor, suggesting that most players use games in a healthy way and as a form of entertainment, and only a minority will develop IGD.

In addition, some users play games to make friends or escape reality. Some games, such as RPGs, provide a complete set of worldview settings in which people can temporarily escape from reality and meet the psychological needs of making friends [49]. This study found that people in the CGU group had a stronger motivation to make friends than those in the MGU group, reflecting that computer game players are more enthusiastic about making friends. Some studies have found that fixed social needs aggravate the progression of internet addiction [50,51]. Therefore, for computer game players, they should not only be encouraged to engage in more offline social interactions to meet their needs but also be helped in social skills.

Limitations

This study had several limitations. First, because this was a cross-sectional study with a nonrepresentative sample, causality and generalizability were limited. Therefore, longitudinal research and recruiting more representative samples are necessary. Second, the research data were self-reported and came from an online survey, which may be biased in terms of the reliability and applicability of the conclusion; thus, comments about the game usage of participants' relatives or acquaintances and offline assessment of IGD by clinicians can be included to obtain more accurate and realistic results in subsequent research. Third, considering the restrictions on game introduction in the Chinese Mainland, the study did not include people using new devices, such as PlayStation, Switch, or virtual reality headsets, and research on new devices can be designed for further study. Fourth, currently, there is no internationally recognized scale for evaluating game addiction; therefore, the results of this study should be based on preliminary results. Fifth, the study did not consider confounding factors, such as smoking, alcohol consumption, household income, and social status, which play important roles in gaming addiction and motivation. These data can be obtained in follow-up studies.

Conclusion

In summary, our study showed that there are significant differences between CGUs and MGUs in gaming usage patterns, game genres, motivations, personality traits, and internet game addiction scores. Furthermore, we found that time and money spent on games, neuroticism, conscientiousness, motivation to seek sensations, escaping reality, and coping with negative feelings are associated with the occurrence and development of IGD. Given the difference between CGUs and MGUs, there are 2 important implications for clinical research on gaming addiction disorders. More attention should be paid to high-quality computer games because of their high picture quality, immersive experience, and potential adverse consequences. The other is that useful regulation for computer game players with impaired social functioning or poor personality traits ought to be implemented. However, targeted measures need to be adopted to help people with IGD, and further studies may consider longitudinal research, including new game devices, to determine the causal relationship between addiction and various devices and other factors and accompany the innovation of game devices.

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Data Availability

The data sets generated and analyzed in this study are available from the corresponding author on reasonable request.

Authors' Contributions

All the authors contributed to the survey design. ZL and HS conceptualized and designed the research. YL and YT wrote the first draft of the manuscript and contributed to the final manuscript. SH, LT, QH, and XC prepared the assessment tools. ZL, YL, and YT performed data collection. SL and JH undertook the statistical analysis.

Conflicts of Interest

None declared.

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Abbreviations

CGU: computer game user
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
IGD: internet gaming disorder
MGU: mobile phone game user
OR: odds ratio
PC: personal computer
PSM: propensity score matching
RPG: role-playing game

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Corrigenda and Addenda

Correction: Effects of Commercial Exergames and Conventional Exercises on Improving Executive Functions in Children and Adolescents: Meta-Analysis of Randomized Controlled Trials

Jinlong Wu[1*], MA; Zhuang Xu[1*], MA; Haowei Liu[1], MA; Xiaoke Chen[2], MA; Li Huang[1], MA; Qiuqiong Shi[3], PhD; Linman Weng[4], MA; Yemeng Ji[1], MA; Hao Zeng[5], MA; Li Peng[1], PhD

[1]College of Physical Education, Southwest University, Chongqing, China
[2]Department of Physical Education, Tsinghua University, Beijing, China
[3]Laboratory for Artificial Intelligence in Design, Hong Kong, China
[4]Faculty of Psychology, Southwest University, Chongqing, China
[5]College of Physical Education, Nanchang University, Nanchang, China
[*]these authors contributed equally

Corresponding Author:
Li Peng, PhD
College of Physical Education
Southwest University
2 Tiansheng Road, Beibei District
Chongqing
China
Phone: 86 13699878189
Email: 804455169@qq.com

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In “Effects of Commercial Exergames and Conventional Exercises on Improving Executive Functions in Children and Adolescents: Meta-Analysis of Randomized Controlled Trials” (JMIR Serious Games 2023;11:e42697) the authors made one correction.

In the corrected article a footnote (*) to denote equal contributions for authors Jinlong Wu and Zhuang Xu was added as follows:

> *Jinlong Wu 1[*], MA; Zhuang Xu 1[*], MA; Haowei Liu 1, MA; Xiaoke Chen 2, MA; Li Huang 1, MA; Qiuqiong Shi 3, PhD; Linman Weng 4, MA; Yemeng Ji 1, MA; Hao Zeng 5, MA; Li Peng 1, PhD*
>
> **these authors contributed equally*

The equal contributions footnote did not appear in the originally published article.

The correction will appear in the online version of the paper on the JMIR Publications website on December 28th 2023, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Review

Mixed Reality in Modern Surgical and Interventional Practice: Narrative Review of the Literature

Mats T Vervoorn[1*], MD; Maaike Wulfse[1*], BSc; Tristan P C Van Doormaal[1,2], MD, PhD; Jelle P Ruurda[1], MD, PhD; Niels P Van der Kaaij[1], MD, PhD; Linda M De Heer[1], MD, PhD

[1]University Medical Center Utrecht, Utrecht, Netherlands
[2]University Hospital Zurich, Zurich, Switzerland
[*]these authors contributed equally

Corresponding Author:
Mats T Vervoorn, MD
University Medical Center Utrecht
Heidelberglaan 100
Utrecht, 3508 GA
Netherlands
Phone: 31 88 7556179
Email: m.t.vervoorn-4@umcutrecht.nl

Abstract

Background: Mixed reality (MR) and its potential applications have gained increasing interest within the medical community over the recent years. The ability to integrate virtual objects into a real-world environment within a single video-see-through display is a topic that sparks imagination. Given these characteristics, MR could facilitate preoperative and preinterventional planning, provide intraoperative and intrainterventional guidance, and aid in education and training, thereby improving the skills and merits of surgeons and residents alike.

Objective: In this narrative review, we provide a broad overview of the different applications of MR within the entire spectrum of surgical and interventional practice and elucidate on potential future directions.

Methods: A targeted literature search within the PubMed, Embase, and Cochrane databases was performed regarding the application of MR within surgical and interventional practice. Studies were included if they met the criteria for technological readiness level 5, and as such, had to be validated in a relevant environment.

Results: A total of 57 studies were included and divided into studies regarding preoperative and interventional planning, intraoperative and interventional guidance, as well as training and education.

Conclusions: The overall experience with MR is positive. The main benefits of MR seem to be related to improved efficiency. Limitations primarily seem to be related to constraints associated with head-mounted display. Future directions should be aimed at improving head-mounted display technology as well as incorporation of MR within surgical microscopes, robots, and design of trials to prove superiority.

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KEYWORDS

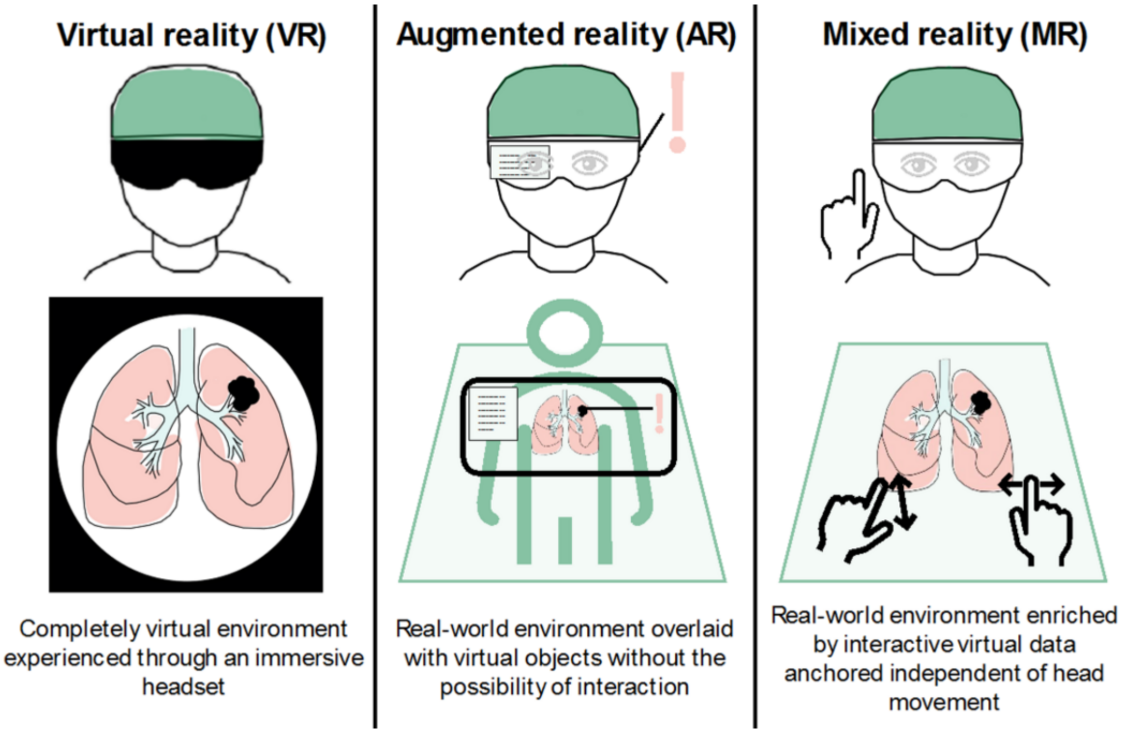
mixed reality; extended reality; surgery; intervention; education

Introduction

Over the recent years, mixed reality (MR) has gained interest within the medical community [1,2]. According to the landmark paper by Milgram et al [3], MR can best be viewed as a real-world environment enriched by virtual data presented within a single display, allowing for interaction through various means. Currently, MR is primarily experienced through head-mounted displays (HMDs) that allow virtual objects to be overlaid onto the real world using optical and video-see-through display techniques [4]. MR should be distinguished from virtual reality, referring to a completely virtual environment experienced through an immersive headset and augmented reality, which refers to virtual objects being overlaid onto a real-world environment without the possibility of interaction. More specifically, augmented reality merely projects visual data onto the real world, whereas MR anchors the visual data into the real world independent of the user's movement and allows for real-time interaction (Figure 1).

Theoretically, MR can offer many advantages for application during medical procedures or interventions by allowing the integration of relevant patient-specific data within real-time, real-world observations in a single display. It provides the ability to create interactive interfaces that facilitate procedural planning and intra-procedural navigation and can support training and education. The goal of this narrative review is to provide a qualitative overview of the different applications of MR across surgical and interventional medicine, identify its advantages and disadvantages, and reflect on its potential for future applications.

Figure 1. Graphical depiction of the differences between virtual, augmented, and mixed reality.

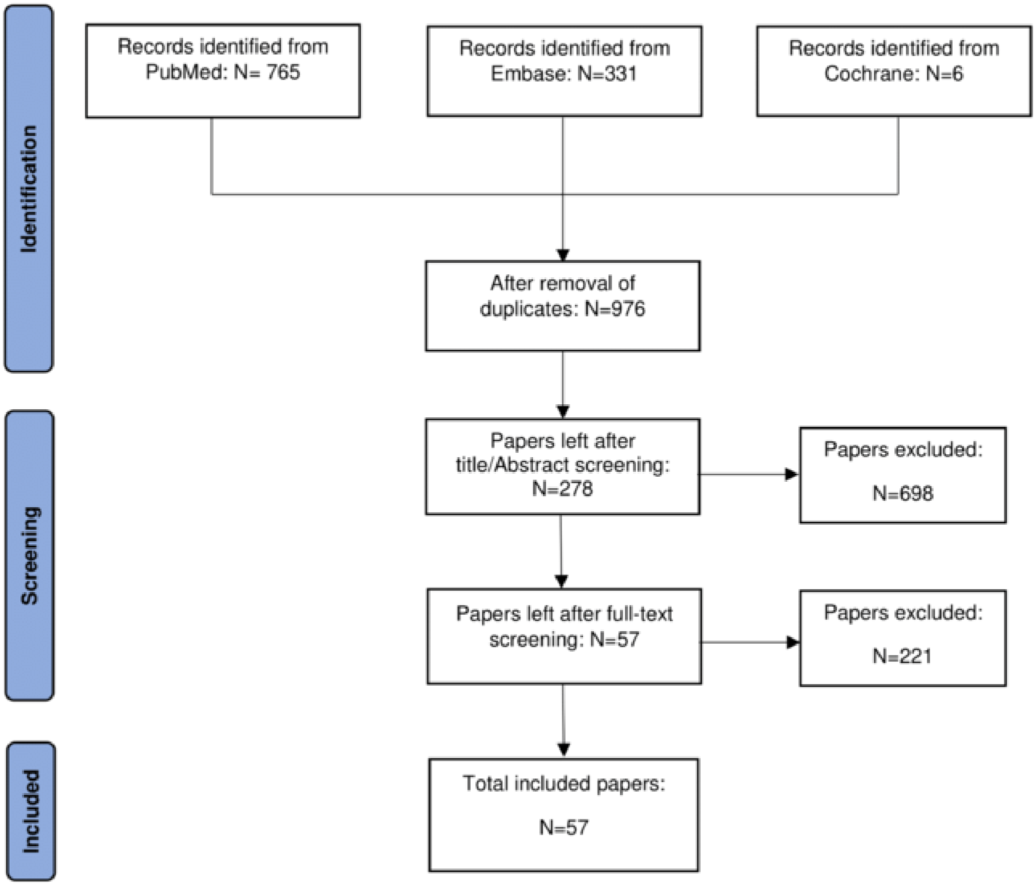


Methods

A targeted literature search within the PubMed, Embase, and Cochrane databases was performed on April 2, 2022, regarding the application of MR within surgical and interventional practice. Keywords in our title and abstract search included all commercially available devices for MR (Multimedia Appendix 1). Papers were screened for relevance and originality by 3 independent researchers (MTV, MW, and LMDH). Studies were included if they met the criteria for technological readiness level 5 or higher, and as such, had to be validated in a relevant environment. In short, technology readiness level is a method developed by NASA (National Aeronautics and Space Administration) in 1974 and adopted by the European Union and is used to assess technological maturation according to 9 levels, with 9 indicating the most mature level.

Papers were excluded if they involved augmented or virtual reality, for which the ability of interaction was used to differentiate between augmented reality and MR. Non-English literature and abstracts or conference proceedings were also excluded. Reference lists of all papers were screened for additional relevant literature. The flowchart of the search is shown in Figure 2. We categorized results into "preoperative and interventional planning," "intraoperative and interventional guidance," and "surgical and interventional training and education."

Figure 2. Flowchart of the conducted search on mixed reality in surgical and interventional practice.



Results

Preoperative and Interventional Planning

Within cardiovascular surgery and interventional cardiology, MR has been evaluated primarily for congenital defects that benefit from improved visualization of structural anomalies. Two studies involving congenital cardiac surgery reported a significant reduction in time required for surgical planning and intraoperative preparation when planning was done using MR instead of two-dimensional imaging [5,6]. Additionally, no intraoperative modifications to predefined surgical plans were reported in the MR group, whereas this was noted in 17.6% of cases in a 2D control group. This difference was attributed to improved spatial representation and visualization of relevant anatomy, improved depth perception, and a satisfactory correspondence to intraoperative findings in the MR group. Additionally, faster intraoperative recognition of structures was reported, presumed to be the result of improved processing of pathological structures and surgical steps by repeated visual representation beforehand [5,6]. Moreover, workload associated with mental transformation of images was reduced due to the more realistic surface features compared to 3D-printed heart models [5]. A reported future step for MR within preoperative planning of cardiac surgery would be the accurate visualization of coronary arteries and intracardiac structures and incorporating simulated movement and blood flow dynamics into the hologram.

Within orthopedic surgery, Lu et al [7] describe a collection of cases in which MR primarily improved preoperative doctor-patient communication and patients' understanding of complex pathology.

In otolaryngology and maxillofacial surgery, studies have demonstrated improved understanding of tumor-related anatomy and planning of surgical approach when MR was used instead of conventional radiological imaging [8,9]. Mitani et al [8] found that MR facilitated recognition of dissection lines in parotid tumor surgery, where consideration of detailed maxillary anatomy is of critical importance.

Within oncological surgery, MR has been applied for preoperative planning of minimally invasive electroporation and microwave ablation for advanced gastrointestinal tumors of hepatic origin. It improved remote and hospital-based analysis of patient-specific anatomy and optimized surgical approach [10]. MR-guided surgical planning for liver resection refined understanding of hepatic vascular anatomy and tumor location, improving accuracy of resection while preserving a larger residual liver volume [11].

In urology, MR-guided preoperative planning for laparoscopic nephron-sparing resection of complex renal tumors resulted in reduced operating time and a lower conversion rate to total nephrectomy when compared to conventional 2D computed tomographic (CT)–guided planning [12,13]. The reduced operating time presumably resulted from the ability to perform a more comprehensive analysis of the renal tumor before surgery, allowing significantly more patients in the MR group to be scheduled for laparoscopic partial nephrectomy instead of total nephrectomy (82% vs 46%; *P*<.001). This suggests that MR improves assessment of surgical risks and allows for modification of surgical strategy as needed, presumably by facilitating a more intuitive, stereoscopic, and comprehensive anatomical study. They also reported significantly increased patient satisfaction when MR was used during preoperative counseling [13].

In studies addressing preoperative planning, no limitations specifically related to the use of HMD are reported.

Intraoperative and Interventional Guidance

In neurosurgery, the efficacy of MR was reported in multiple studies that demonstrated adequate technical feasibility and safety for intracranial tumor surgery, epilepsy surgery, and spinal surgery [14-20]. Benefits mentioned include the following: (1) the ability to display holographic images of (tumor-related) anatomy onto a patient; (2) enhanced ergonomics; (3) improved preservation of attention and focus of the surgical team; (4) an intuitive workflow supported by voice commands and hand gestures; (5) cost efficiency of MR with HMD compared to conventional systems for neuronavigation; and (6) the possibility to share the surgeon's real-time perspective with other team members and residents during surgery [14-16,18]. Overall, the reported accuracy of lesion localization was satisfactory in both intracranial and spinal procedures [16,17,20,21]. Furthermore, MR guidance demonstrated improved efficacy during transforaminal percutaneous endoscopic lumbar discectomy and external ventricular drain placement compared to conventional methods of neuronavigation, resulting in a significantly reduced operating time and exposure to radiation, increased accuracy, and a reduction of attempts required for correct drain positioning, with comparable postoperative outcome [22-24]. Interestingly, this effect was particularly strong in novice residents, practically eliminating the learning curve associated with external ventricular drain placement by performing as well as experienced surgeons while guided by MR [24]. In addition, MR-based neuronavigation for surgical treatment of hypertensive intracerebral hemorrhage has deemed feasible [25].

Several feasibility studies and case reports within interventional cardiology and cardiovascular surgery have been published that highlight positive experiences with MR during implantation of a vena cava filter [26,27] and percutaneous interventions on noncongenital pulmonary artery stenosis [28], resulting in lower doses of contrast medium and radiation exposure. This could be of particular importance in patients with reduced kidney function. A desired future development that is mentioned is the development of dynamic heart models that incorporate movement of the heart and related structures during the cardiac and respiratory cycles [29,30].

Within orthopedic surgery, MR has mostly been used in spinal procedures, such as lumbar pedicle screw implantation, operational treatment of lumbar intervertebral disc herniation, and percutaneous kyphoplasty [31-33]. Several comparative studies report reduced bleeding and radiation exposure, shorter operating times, improved accuracy of screw placement, higher success rates, and improved pain and functionality scores when MR was compared to traditional x-ray guidance [31-33]. These results were attributed to improved anatomical understanding, resulting in smaller surgical trauma and a clearer incision site [32]. Reported disadvantages to MR include higher requirements for preoperative CT imaging, which might restrict its use to more specialized centers [31-33]. General acceptance of MR using HMD was reported as good in a study that investigated surgeon experience [34]. The devices were rated as comfortable to wear and image quality and accuracy were deemed satisfactory. Learnability of voice commands and hand gestures was well rated, although surrounding noise or lack of command understanding limited practical functionality. The potential added value for MR guidance was rated highest for surgical correction of deformities, followed by osteotomy revision and tumor surgery, especially within spinal and pelvic surgery. Greatest benefit was expected in terms of increased intraoperative accuracy, improved surgical outcome, and reduced exposure to radiation. These results demonstrate that MR can establish a sufficient support base for its application among orthopedic surgeons.

In otolaryngology and maxillofacial surgery, evidence suggests that MR enables easier extracapsular dissection of parotid tumors, which is related to lower complication rates, improved preservation of glandular tissue, and decreased incidence of saliva fistulas [9]. Tian et al [35] reported satisfactory use of intraoperative MR in cochlear implant surgery due to improved positioning of the implant. In temporal bone surgery, MR enables the surgeon to distinguish vital anatomical structures, resulting in improved surgical confidence [36]. Another reported advantage of MR is the undisrupted visual-motor axis during surgery by allowing the surgeon to preserve focus on the patient by eliminating the need for an external monitor for guidance, improving ergonomics. This was highlighted by Tang et al [37] during mandibulectomy for maxillofacial tumor resection, in which deviation from the intended surgical plane was reduced by alleviating the need to look at a monitor. They also reported improved efficiency and safety of the procedure.

Within oncological surgery, one study reported a reduction in operating time by a third and improved perceived surgical precision during minimally invasive resection of gastrointestinal tumors [10]. Moreover, MR enabled better identification of dissection lines and understanding of vascular anatomy in hepatic surgery, facilitating segmental resection [38,39]. This was highlighted in a study [11] that demonstrated MR-guided hepatectomy for hepatocellular carcinoma resulted in shorter operating time, fewer intraoperative bleeding, and a reduction in portal vein occlusion time due to an improved understanding of spatial anatomy. Furthermore, these patients had better recovery of liver function and fewer postoperative complications compared to traditional hepatectomy [11]. Percutaneous indocyanine green injection for guidance during laparoscopic anatomic liver resections was also improved when guided by MR [40]. Other feasibility studies highlight satisfactory outcomes and improved intraoperative lesion localization in breast cancer surgery [41], pediatric nephron-sparing Wilms tumor surgery [42], and robot-assisted transanal total mesorectal excision [43]. In laparoscopic cholecystectomy, MR guidance is feasible, but it was not preferred over traditional 2D methods in one study. Especially more experienced surgeons responded neutrally or negatively toward the implementation MR for laparoscopic cholecystectomy due to increased operating time and no significant improvements in outcome [44]. Lastly, in an extensive survey-based study [45], the reported overall experience with MR using HMD was good, with an important advantage being the ability to superimpose (visual) information on the patient's body. They concluded that MR using HMD improved the overall speed and comfort of a surgical procedure by providing intraoperative support and additional guidance to the surgical team [45]. A reported disadvantage of concern to MR is the inability to integrate the real-time movement of abdominal organs and the effects of soft-tissue deformation into the hologram, limiting translation of preoperatively acquired images to the real-time surgical site [38]. This is especially problematic during minimally invasive procedures and requires the development of complex prediction models to overcome these problems.

Evidence from comparative studies supports the use of MR within urology [12,13]. In laparoscopic nephron-sparing surgery for complex renal tumors, MR resulted in reduced operating time, warm ischemic time associated with renal artery clamping, reduced estimated blood loss, and a lower conversion rate to total nephrectomy when compared to a conventional approach with 2D CT guidance. Other factors such as inhospital stay, postoperative serum creatinine, and complication rate were similar among groups. The authors attributed the observed benefits to improved intraoperative identification of relevant anatomical structures, such as a tumor's feeding arteries, thereby preventing clamping of the main renal artery [12,13].

Within interventional radiology, Deib et al [46] conducted a feasibility study into MR-guided percutaneous spine procedures. They concluded that MR using HMD was noninferior to guidance by traditional monitors and might prove especially valuable during procedures that are conducted in spatially limited environments, as key anatomic landmarks could be reliably projected onto the procedural site, which limits disruption of the visual-motor axis.

MR might also be beneficial in plastic and reconstructive surgery due to the ability to project holographic visualizations of anatomical structures onto the patient to guide reconstruction. An example of this was a study [47] into auricular reconstruction, in which an image of the contralateral auricle was projected onto the ipsilateral surgical site. After appropriate positioning was ensured, MR resulted in improved perceived reconstructive results compared to a conventional approach with transparent film guidance [47]. Application of MR during vascular flap transfers and reconstructions that require identification and preservation of target perforator vessels, such as deep inferior epigastric perforator flap reconstruction of breast tissue, resulted in improved localization of the target perforating vessels when compared to Doppler-ultrasound [48]. An encountered problem, however, was related to adequate depth perception of the target vessels, which was limited using MR [49].

Within pulmonary surgery, MR can be used to visualize the location of small pulmonary nodules in patients scheduled for resection by video-assisted thoracoscopic surgery based on images acquired by preoperative CT. Using HMD, one study [50] reported that 94% of nodules were accurately localized, compared to 30% by manual palpation. This is especially relevant, as failure to localize a target nodule might lead to unplanned lobectomy or sampling error. Another study [51] reported the ability to integrate simulated lung deflation into the hologram, which improved surgical instrument placement and allowed for easier identification of nonpalpable lesions, which are notoriously difficult to localize once the lung is deflated [50,51].

Although the above demonstrates the feasibility of MR using HMD, some limitations specifically related to the use of HMD are reported. A recent meta-analysis proposed that using HMD during intracranial tumor surgery might provide additional challenges regarding depth perception, possibly increasing inaccuracy in surgery with small target lesions [52]. These issues restrict HMD use during intracranial procedures that require navigation on submillimeter level and are performed with a microscope. A solution could be the integration of preoperatively acquired holograms into the visuals obtained through the surgical microscope instead of HMD [15]. A reported drawback in cardiovascular surgery is the lack of integration with other often used head-worn devices, such as surgical loupes and headlamps [29]. Other reported limitations related to HMD are as follows: (1) holographic drifts while walking around the hologram [14]; (2) delayed image tracking with fast head movement [37,53]; (3) the perceived parallax effect [45]; (4) holograms being affected by surgical light [37,53]; and blind spots caused by obstruction of the surgical field by the hologram [14,54]. The latter, however, seems manageable with adjustable hologram opacity [14]. Another technological limitation is the relatively short battery life of the HMD, which poses difficulties for long surgeries [37,45,53]. Ergonomic disadvantages were related to perceived added strain on the musculoskeletal system of head and neck, eye strain, and visual discomfort [45,54].

Surgical and Interventional Training and Education

Due to its inherent qualities, MR could benefit surgical and interventional training and education. Condino et al [55] developed a multimodal MR-based surgical simulator for hip arthroplasty. Authors reported that this improved perception of spatial relationships between real and virtual objects. Such a simulator could be of relevance, since hip arthroplasty accounts for a multitude of reported adverse events in orthopedics, and risk of complications during the procedure is strongly related to surgeon experience.

Within otolaryngology and maxillofacial surgery, MR facilitated surgical training of maxillary carcinoma resection, and its overall usefulness was rated 4.5 on a 5-point scale in a survey study among otolaryngologists. This was attributed to improved understanding of the surgical procedure [8]. Additionally, MR can provide a training method for transcanal endoscopic ear surgery and cochlear implantation [36].

The possibility to establish a bidirectional audiovisual connection between the observer wearing an HMD and other participants at a remote site offers unique opportunities for training and education, as it allows medical students and residents to participate in (surgical) ward rounds and procedures remotely from a first-person perspective, providing teaching that was otherwise inaccessible to students [56]. This was recently supported in a study regarding introduction of an HMD within grand surgical rounds [57]. Moreover, it allows for telementoring through data sharing and communication with other surgical team members or surgical residents [45]. Telementoring by off-site experts using HMD has already been demonstrated in neurovascular procedures and cancer surgery [58,59].

Furthermore, evidence suggests a benefit to patient education as well, as an increase in comprehension and a decrease in anxiety was experienced by patients after being subjected to MR-based counseling [60], while simultaneously providing a potential method of intervention to improve patients' understanding of their own disease and adherence to treatment, and hence, facilitate knowledge transfer between health care professionals and individual patients [61].

In studies addressing surgical and interventional training and education, no limitations specifically related to the use of HMD are reported.

Discussion

The introduction of MR seems to have impacted the role of technology within surgical and interventional practice. The increasing number of studies on MR-based modalities using HMD has accelerated this development. It is likely that this number will continue to grow in the following years, mirroring the technological developments that succeed each other in rapid pace. Based on our findings, we can hypothesize that MR-based strategies for preoperative planning and intraprocedural guidance have certain benefits including, but not limited to the following: (1) challenging procedures with high anatomical complexity; (2) procedures that are performed infrequently or are otherwise highly specialized and of low volume, such as rare congenital cardiac defects; (3) procedures that involve an extensive learning curve; (4) procedures that rely on extensive preoperative imaging for intraprocedural guidance; and (5) general education and skill training purposes. Additionally, an increasing number of studies are emerging that highlight the feasibility and potential superiority of MR for more common procedures. In this regard, it is important to note that the benefits of this technology, although complex in nature, do not have to be limited to complex, uncommon procedures but can also further improve safety and efficacy of more simple and routine procedures by improving workflow.

An often reported benefit of MR is related to improved efficiency, which could be the result of improved planning and execution. The immersive, high-quality holographic models of patient-specific anatomy that are compatible with the newest HMD facilitate interaction and allow for improved understanding of complex spatial relationships between relevant anatomical structures, improved spatial orientation, and identification of target pathologies, thereby enabling better visualization and preparation beforehand. As modern medicine is moving toward personalized precision treatment, these patient-specific holograms and qualities of MR could further enhance individually customized surgical plans, including decision-making regarding surgical approach. During a procedure, the ability to project a reconstructed holographic image onto a patient allows for better identification of important patient-specific anatomical landmarks, prevents disruption of the visual-motor axis, and intuitively improves the accuracy of most interventions, resulting in improved surgical performance and reduced operating time. As many procedures that rely on real-time imaging and monitoring for guidance are radiation-based, improved efficiency can result in a significant reduction in total radiation exposure to both patient and physician. This is further illustrated by an experimental model that was developed for real-time radiation exposure dose visualization [62]. Patients and health professionals regularly exposed to radiation could benefit from such a model by creating awareness and ultimately avoiding unnecessary radiation, although validation in a relevant environment is still needed. Furthermore, by decreasing the need for contrast fluids, patients with reduced renal function could benefit as well. Data sharing options could result in better cooperation between team members and improve telementoring and remote counseling by facilitating transfer of knowledge between experienced physicians and resident doctors, thereby improving skill and merit in the inexperienced colleague. Besides, MR seems to possess added value for medical education, skill training, and patient counseling, as suggested by multiple reports that support improved efficiency and engagement as well as increased surgical confidence and skill level when MR-based technologies are used. Ultimately, this could result in more skilled surgeons in the operating room, decreasing the complication risk associated with human inexperience.

Although the overall experience with MR is rated positively in most studies, drawbacks of this technology seem primarily related to HMD and include ergonomic and visual concerns through the added strain of an HMD on head and neck musculature as well as visual fatigue. The experienced field of view might be limited, and occurrence of the parallax effect has been described, which refers to the phenomenon when content in the background moves at a different speed compared to content that is positioned on the foreground [45]. For certain areas that involve dynamic organs, the static nature of holograms based on preoperatively acquired imaging is perceived as an important hurdle for satisfactory and accurate intraoperative guidance, as well as problems related to soft-tissue deformity and disturbed depth perception. These problems hinder the application of MR during intra-abdominal and cardiovascular procedures and warrant the development and integration of prediction models for soft-tissue deformation and dynamic movement of organs into the displayed holograms. In that regard, the development of technology that allows the integration of simulated lung deflation into holograms for pulmonary surgery seems promising [51]. Other reported minor disadvantages are related to battery life, delayed image tracking with swift head movements, and the need for additional training to tolerate eye strain and visual discomfort caused by the hologram. However, these disadvantages do not seem to impact the generally reported positive experience of MR technology, and we expect most of these problems to be solved with ongoing technological development or integration within other emerging technological supportive tools for surgery, such as the surgical robot and surgical microscopes, which seem less susceptible to most reported HMD-related drawbacks of current MR technology. In this regard, it seems of utmost importance that we do not blind ourselves for the potential applications of MR beyond HMD to further accelerate the advancement of this technology.

Since the introduction of HMD for MR, they have evolved from heavy, obstructive, and wired devices to become lighter, see-through, and wireless. Especially the emergence of the Hololens (Microsoft) has offered a more immersive experience compared to previous generations of HMD and has accelerated both innovation and interest in the usefulness of this technology. As a result, almost all studies use Hololens as the designated HMD, whereas the use of other commercially available HMD within health care is limited. Given the value of competition for technological advancement, a more heterogeneous field of HMD suppliers besides Microsoft would be desirable to improve and accelerate development of this technology. Future developments should include the integration of MR within images acquired through surgical microscopes, in robotic surgery, and in the construction of holograms based on real-time data with prediction models that reflect the dynamic nature of organs as opposed to holograms based on preoperatively acquired static imaging. This seems a prerequisite next step for the maturation and adoption of MR technology in current clinical practice and can be designated as the next frontier to overcome for this technology. Besides, focus should be aimed at designing clinical studies to validate the superiority of MR-guided procedures compared to conventional ones. This warrants specific outcome parameters that assess outcome on both the surgical (for example NASA task load index) and patient side (composite end points), which obviate the need for an extensive sample size to prove superiority and make clinical trials more executable.

Limitations to this narrative review are related to the qualitative nature of the paper, which limits its level of evidence. Therefore, the paper should primarily be viewed as a general summary of the topic and a document that could be used to guide future research. The results of our search might also be troubled by the lack of a clear and universally applied definition of MR. As we have noticed, the terms augmented reality and MR seem to be used interchangeably in the literature. We hypothesize that this finding is primarily related to the novelty of the technique, and we expect that, as development progresses, they will become more established in clinical practice.

In conclusion, the implementation of MR seems to possess certain benefits, primarily related to efficiency and accuracy by facilitating preoperative planning and intraoperative guidance, especially in complex, low-volume cases that involve complex anatomy. However, this does not preclude its use in more common, less complex procedures. Besides, it may also benefit surgical training and education of younger residents and peers. Areas of improvement seem to be primarily related to issues involving the use of HMD, which warrant attention to applications beyond HMD in future developments.

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We would like to thank Floor Patist for her contribution to Figure 1.

Conflicts of Interest

TPCVD is the founder and current Chief Medical Officer of Augmedit B.V., Naarden, The Netherlands.

Multimedia Appendix 1
Keywords in title and abstract search.
[DOCX File , 13 KB - games_v11i1e41297_app1.docx]

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Abbreviations

CT: computed tomography
HMD: head-mounted display
MR: mixed reality
NASA: National Aeronautics and Space Administration

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Review

Children and Young People's Involvement in Designing Applied Games: Scoping Review

Michael John Saiger[1], BA, MPhil; Sebastian Deterding[2], MA, PhD; Lina Gega[3], RMN, BA, BN, PhD

[1]Department of Computer Science, University of York, York, United Kingdom

[2]Dyson School of Design Engineering, Imperial College London, London, United Kingdom

[3]Department of Health Sciences & Hull York Medical School, University of York, York, United Kingdom

Corresponding Author:
Sebastian Deterding, MA, PhD
Dyson School of Design Engineering
Imperial College London
25 Exhibition Road
South Kensington
London, SW7 2DB
United Kingdom
Phone: 44 020 7594 8888
Email: s.deterding@imperial.ac.uk

Abstract

Background: User involvement is widely accepted as key for designing effective applied games for health. This especially holds true for children and young people as target audiences, whose abilities, needs, and preferences can diverge substantially from those of adult designers and players. Nevertheless, there is little shared knowledge about how concretely children and young people have been involved in the design of applied games, let alone consensus guidance on how to do so effectively.

Objective: The aim of this scoping review was to describe which user involvement methods have been used in the design of applied games with children and young people, how these methods were implemented, and in what roles children and young people were involved as well as what factors affected their involvement.

Methods: We conducted a systematic literature search and selection across the ACM Digital Library, IEEE Xplore, Scopus, and Web of Science databases using State of the Art through Systematic Review software for screening, selection, and data extraction. We then conducted a qualitative content analysis on the extracted data using NVivo.

Results: We retrieved 1085 records, of which 47 (4.33%) met the eligibility criteria. The chief involvement methods were participatory design (20/47, 43%) and co-design (16/47, 37%), spanning a wide range of 45 concrete activities with paper prototyping, group discussions, and playtesting being the most frequent. In only half of the studies (24/47, 51%), children and young people participated as true design partners. Our qualitative content analysis suggested 5 factors that affect their successful involvement: comprehension, cohesion, confidence, accessibility, and time constraints.

Conclusions: Co-design, participatory design, and similar high-level labels that are currently used in the field gloss over very uneven degrees of participation in design and a wide variety of implementations that greatly affect actual user involvement. This field would benefit from more careful consideration and documentation of the reason of user involvement. Future research should explore concrete activities and configurations that can address the common challenges of involving children and young people, such as comprehension, cohesion, confidence, and accessibility.

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KEYWORDS

serious game; game design; end user; participatory design; co-design; user involvement method; interventions; game development; children; pediatric; young people; child; youth; review method; scoping; applied game

Introduction

Applied Games

Applied games, or serious games, describe (usually digital) games designed to drive desired cognitive, behavior, or other changes in players and the wider community [1-4]. In recent years, applied games have seen increasing interest in areas, such as *well-being* [5], *mental health* [6], *and education* [7,8].

Applied games markedly differ from entertainment games in that they need to fit the capacities, needs, preferences, and contexts of often highly idiosyncratic target end-user audiences; find game mechanics and content that are both appealing or "fun" to the target audience; and deliver the "active ingredients" producing the desired changes, be it learning content, persuasive messages, or medical treatment regimes [4,9]. This is particularly true for applied games targeting children and young people (CYP), whose general and gaming capacities, preferences, and contexts not only drastically differ from those of adult designers and players but also from each other, depending, for example, on their developmental stage [3,10].

As in general design and development, one major successful strategy for sensitizing applied game designers to the specifics of target end users is to directly involve end users (and other relevant stakeholders) in the design, implementation, and evaluation of the game in question [11-13]. Involving users in the design process has been shown to improve use and treatment engagement [13,14], usability [15], and system adoption and adherence across stakeholders [16-18]. On the side of developers, it promises improved understanding of user needs, reduced development costs and time, and improved design quality [19]. Consequently, there are growing calls for regularly using user involvement methods in the design of applied games for health [10,11,20].

User Involvement

However, "user involvement" describes a wide and messy field. Different research and practice communities have developed parallel traditions with confusing differences and overlaps in name, underlying values, and details of implementation, for example, human-centered design [15,21] in computing and human-computer interaction (HCI); participatory design [22,23], co-design [21], or coproduction [24] in design; patient and public involvement in health [25,26]; or action research, participatory research and science, or citizen science across the (social) sciences [15,25,27-29]. Despite regularly involving end users in the form of playtesting, applied game design still has no strong tradition of granting users more agency and input, particularly in the early stages of the design process [30,31]. In addition, recent analyses have shown that digital mental health intervention projects vary greatly in how they approach user involvement and often fail to document how user involvement methods are implemented in detail [10,20]. Bergin et al [16] observed in their recent review that few studies similarly reported any user experience of the involvement processes used—there is no even consensus on how the user experience of study participation should be captured. As a result, there is presently little empirical data on how differences in the detailed implementation of user involvement would affect end-user engagement and the overall efficacy of involvement. Consequently, we do not have evidence-based guidance on how to best involve end users and other stakeholders in the design of applied games [32], for example, for mental health [1,16,33] or education [8,34].

This lack of evidence and guidance is particularly pertinent for user involvement of CYP, and we neither know what roles, activities, or tools help engage and maintain their participation [17,29] nor what implementation factors would affect their involvement or actual adoption, adherence to, and efficacy of developed interventions (an exception was found in a study by Shah et al [35]).

Research Questions

Thus, before we can begin to articulate potential best practice guidelines for the implementation of user involvement in designing applied games with CYP, we need basic stocktaking of actual existing practice and evidence. To this end, this scoping review aimed to describe *how user involvement has been implemented in designing games for CYP and what factors (if any) likely affect effective CYP involvement*. We articulated this aim in 4 research questions (RQs):

- RQ1: What user involvement methods are used for what purpose?
- RQ2: In what roles are CYP being involved?
- RQ3: How are user involvement methods implemented in detail?
- RQ4: What factors affect effective CYP involvement?

Methods

Study Design

For our scoping review, we combined a systematic literature review [36] with inductive qualitative content analysis [37]. We report our method following the revised 2020 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [36]. We did not preregister this scoping review because of the descriptive and exploratory nature. All study materials can be found in the Open Science Framework repository (Multimedia Appendix 1).

Eligibility Criteria

As noted, our review focuses on *user involvement methods* in the design of *applied games* with *CYP*. With "user involvement methods," we capture any approach that involves end users in the design of a game, such as participatory design, co-design, play-centric design, or user-centered design. With "applied games," we mean any attempt to create or use game-based software for a nonentertainment change. "CYP" was interpreted verbatim from the records that captured a variety of age ranges, for example, 2 to 4 years or 16 to 25 years.

Unfortunately, there are no well-established standard terms or controlled vocabularies for our search focus; for example, applied games are commonly called "serious game," "game-based," "game for X," or "gamified X." Following similar reviews [10,11,38], we developed a core search string that combined a range of synonymous keywords for each aspect, such as *CYP*, *games*, *applied contexts*, and *user involvement methods* (Textbox 1).

We analyzed papers published in the last 10 years (January 1, 2010, to December 7, 2021), and as the field of applied games is quite new, we did not expect a great number of texts before this date. We implicitly focused on selecting papers that had a specified “applied context” (Textbox 1) in which, for example, games were developed with young people for “mental health” or “education.” Furthermore, we focused on the last 10 years of records owing to the development and changes in technologies and methodologies. Capturing recent (within 10 years) studies provides an up-to-date overview of the state of the literature.

We included full length papers that reported on the design of game-based software targeting CYP and explicitly featured and reflected on user involvement methods. As we are interested in understanding the factors affecting user involvement, we excluded papers that did not reflect or evaluate the user involvement methods they used. We did not exclude papers based on application contexts—we wanted to avoid unnecessary focus on a specific domain, such as health-related literature, because insights may already have been made in educational gaming or entertainment game design but ignored by us because of a narrow focus on health-related literature. We excluded short or work-in-progress papers, because they did not provide enough space for detailed reflection and reporting on the methods used. We did not investigate gray literature because of the difficulty of creating a reliable and reproducible search strategy for such a dispersed and unstructured collection of materials with no core databases. See Textbox 2 for the full inclusion and exclusion criteria.

Textbox 1. Full list of used synonymous key terms for constructing search strings, in which a search string combines all terms, that is, children and young people (CYP) synonyms AND games synonyms AND applied context synonyms AND user involvement method.

CYP

- Young people
- Young adults
- Students
- Kid
- Child
- Adolescent

Games

- Game
- Video game
- Computer game
- Gamified
- Game based

Applied contexts

- Mental health
- Mental disorders
- Anxiety or depression
- Therapy
- Cognitive behavioural therapy
- Human computer interaction (HCI)
- Education
- Learning
- Behaviour change

User involvement method

- Co-creation
- Co-design
- Co-production
- Participatory design
- Patient centred design
- Patient partner involvement
- User-centred design
- Person-centred
- Collaborative
- Iterative design
- Cooperative

Textbox 2. Inclusion and exclusion criteria.

Inclusion criteria

- Article features user involvement methods
- Article reports on the design of game-based software
- Game-based software targets audience of children or young people
- User involvement methods are evaluated or reflected on
- Full paper

Exclusion criteria

- No user involvement method
- No reflection or evaluation of user involvement method
- Not related to game-based software
- Not published in English
- Not a full or original paper (eg, work in progress, conference summary, or workshop)
- No children and young people involved
- Not retrievable

Information Sources and Search Strategy

We searched 4 databases: the ACM Digital Library, IEEE Xplore, Scopus, and Web of Science. These databases mirror the interdisciplinary structure of research on applied games: the Association for Computing Machinery Digital Library and IEEE Xplore, which cover computing and HCI conferences and journals in which the bulk of technical games research is published, while Web of Science and Scopus capture disciplines such as medical research, psychology, and education.

Before starting our search, we iterated on variations of search strings implementing our target keywords (Textbox 1) for each database, because each database afforded different search strings tools. The final search strings are presented in Multimedia Appendix 2. We conducted the first full search on May 7, 2021, and the last search on July 5, 2021.

The studies retrieved from the databases were managed using State of the Art through Systematic Review (StART; version 3.3, Beta 03; Laboratório de Pesquisa em Engenharia de Software). StART identified additional studies through snowballing, which were added to the selection for screening. In addition, 14 studies were manually added.

Selection Process

We first removed duplicate records using StART, which identified duplicates across databases. Additional duplicates were then manually removed from the selection. The first author then manually screened titles, keywords, and abstracts against the eligibility criteria; sourced full texts of the eligible studies; and then manually assessed full texts for eligibility. Finally, records that were reported in the same study were merged.

Data Items and Collection Process

All relevant information was extracted in StART, which was then exported (xlsx format) into the qualitative data analysis software NVivo (version 12; QSR International) for open coding across the extracted information. For each eligible study, the first author extracted standard metadata (title, authors, abstract, and year) in addition to a range of descriptive data.

To describe our sample and study characteristics, the first author coded papers by the following parameters:

1. Discipline: disciplines were coded first verbatim by the title and self-description of the publication venue and then inductively aggregated; for example, a paper published in ACM HCI was coded as “human-computer interaction,” as it describes itself as “The ACM CHI Conference on Human Factors in Computing Systems is the premier international conference of Human-Computer Interaction (HCI).”
2. Date of publication: extracted from paper metadata
3. The country where the study was conducted: extracted verbatim from the Methods section
4. The number of CYP involved: extracted from the Methods section of the paper
5. The age and age range of CYP involved: extracted from the Methods section of the paper
6. The kind and number of participant groups involved: participant groups (eg, children, parents, and clinicians) were first extracted verbatim from the method sections, and then the number of different groups was counted.

To describe user involvement methods and roles, the first author coded papers for the following factors:

1. The self-labeled user involvement methods used: extracted verbatim from how the authors labeled their study in the title or Methods section; this resulted in multiple labels for some studies in which terms were used interchangeably.
2. The authors’ stated aims of user involvement: first extracted verbatim from the “goal” or “aim” statements of each paper, then inductively coded into higher-level categories, such as “determine features and functionality” or “explore methodology”; 1 paper could entail multiple aims.

3. In what capacity were CYP involved: first extracted as verbatim labels given to their roles in the paper (Multimedia Appendix 2); where roles were not explicitly labeled in the paper, we noted them as "not stated." On the basis of the full paper description of children's involvement, we inductively mapped each study on the Druin [39] 4-fold typology of children's roles in the development of new technologies.

Finally, to describe *how user involvement was implemented and how to identify emerging factors affecting it*, we imported the extracted data fields and full-text PDF documents into NVivo for inductive qualitative content analysis [37]**.** The first author inductively coded the method, discussion, and conclusion sections of papers for related emerging themes in the first and second focused coding cycle [40]. Descriptively, (10) *study structure*, (11) *activities*, and (12) *media and tools* have emerged as high-level categories. Of these, the activities were clear and distinct enough that we could conduct a follow-up frequency count. In terms of (13) *factors affecting user involvement*, 4 themes emerged.

Bias and Certainty Assessment

Because the aim of our study was narrative description, not establishing summary effects, no bias or certainty assessments were performed.

Synthesis of Results

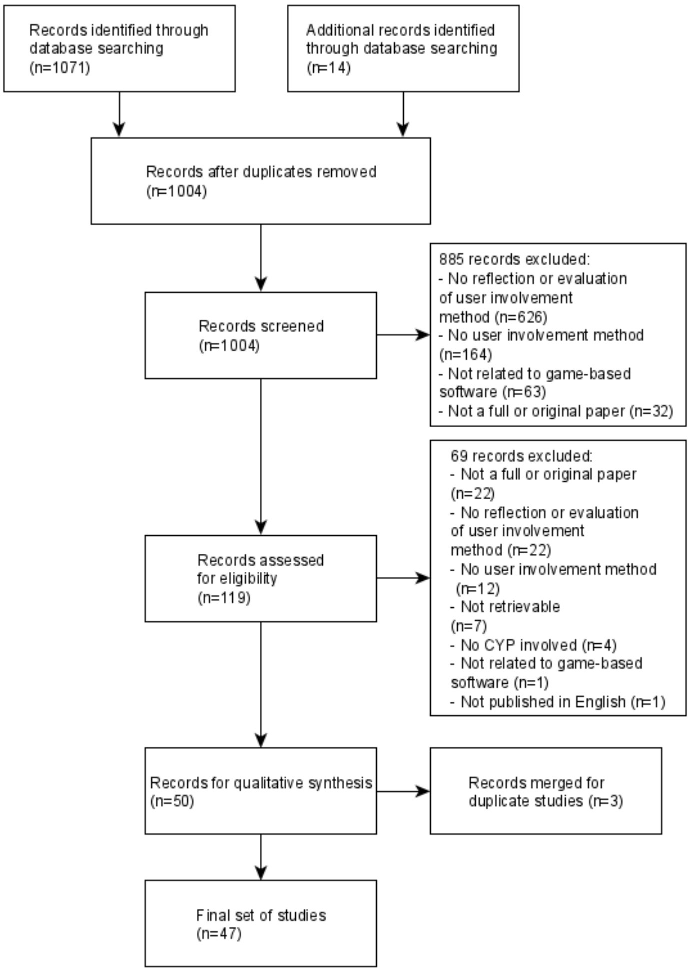
For descriptive summary reporting, we calculated the frequencies for (1), (2), (4), (5), (6), (7), and (11). Emerging themes and observations were synthesized through standard inductive qualitative content analysis.

Results

Study Selection

Our search returned 1085 records. Title and abstract screening removed 81 duplicate records and further excluded 885 records, of which 164 (18.5%) did not clearly incorporate user involvement methods, 626 (70.7%) lacked explicit reflection of user involvement methods, 63 (7.1%) were not related to game-based software, and 32 (3.6%) were not full papers. At the full-text stage, of the remaining 13.4% (119/885) of records, we excluded a further 69 (58%), of which 22 (32%) were not full papers, 12 (17%) lacked user involvement methods, 22 (32%) lacked a detailed reflection of them, 4 (6%) had no CYP involvement, and 1 (1%) was not related to games; we could not obtain access for 7 (10%) records, and 1 (1%) was not published in English. Of the 50 remaining papers, we merged 3 (6%) paper pairs that reported the same study, resulting in 47 final studies in the analysis. Figure 1 presents the PRISMA flow diagram.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. CYP: children and young people.



Study Characteristics

Table 1 presents the characteristics of the included studies; 47% (22/47) of the studies were from computer science and HCI, 19% (9/47) were from education, 17% (8/47) were from serious games or games design, 11% (5/47) were from health, and 6% (3/47) were from psychology. There was no clear upward or downward trend in the publications over time. In total, 85% (40/47) of studies were conducted in the Global North, led by European countries (15/47, 32%), then the United Kingdom (13/47, 28%), Australia and New Zealand (7/47, 15 %) and the United States (4/47, 9%), followed by Brazil (3/47, 6%) in the Global South.

The sample size of CYP involved ranged from 2 to 109, with an average of 23 (SD 24.8) and a median of 13. Table 2 shows the frequency of sample sizes with 26% (12/47) studies involving 6 to 10 participants, 23% (11/47) involving 11 to 25 participants, 19% (9/47) involving 26 to 50 participants, 17% (8/47) involving 1 to 5 participants, and 15% (7/47) involving >51 participants. This is likely because (1) most studies focused on interventions for intersectional groups, such as children with learning difficulties, in which sampling can be challenging; and (2) user involvement methods often value “thick data” with small-sample qualitative methods and a struggle to scale to large participant numbers. Nevertheless, many studies have reported “small sample sizes” as a limitation.

Table 1. Characteristics of studies.

Study	What method or methods were labeled or framed?	Participant groups, n	Groups involved	Discipline	How long was the study?	Median age (years)	Young people, n
All et al [41], 2012	Co-design	3	CYP[a], teachers, other experts, designers and developers, and researchers	Interaction design	Unknown	17.5	72
Alves and Hostins [42], 2019	Design-based research	3	CYP, designers and developers, and researchers	HCI[b]	4-6 months	9	4
Al-Wabil et al [43], 2010	User-centered design	4	CYP and clinicians	HCI	Unknown	15.5	6
Anacleto et al [44], 2012	Participatory design	3	CYP, clinicians, and support group	HCI	2-3 months	9.5	2
Anthony et al [45], 2012	Participatory design	4	CYP, designers and developers, and researchers	Game design	<1 day	20	12
Aufegger et al [46], 2020	Co-design	4	CYP, carers and family members, designer and developer, clinicians, and researchers	Computer science	2-3 months	9	14
Benton et al [47], 2012	Participatory design	5	CYP, teachers, and researchers	Health	2-3 months	12.5	12
Benton and Johnson [48], 2014	Participatory design	3	CYP, carers and family members, teachers, and researchers	Education	2-3 months	12	12
Bonsignore et al [49], 2016	Co-design	3	CYP, other experts, designers and developers, and researchers	Interaction design	10-12 months	15	40
Bossavit and Parsons [50], 2016	Participatory design	2	CYP and researchers	Computer science	2-3 months	13	4
Cassidy et al [51], 2015	Participatory design	6	CYP and researchers	Health	<1 day	7.5	29
Cheng et al [52], 2018	Participatory design	2	CYP, designers and developers, other experts, and researchers	Serious games	>1 year	20.5	14
Christie et al [53], 2019	Co-design	3	CYP, clinicians, designers and developers, and researchers	Interaction design	<1 day	Adolescents	30
de Jans et al [54], 2017	Co-design	3	CYP, teachers, support group, and researchers	Computer science	4-6 months	15	109
Durl et al [22], 2017	Co-design	3	CYP, teachers, support group, and researchers	Serious games	1-7 days	11.5	58
Eriksson et al [55], 2019	Co-design	4	CYP, other experts, designers, and developers	Computer science	<1 day	11	6

Study	What method or methods were labeled or framed?	Participant groups, n	Groups involved	Discipline	How long was the study?	Median age (years)	Young people, n
Gennari et al [56], 2019	Co-design	3	CYP, researchers, and other experts	Education	1-7 days	14	4
Gonsalves et al [57], 2019	Person-centered approach	3	CYP and teachers	Game design	4-6 months	10.5	46
Kang et al [58], 2021	Participatory design	3	CYP, teachers, and researchers	Health	2-3 months	9.5	7
Kangas [59], 2010	Design-based research	3	CYP, carers and family members, and researchers	HCI	<1 day	10	68
Khaled and Vasalou [60], 2014	Participatory design	3	CYP, teachers, and researchers	Computer science	2-3 months	11	13
Kostenius et al [61], 2018	Participatory design	5	CYP, carers and family members, teachers, and researchers	Psychology	N/A[c]	10.5	18
Lee et al [62], 2019	Co-design	3	CYP, teachers, and researchers	Psychology	2-3 months	13	4
Leitao et al [63], 2019	Participatory design	3	CYP, clinicians, and researchers	Education	N/A	9.5	36
Malinverni et al [64], 2014	Participatory design	3	CYP, carers and family members, designer and developer, teachers, and researchers	HCI	7-9 months	7.5	4
Martens et al [65], 2018	Co-design	2	CYP, teachers, designers and developers, clinicians, and other experts	Computer science	2-3 months	10	24
Marti et al [66], 2016	Co-design	2	CYP, carers and family members, teachers, and support group	Game design	2-4 weeks	9.5	6
Metatla et al [67], 2020	Co-design	3	CYP, teachers, and researchers	Interaction design	>1 year	10	8
Nouwen et al [68], 2016	Participatory design	3	CYP, other experts, designers, and developers	Computer science	10-12 months	18	16
Patchen et al [69], 2020	Participatory design	3	CYP, designers and developers, and researchers	Health	N/A	16.5	86
Pavarini et al [70], 2020	Participatory design	4	CYP, researchers, designers, and developers	Education	>1 year	18	30
Pollio et al [71], 2021	Participatory design	2	CYP and researchers	HCI	N/A	6.5	13
Porcino et al [72], 2015	Participatory design	4	CYP, carers and family members, and clinicians	Game design	4-6 months	9.5	6
Powell et al [73], 2019	Realist evaluation	5	CYP, teachers, and researchers	Interaction design	2-3 months	13.5	7
Rötkönen et al [74], 2021	Co-design	3	CYP and researchers	Education	N/A	9.5	5

Study	What method or methods were labeled or framed?	Participant groups, n	Groups involved	Discipline	How long was the study?	Median age (years)	Young people, n
Raynes-Goldie and Allen [28], 2014	Participatory action research	4	CYP, teachers, and researchers	Education	1-7 days	19.5	7
Regal et al [75], 2020	Cocreation or co-design	2	CYP, designers and developers, and researchers	Game design	1-7 days	Adolescents	9
Romero et al [76], 2018	Cocreation or cocreativity	3	CYP, teachers, and clinicians	Serious games	N/A	4.5	8
Stalberg et al [77], 2016	Co-design	4	CYP, carers and family members, and clinicians	Health	<1 day	11.5	54
Sutton et al [78], 2020	Co-design	9	CYP and other experts	Computer science	10-12 months	11	8
Terlouw et al [79], 2021	Iterative design	6	CYP and researchers	Education	<1 day	22	37
Triantafyllakos et al [80], 2011	Participatory design	3	CYP, designers and developers, researchers, clinicians, and other experts	Psychology	1-7 days	16	28
Vallentin-Holbech et al [81], 2020	Cocreation or cocreativity	6	CYP, other experts, designers and developers, and researchers	Computer science	7-9 months	15	35
Vasalou et al [82], 2012	User-centered design	4	CYP, teachers, and researchers	Education	2-4 weeks	10	60
Waddington et al [83], 2015	Participatory design	5	CYP and researchers	Computer science	2-4 weeks	16.5	4
Werner-Seidler et al [84], 2017	Participatory design	2	CYP, designer and developer, and researchers	Computer science	<1 day	14	21
Zhu et al [85], 2019	Co-design	3	CYP, support group, carers and family members, and researchers	Education	10-12 months	15	6

[a]CYP: children and young people.
[b]HCI: human-computer interaction.
[c]N/A: not available.

Table 2. Sample size variance (n=47).

Sample size groups	Frequency, n (%)
1-5	8 (17)
6-10	12 (26)
11-25	11 (23)
26-50	9 (19)
>51	7 (15)

The youngest age sampled across all studies was 3 years, and the oldest was 25 years as a part of a "young people" sample spanning ages 16 to 25 years [52]. The median age sampled was 11.5 years. Most studies (30/47, 64%) sampled an age range from 0 to 3 years (where 0 would be a precise age in years and 3 would be an age range of, eg, 6 to 9 years; Table 3).

Although our review focused on studies involving children, we were also interested in the participant groups that were involved. The plurality of studies (23/47, 49%) involved 3 different participant groups. The predominant groups were CYP (n=47, 100%) owing to inclusion criteria specifying CYP involvement. Studies also label CYP as patients, learners, or target audiences.

Subject-matter experts (39/47, 83%), such as health professionals (11/47, 23%), teachers (18/47, 38%), and other experts (10/47, 21%), were cumulatively the second-most frequent participating group (Table 4). Other experts encompassed were from areas such as film, photography, art, and music. The researchers conducting or facilitating the study were the next most frequently involved group (36/47, 77%) in the design process. Researchers included those carrying out the study and references to scientists who were also involved in the study. Some studies also used designers and developers (17/47, 36%), which included game design companies, masters' students in HCI, game designers, graphic designers, and artists, to help with the development of games or interactive technologies. Support groups (5/47, 11%) included learning assistants, pastoral care coordinators, and special education coordinators who helped support CYP participation.

Study length varied greatly, and in 17% (8/47) of studies, the study length could not be determined from the sampled records. The most frequent duration was 2-3 months (10/47, 21%), followed by studies conducted in ≤1 day (8/47, 17%). Studies conducted in ≤1 day were often short workshops or sessions of 1- to 2-hour activities. Studies conducted over 1 to 7 days (5/47, 11%) were the next most frequent. This was followed by studies that took either 4-6 months (4/47, 9%) or 10-12 months (4/47, 9%). Studies conducted between 2 and 4 weeks (3/47, 6%) and 10-12 months (4/47, 6%) were less frequent, and the lowest frequency was 7 to 9 months (2/47, 4%). A consideration to take into account is that it is not clear whether some studies are reporting the length of the whole study, including recruitment, procedure, and analysis, or whether they are reporting the duration of participants involvement in the study.

Table 3. Age variance (n=47).

Age range variance (years)	Frequency of studies, n (%)
0	7 (14)
1	5 (11)
2	10 (21)
3	8 (17)
4	6 (13)
5	2 (4)
6	3 (6)
7	3 (6)
8	0 (0)
9	3 (6)

Table 4. Stakeholder groups involved (n=47).

Stakeholder group	Frequency in studies, n (%)
Children and young people	47 (100)
Researchers	36 (77)
Teachers	18 (38)
Designers and developers	17 (36)
Health professionals	11 (23)
Other experts	10 (21)
Carers and family members	9 (19)
Support groups	5 (11)

User Involvement Methods Used

Self-labeled User Involvement Method

The overwhelming majority of studies self-labeled their user involvement method as "participatory design" (20/47, 43%) or "co-design" (16/47, 34%; Table 5). However, different studies have used and understood these terms differently with no stable consensus. Some considered participatory design as the overall research area and co-design as the method [56,60,77,82]. Others positioned the 2 as separate methods [62,66], while others used terms interchangeably [75,85]. The most common definition of "participatory design" was to "involve end users in the design process" [45,48,68,72,86], which some interpreted strongly because end users fully and equally participated throughout the whole design and development process [68,70], while others read it weakly as "invit[ing] users to contribute ideas" [71]. There was further less consensus and clarity regarding the meaning and use of "co-design."

Table 5. Frequency of self-labeled user involvement methods (n=47).

User involvement method labeled	Frequency in studies, n (%)
Participatory design	20 (43)
Co-design	16 (34)
Cocreation or cocreativity	3 (6)
Design-based research	2 (4)
User-centered design	2 (4)
Realist evaluation	1 (2)
Iterative design	1 (2)
Participatory action research	1 (2)
Person-centered approach	1 (2)

Stated Goals of User Involvement

Several studies have expressed >1 goal of involving users (Table 6). The most frequently stated aim was to design a game, either a prototype or a finished system (22/47, 47% of studies); 38% (18/47) of studies aimed to gather feedback on features and functionality; 26% (12/47) of studies were "meta"-studies aimed at examining involvement, that is, understanding the impact and form of CYP involvement overall; and a further 21% (10/47) of "meta"-studies explored a particular user involvement method or technique. For example, Benton and Johnson [48] explored the use of the participatory design approach to meet the needs of young people with autism spectrum disorder. A further 19% (9/47) of studies aimed to develop skills, meaning that the process served as a learning outcome, such as developing CYP design skills. Overall, 17% (8/47) of studies aimed to understand CYP needs and preferences around gaming, and a further 15% (7/47) of studies aimed to understand CYP's perception and concerns around the context or technology of the study. Overall, 6% (3/47) of studies focused on improving the user experience of existing products or prototypes, and finally, 4% (2/47) of studies explicitly aimed to create guidelines on how to conduct co-design with CYP (other studies did produce recommendations or guidelines but did not state this as the intended goal behind user involvement [47,62,64,73,82]).

In summary, the included studies stated a wide range of reasons for involving users, with the overwhelming majority focusing on directly informing design and development, from formative research on user needs, preferences, concerns, and contexts (15 studies) to feedback on features and functionality (18 studies), directly making a game (20 studies), or improving user experience (3 studies). Against this stand comparatively fewer "meta"-studies in user involvement and supporting methods themselves (22 studies) and the aim to skill up CYP (9 studies).

Table 6. Frequency of user involvement goals (n=47).

Goals of studies	Frequency, n (%)
Design a game with participants	22 (47)
Feedback on features and functionality	18 (38)
Examine involvement	12 (26)
Explore methodology	10 (21)
Develop skills	9 (19)
Understand children and young people needs and preferences	8 (17)
Understand perceptions and concerns	7 (15)
Improved user experience	3 (6)
Create guidelines	2 (4)

Involvement Roles of CYP

The dominant verbatim labels used for CYP involvement roles were "informant" (26/47, 62% of studies) and "co-designer" (20/47, 42%), followed by "playtester/tester" (4/47, 9%), "validation" (4/47, 9%), "co-creator" (4/47, 9%), "end user" (2/47, 4%), and "co-researcher" (1/47, 2%). Overall, 11% (5/47) of studies did not indicate a particular role of involvement (note that a single study could identify multiple roles for CYP; hence, percentage added up to >100%).

Similar to self-labeled methods, these role labels can cover a wide variety of actual degrees and types of involvement. In addition, we coded all studies using the Druin [39] influential taxonomy of 4 possible roles children can play in the design of new technology, in which each successive role can be seen to be more agentic than and encompass the previous ones: ([[[[user]tester]informant]design partner]). Each role also differs in the CYP-adult interaction (from indirect observational input to feedback, dialogue, and elaboration on adult ideas), forms of technology materializations engaged with (from ideas to prototypes to existing products), and goals of inquiry (from developing theory about use to assessing technology effects to improving design and usability):

1. *CYP as users* describes studies in which adults observe CYP using technology to assess technology effects and build use theory.
2. *CYP as testers* describes studies where CYP act as usability (or play-) testers, usually of prototypes, which can help assess effects, build theory, and improve designs; here, CYP can provide direct feedback on designs.
3. *CYP as informants* describes studies in which CYP can be involved in the full spectrum of human- or user-centered design methods, from formative research, such as interviews, contextual inquiries, and the like, to testing and validating prototypes at the evaluative end; here, CYP can engage in dialogue with adults and elaborate on their ideas and concepts.
4. *CYP as design partners* describes studies where CYP are equal stakeholders to adults; throughout the design process, they may engage in all the previously described activities, but in addition, CYP may engage in user research and design activities, such as data collection, brainstorming, or prototyping themselves, directly and jointly with adults.

We coded each included study according to these roles by examining how CYP had been involved in the procedure of the user involvement method and mapping this to the Druin [39] taxonomy (Table 7). According to this classification, in 51% (24/47) of the studies, CYP were involved as design partners; 70% (33/47) of studies involved CYP as informants; and testers and users were involved in 11% (5/47) of studies each. In 2 studies, CYP were only involved as users, and 1 study involved them only as testers. Finally, it is worth noting that 2 studies explicitly adopted Druin [39] taxonomy and ensured the involvement of CYP in each of the 4 roles [43,75].

Table 7. Role of children across studies.

Role	Total number of occurrences	Studies
User	5	[43,58,66,72,75]
Tester	5	[28,43,53,62,75]
Informant	33	[41-43,45,46,48-50,52,53,55-57,59,60,63,64,66-70,74-84]
Design partner	24	[22,43,44,46,47,49,51,54,55,59-63,65,68,69,71,73,75,79-81]

How User Involvement Is Implemented in Detail

Inductive coding of the studies' method descriptions yielded 3 high-level categories of how user involvement was implemented in detail: structure and sessions, activities, and media and tools. *Session structure* describes recurring stages and an overarching facilitation organization. *Activities* captures the specific tasks conducted with stakeholders, while *media and tools* describe the range of media and existing games used in activities.

Session Structure

In total, 8 studies involved an initial *onboarding or sensitizing stage* to create familiarity with the project topic and team, communicate its goal, and help in understanding the upcoming process [22,50,54,68,74,75,78,81]. This was suggested to build trust between participants, foster user engagement, and make an effective co-design process more likely [22,81]. In 2 studies, onboarding consisted of exploring an existing solution to familiarize oneself with the technology and underlying concepts of the research area [48,81]. In another study, the sensitization steps involved introducing users to the topic through challenges and competitions, which also helped build trust with facilitators [22].

Ten studies [41,42,44,47,48,59,63,64,82,85] described an *ideation or brainstorming stage* to help frame user needs and provide users with a starting place. Notably, brainstorming could be used to generate game ideas [42] or to understand existing user practices and areas of technology-based support [44]. This was often supported by starting exemplars and paper templates [41,47,59,63,64], such as empty scenario storyboards or empty mobile phone screens, or a homework task and prepared video-seeding material for ideas [50]. Two repeatedly mentioned challenges and considerations for this phase are the common "groupthink" converging of participant groups on a first or loudly voiced idea blocking further ideation [47,48] and CYP capabilities to actually conduct ideation [47]—although some noted that CYP tends to bring a beneficial high degree of gaming literacy [82].

In total, 17 studies [45,47,49,51,52,55,56,58,62,63,65,70,71,74,75,77,79] reported the *prototyping stage*. These prototyping stages included sessions in which CYP were involved in the design and development of game ideas [52,58,75], game characters or narrative [49,62,71], and generated alternative ideas to an existing idea [63,77]. Prototyping was seen to afford a sense of ownership in the resulting designs for CYP [62], often challenging researchers' assumptions on end users, and often leading to in-depth reflection from participants [55,70,71]. Reflection was 2-fold, in which studies designed sessions of reflection, and reflection surfaced unexpectedly. For example, 2 studies designed reflection meetings to iterate and improve future design sessions [45,74], whereas another study found that the design process led to participants reflecting on their game-play experiences compared with other participants [55]. One study deliberately scheduled reflection meetings after prototyping as the basis for future iterations [74]. Two challenges observed in this phase were the limitations of the prototyping tools used and what CYP wanted to portray, in which the limitations of paper prototyping were challenging for CYP to articulate the actions they expected from a digital prototype [51].

An *evaluation stage* was rarely mentioned across studies, where the design process was discussed with participants on its engagement, effectiveness, and efficacy as a user involvement method. Outside the reflection meetings, 4 studies scheduled an evaluation stage to gather feedback on the user involvement process [45,47,80,81]. These studies discussed how to make the interaction during the design process more engaging [45], how they found the process as a whole [80], how they could be more involved [47], and how they could cooperate with others [81]. Notably, only 7 studies evaluated the prototypes developed at the end of the study [43,45,47,52,53,80,81].

Activities

Our coding resulted in 45 different activities, of which 19 (42%) were only shown in a single study (omitted in Table 8). Paper prototyping was the most frequently conducted activity, mentioned in 20 studies with labels, such as "paper play activity" [44] or "sketchbook prototyping" [52]. We coded this separately from low-fidelity prototyping (used in a further 7 studies); even though the boundaries between the 2 are not clear-cut, some low-fidelity prototyping would involve paper storyboards and sketches. Regardless, both were reported as affording a positive experience to end users [58,68,80], for example, by giving every participant some hands-on experience [45]. Hands-on experience affected both agencies, in which hands-on experience was a method to assess games with users and understand outcomes [65,66], and learning, in which hands-on experience served as a method of learning technology or understanding the context [28,45,59]. The prepared templates were repeatedly mentioned to facilitate prototyping [63,86]. Paper prototyping was reported to be inclusive [45], low cost [51,65], and using only easily accessible materials [51]. Observed challenges in prototyping included struggling to represent the intended playful interaction with digital technology [51], and that was less suited to older teens because of the hypothetical or "blue-sky" situations when they are at a developmental point of building their own opinions distinct from others [49].

Mapping between activities and design stages was difficult because activities were used across different design stages and in cases that were not transparent when and why activities were used. For example, (focus) group discussions, the second-most prevalent activity (19 studies), were used as icebreakers [45,56], to generate ideas [46,50,63] and reflect on the end product [22,55,57,61]. In another instance, the fourth-most prevalent activity interviews (used in 17 studies) were used equally formatively to discover and define the problem space [41,59,82] and evaluate prototypes or concepts [24,52,53,81]. Presumably because our study sample overall leaned toward "earlier" sensitizing, ideation, and prototyping stages, most activities were used in these stages; only *feedback sessions*, some instances of *game-play evaluation*, and 1 *timeline activity* [68] (asking CYP players to chart their game-play likes and dislikes and experiences of challenge) occurred during an evaluation phase.

The included studies entailed little explicit reflection or evidence of the effectiveness of the conducted activities, with a few exceptions. For example, Nouwen et al [68] outlined which particular activities generated particular user insights and related design impacts. Pavarini et al [70] organized feedback sessions in which CYP could suggest features and processes for better future user involvement. However, even these observations remain unvalidated and can disagree with one another. Thus, although several studies recommended "free play" to provide CYP creative freedom of expression [55,68,86], Nouwen et al [68] found that this had little design impact because the media created during free play were unsuitable for the design brief. Further details of methods and activities can be found in Multimedia Appendix 3.

Table 8. Frequency of activities across studies that were used in more than one study (n=47).

Activities	Description	Frequency, n (%)
Existing games (demonstration or play)	Participants are given existing games, game prototypes, or materials to play or interact with	18 (38)
Group discussion or focus group discussion	Participants work together and talk about ideas, concepts, or solutions	19 (40)
Paper prototyping	Participants use mainly paper to design ideas and solutions	20 (43)
Interviews (with end users)	Researchers interview end users (CYP[a]) for their thoughts, preferences or feedback on a prototype, context, or problem area	17 (36)
Playtesting	Participants are given a prototype game and asked to play it (feedback is optional sometimes)	14 (30)
Storyboarding	Participants are given panels, comic strips, and slides and asked to generate how they would use the game, a scenario, or a solution	11 (23)
Surveys or Questionnaires	Both qualitative and quantitative surveys. Includes tools such as Likert scales and researchers directly asking CYP to give an answer on a scale	12 (26)
Brainstorming	Participants work together to generate ideas through group discussions, activities, or in some cases, individually	9 (19)
Role-play (or simulation)	Participants take on the role of others, for example, CYP acting as doctors, to bridge the challenges different stakeholders undergo	9 (19)
Feedback Session	Participants are shown a prototype and asked to give feedback	7 (15)
Introductory media (presentation, movie, etc)	A presentation, movie, talk, or activity is used to help onboard young people on what the goal of the workshop or activity is	6 (13)
Low-fidelity prototyping	Prototyping with models, figures, blocks, and early development digital games	6 (13)
Free play	Participants are given a game or demo and no goals are set; they can interact how they choose	5 (11)
Sticky notes	Tasks involving sticky notes or post its, usually a group-driven task	5 (11)
Scenario-based tasks	Participants are given a scenario in relation to the applied content with which to design a solution	4 (9)
Blank template task	Participants are given a template, for example, the wireframe of a phone screen, and use these to design solutions	3 (6)
Game idea or feature evaluation	Specifically when participants evaluate a component or proposed idea of a game	3 (6)
Logbooks (or taskbook or diaries)	Participants complete a workbook or taskbook after activities; also includes participants keeping a log of their behavior	3 (6)
Storytelling	Users create and share stories or concepts	3 (6)
Timeline (narrative design)	Creating a journey, or series, of steps in which a procedure, process, or story occurs over time or between different users	3 (6)
Game design workshops	Workshop that encompassed ideation and then evaluation and reflection of those ideas on how they can be improved	2 (4)
Icebreakers	Informal discussions and activities for participants to get to know each other	2 (4)
Map task	Using real world maps to choose a setting for their game idea and generate ideas [41,66]	2 (4)
Peer interviews	Interviews conducted by CYP to other CYP to gather data and help understand the context area	2 (4)
Question and answer	An activity were users presented predetermined answers (eg, cards) to questions proposed by researchers	2 (4)
Sensitization session	“Packages” or information circulated before user involvement sessions to understand CYP experience with context and games	2 (4)

[a]CYP: children and young people.

Media and Tools

Following the study by Brandt et al [87], participatory design tools and media can be classified into whether they support the practices of *making*, *telling*, and *enacting*. Bossavit and Parsons [50] observed that 2D mapping (making tool) and videos (telling tool) were useful for understanding concepts, while playing games (enacting) supported idea generation.

The choice of the media or tools used was a point of contention. Some suggested that CYP struggled to express themselves speaking while at the same time preferred speaking to writing [45,47]. In comparison, visual approaches and working with visual aids proved more engaging and effective, especially in younger age groups, potentially owing to their less-developed reading and writing abilities [49,50,62,66]. An exception to the method of media was seen in the studies by Metatla et al [67] and Regal et al [75] with visually impaired children, in which educational robot toys and physical building blocks were used to facilitate creativity through touch and sound. Overall, it seems that preferences for spoken, written, or visual media are related to the age of participants [45,49,62]. Therefore, this suggests that the choice of media and tools used should be determined by understanding participant preferences before the activities take place.

In total, 18 studies used existing games as activities. Existing games varied between existing prototypes developed before the study and existing commercial games [71,76,88]. Existing games were used not only as a tool for narrowing the scope of the research and "managing the expectations" of young participants but also as an icebreaker activity [76,88]. Existing prototypes were sometimes used as a starting point for prototyping or were introduced to users for feedback [45,47,76]. That said, several studies found that concepts and features proposed by CYP were usually informed by the commercial games they were familiar with [50,60,82,85].

Factors Affecting User Involvement

Overview

In this section, we report 5 prominent themes that studies have repeatedly covered as affecting user involvement: *comprehension*, *cohesion*, *confidence*, *accessibility*, and *time constraints*. We intentionally did not tie these themes to one particular conception or standard of "good" involvement. Rather, we took the study authors' own conceptions at face value: if a study articulated something as problematic or positive, we took it as such, also to reflect the variety of goals studies articulated for user involvement.

Comprehension

This theme captured that CYP *regularly struggled to understand the design process and context they participated in*. CYP repeatedly reported that they did not fully comprehend or remember the benefits or outcomes of the project and how it would impact their daily life [44] nor the aim or purpose of the task assigned to them [72,77,81]. A usability evaluation of one involvement method similarly revealed that tasks were either hard to identify and understand or hard to perform [77]. This problem could be even more common, as Waddington et al [83] observed that CYP did not mention when they struggled with an activity or prototype in their study, so long as they could engage with it; they therefore found it often necessary to gather additional external stakeholder feedback, because CYP did not complain. According to Porcino et al [72], some of these comprehension issues could arise from the lack of a clearly stated objective, insufficient time for a task or technology to become familiar with it, or facilitators not familiar with a given technology or method.

Relatedly, *how well-informed CYP were about a subject matter* impacted the efficacy and efficiency of user involvement: participants who were familiar with a given context proved to be more productive and gave much more concise feedback than unfamiliar ones [53]. Similarly, studies have found it difficult to define problems and identify designs in areas where participants were ill-informed about [54,81]. This should not be considered a one-way street. For example, Durl et al [22] found that involving vulnerable adolescents in a co-design study on alcohol abuse not only resulted in better design results but also made the adolescent participants more informed about alcohol abuse.

A final challenge to comprehension was *lacking familiarity with used technologies and methods*: this could be the use of basic technology like microphones [74] or the fact that participatory methods differ strongly from what CYP may be used to do in adult-guided activities in school. CYP expected asymmetry in power with adults dictating the direction of the study but experienced more symmetry in power and decision-making because of their suggestions being acknowledged [81]. This challenge could be addressed with additional introductory training and warm-up activities, which consume additional money and time [60].

Cohesion

Most studies involved ≥3 different groups of stakeholders. Therefore, it was unsurprising that many studies reflected on *different groups working together effectively as a united team* as a major factor of effective user involvement, which we here will call *cohesion*.

First, several studies reported *struggling to achieve agreement on a concept, solution, or decision*, likely because of the control each stakeholder group was given [42,74,76]. Control in terms of decision-making and contributing to the design process could be caused by expecting CYP to come to a natural agreement without clear constraints or guidance from adults. Two studies in particular presented open questions to young people and then presents "no right answer," which could be the cause of friction between young people [74,76]. Common approaches to this issue were discussion (for understanding different points of view) and voting mechanisms (for integrating disagreeing points of view into a decision) [76]. A connected challenge was ensuring that different end-user groups contributed more or less equally to decisions and end results [42,50,64,65]. Several authors observed that cohesion required *trust* between participants, although no particular approach has been suggested to build trust [42,76].

Another key factor for cohesion was a *cooperative and collaborative mindset and atmosphere*. Seven studies noted that these allowed CYP to express their views, support each other, and share ideas [22,28,42,55,59,80,81]. In contrast, a competitive dynamic was found to result in less-open idea sharing [76]. The study by Triantafyllakos et al [80] was one of the only studies to reference incentives, in which they used competition and challenges among participants to generate more ideas.

Breakdown in *communication* could lead to frustration and disappointment [76]. So, how can we afford to function in communication? One study found that a "natural" flow of communication among CYP in which each would have a chance to speak required dedicated facilitation [74], whereas another found that CYP compared with adults were much more direct and unfiltered in criticism, suggesting adult stakeholders should capitalize on this and not be guarded or protective of their ideas [47]. Using existing examples of games [45], as well as explicit tools and conceptual frameworks [55], was found to facilitate discussion.

Confidence and Empowerment

Confidence describes CYP's beliefs in their ability to effectively participate in user involvement, akin to the psychological construct of self-efficacy [89], and influences their participation in several ways [43,68].

CYP would participate more deeply if they felt more confident, which was largely seen as grounded in their past experience; for example, CYP's past experience with film production or game-making [81], using existing technology CYP are familiar with [44,85], immediate past experience of progress in particular workshop activities [68], or simply longer participation over time [47] would all increase CYP confidence, with positive effects.

However, studies differed in their view of whether CYP are generally confident to voice their opinions [43,83]. Two studies found that CYP had no apparent issue voicing their views directly [47,53], whereas others suggested to use behaviorally "honest signals," such as eye tracking, because CYP aged 5 to 12 years may say what adults like to hear [43,76] or observed parental interference as an obstacle to CYP sharing unfiltered feedback around sensitive topics like sexual health [62]. Flexibly adjusting group sizes and session lengths to fit CYP needs was found to make them more comfortable overall and share their views more openly [86].

Empowerment was also discussed in studies where young people were given control to make decisions or choices, facilitated by participating in activities, ownership of end products, and the innate challenge of designing a game, all contributed to a sense of empowerment [45,61,81]. While giving CYP power to make decisions over the end product increased a sense of empowerment [77,86], multiple and repetitive user involvement activities were reported to diminish it over time [64]. In addition, there were concerns about the misuse of empowerment as a method of manipulating participants to support the findings desired and empowerment tokenism, where the control over things lacks importance and others make important decisions [61]. Treating CYP as true design partners in game design was found to make it easier for adult participants to connect with CYP's concerns and, in turn, foster creativity [28].

Accessibility

Accessibility describes whether the CYP felt the involvement process was accessible to them and included them in the design. Accessibility was mentioned as a concern, especially in studies that targeted an end-user CYP population with specific needs that forced shaping user involvement around them [64,74,79,83]. Tailoring involvement tools for CYP's varying abilities [50] and engaging experts associated with CYP's disabilities (such as carers or teachers) [67] were 2 proposed strategies for improving accessibility. One game-specific accessibility issue mentioned was the development of game mechanics that would be accessible to all players, including those with disabilities, but remains challenging for all end-user groups [74,83].

Time Constraints

Time constraints have emerged as a major consideration in structuring user involvement. Co-designing games is time-consuming [65], to the point where de Jans et al [54] suggested that the months required for adults and CYP learning how to collaborate does not fit industry game development timelines. Several studies found that practical time constraints resulted in insufficient discussion of all ideas [74], insufficient preparation, and insufficient time for producing deliverables [76]. Three studies reported breaking the design process into separate phases across different days or sessions to maintain interest, attention, and energy as another important time-related constraint 51,75,76

Discussion

Principal Findings

Out of a total of 47 studies, 36 (77%) of our sample were self-labeled participatory design or co-design (Table 5). In line with previous reviews in related fields, such as co-design in health [90] or CYP involvement in child-computer interaction [91], these 2 broad labels gloss over a wide variety of actual involvement roles, aims, and activities. Most studies sampled (35/47, 74%) involved CYP as "mere" informants and about half (24/47, 51%) as true design partners (Table 7). These numbers appear to indicate deeper user involvement for CYP than in recent systematic review of general serious game development processes by Maheu-Cadotte et al [92] (who found only 1 in 21 processes involved participants as co-designers). However, because their inclusion criteria did not limit eligible studies to those with explicit user involvement, this is an unequal comparison.

The stated aims for user involvement ranged from instrumental ones of making a game or identifying features and functionality to meta-methodological interests, upskilling, and many others. We counted 45 different activities, with prototyping, interviewing, playtesting, and playing existing games being the most common. Studies commonly reported "early" onboarding, ideation, and prototyping phases; we found little mention of "later" development or production stages [64,78,82]. Furthermore, no records linked or referenced openly shared user-created design materials outside of screenshots and workshop photographs. Studies used a wide variety of tools and media, with some consensus that these should be tailored to the (developmental) preferences and abilities of the involved CYP. The reviewed studies did not discuss users' accreditation or rewards for their contributions, outside of 1 example, which suggests uncertainty on how to motivate or reward CYP for their participation.

Our qualitative coding of method reflection produced five factors that are likely to affect successful CYP involvement:

1. Comprehension: the better the CYP know and understand the context and subject matter and design process and used methods, tools, and technologies, the better their engagement and results seem to be.
2. Cohesion: engaging and effective CYP involvement depends on different stakeholder groups working collaboratively as one team, with reaching an agreement as a common challenge and facilitating a comparative noncompetitive mindset as an important success factor.
3. Confidence: the more confident the CYP were in their ability to participate, license to participate, and agency granted to them, the deeper they seemed to engage.
4. Accessibility: both age and disabilities or special needs put extra demand on making user involvement accessible to all participating CYP.
5. Time and space: affording creative time and space can help further the discussion of ideas and maintain interest throughout participation.

Reflection

Perhaps the strongest overarching observation when conducting this systematic review was how differently studies understood and used relevant terms such as "co-design" (2 studies could label their activity "co-design" and "focus group" yet do drastically different things); how differently and unevenly studies reported methods; how differently studies implemented these methods; and in how little detail studies actually documented their involvement methods, despite the fact that our review systematically sampled studies that explicitly reported and reflected on their user involvement. For instance, although we tried to map activities onto "where" in a standard design process, following the example in Vandekerckhove et al [20], we were not able to do so because of the low to absent detail of reporting. This is sadly in line with prior findings on co-design methods: studies rarely report sufficient detail to reproduce them, and there is no standard reporting format [90]. This lack of consensus terminology and reproducible method documentation standards hinders replication. This makes systematic assessment and integration of evidence difficult. In addition, it impedes actual know-how flows beyond tacit and in-person sharing between the members of a research group and project.

Unless we have clear, reliable, and reproducible standards for identifying and reporting types or degrees of user roles and identifying and reporting involvement methods, it is difficult to generate a meaningful systematic body of evidence on which roles or methods work better or worse for which groups of participants, contexts, or aims. This may be one reason why only 4 of the sampled studies reported any qualitative empirical evaluation of what worked and what did not with their involvement methods, even though 46% (22/47) of studies stated meta-methodological aims, such as assessing end-user involvement or involvement methods. Consequently, most reflections and derived recommendations on how to conduct user involvement remain speculative. Thus, we cannot conclude with much certainty anything about, for example, which user roles might work "better." Although there is a normative preference for the "deepest" possible involvement in much of participatory design, several studies in our review suggested that CYP struggled to act as meaningful co-designers in applied game design [76] and were more able to express themselves as play testers than when sketching their own concepts [63]. This may be partially because of the fact that applied game design requires both domain and game design expertise, which CYP likely does not bring, which may be bridged by more careful onboarding activities or involving multiple stakeholder groups with complementary expertise [60]. Although the involvement of young people has been reported to be essential to realize game prototypes, whether CYP has expertise, or even the availability to consistently collaborate, is a challenge for future research [93]. The important point here remains that we are at present not able to answer such questions or advise on "what works best" because of poor reporting.

Limitations

Our sample is obviously limited by its English-only focus and 10-year date range. The literature before 2010 would potentially paint a distinctively different picture, which would lead to divergent conclusions in this review. Study selection and coding were all performed by the primary author alone, meaning that we could not quantify the likely reliability and reproducibility of these steps, for example, intercoder reliability. The overall poor quality of method reporting in the sampled studies and the lack of existing controlled vocabularies or taxonomies of involvement methods means that our coding involved substantial degrees of judgment and construction in categorizing different kinds of involvement activities or classifying studies by user role. This does not impact verbatim extractions of self-labeling or similar, and we believe our overall assessment of the sheer diversity of reported practices is not touched by this.

Future Research

The first obvious direction for future work is to provide a robust shared basis for reporting and assessing user involvement in applied game development (with or without CYP); we need better consensus methods for defining, labeling, and identifying user involvement roles and methods and better guidance and standards on reporting user involvement in sufficient detail for later analysis or replication. Second, on this basis, we can start to analyze and empirically evaluate what kinds of session structures, methods, roles, media, and tools are more engaging in CYP and more effective for different involvement aims. Third, our review suggests that comprehension, cohesion, confidence, accessibility, and time constraints are likely to impact CYP involvement. Here, methodological research can explore whether and how much these factors matter, and then again, which structures, methods, roles, media and tools, and specific implementations thereof are better suited to support them.

Conclusions

This scoping review aimed to explore how CYP have been involved in the design of applied games. We found that a small range of labels (co-design and participatory design) hid a wide variety of actual involvement methods, aims, structures, roles, and implementations. Comprehension, confidence, cohesion, accessibility, and time constraints emerged as 5 likely nonexhaustive factors affecting effective and engaging CYP involvement. However, the reviewed literature documented its user involvement practices inconsistently and in little detail, and its recommendations for future practices are largely not grounded in robust empirical evaluations of (alternative) involvement approaches. Future work is needed to advance more robust and reproducible documentation of user involvement to enable knowledge sharing, as well as more systematic research on "what works" in user involvement of CYP in applied game design.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Open Science Framework repository.

[DOCX File , 12 KB - games_v11i1e42680_app1.docx]

Multimedia Appendix 2

Search strategies.

[DOCX File , 14 KB - games_v11i1e42680_app2.docx]

Multimedia Appendix 3

Definition of methods labeled and activities.

[DOCX File , 26 KB - games_v11i1e42680_app3.docx]

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Abbreviations

CYP: children and young people
HCI: human-computer interaction
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RQ: research question
StART: State of the Art through Systematic Review

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Review

Effectiveness of Digital Health Interventions Containing Game Components for the Self-management of Type 2 Diabetes: Systematic Review

Linda Ossenbrink[1*], MPH; Tina Haase[1*], Dr rer biol hum; Patrick Timpel[1], Dr rer med; Olaf Schoffer[1], Dr rer nat; Madlen Scheibe[1], Dr rer med; Jochen Schmitt[1], MPH, Prof Dr; Stefanie Deckert[1], MPH, Dr rer med; Lorenz Harst[1], Dr rer med

Center for Evidence-based Healthcare, University Hospital and Faculty of Medicine Carl Gustav Carus, Technische Universität Dresden, Dresden, Germany

[*]these authors contributed equally

Corresponding Author:
Lorenz Harst, Dr rer med
Center for Evidence-based Healthcare
University Hospital and Faculty of Medicine Carl Gustav Carus
Technische Universität Dresden
Fetscherstraße 74
Dresden, 01307
Germany
Phone: 49 37133335325
Email: lorenz.harst@tu-dresden.de

Abstract

Background: Games and game components have become a major trend in the realm of digital health research and practice as they are assumed to foster behavior change and thereby improve patient-reported and clinical outcomes for patients with type 2 diabetes.

Objective: The aim of this systematic review was to summarize and evaluate the current evidence on the effectiveness of digital health interventions containing game components on behavioral, patient-reported, and clinical outcomes for patients with type 2 diabetes.

Methods: An electronic search was conducted in MEDLINE and PsycINFO in April 2020; updated in April 2022; and supplemented by additional searches via Google Scholar, Web of Science (which was used for forward citation tracking), and within the references of the included records. Articles were identified using predefined inclusion and exclusion criteria. In total, 2 reviewers independently conducted title, abstract, and full-text screening and then individually performed a critical appraisal of all the included studies using the Cochrane risk-of-bias tool version 2. A consensus was reached through discussion.

Results: Of 2325 potentially relevant titles (duplicates excluded), 10 (0.43%) randomized controlled trials were included in this review. Quality assessment revealed a high risk of bias for all randomized controlled trials except for 10% (1/10), with performance bias due to the lack of blinding being the major source of bias. There is evidence suggesting that digital health interventions containing game components can substantially improve motivation for physical activity (1/1, 100% of the studies dealing with PA motivation), exercise intensity (3/5, 60%), dietary behavior (4/4, 100%), health literacy (1/3, 33%), mental quality of life (2/2, 100%), glycated hemoglobin level (2/6, 33%), BMI (1/3, 33%), fasting plasma glucose level (1/2, 50%), waist circumference (1/1, 100%), and aerobic capacity (1/1, 100%).

Conclusions: Published studies indicated that digital health interventions containing game components might improve health behavior patterns, quality of life, and clinical outcomes in patients with type 2 diabetes. However, the intervention types and outcomes studied were heterogeneous, and study quality was mostly low, which translates to ambiguous results. Future research should focus on sound methodology and reporting as well as on identifying game components that contribute to significant positive effects.

Trial Registration: PROSPERO CRD42020209706; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=209706

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KEYWORDS

diabetes; gamification; digital health; diabetes self-management; mobile phone

Introduction

Background

According to the 2021 and most recent Diabetes Atlas provided by the International Diabetes Federation, diabetes affects 537 million people worldwide, which equals a share of almost 7% of the world's total population [1]. Compared with the data provided in the 2019 Atlas, this is an increase in diabetes prevalence of almost 16% within 2 years [1]. The vast majority of people diagnosed with diabetes (95%) live with type 2 diabetes [2,3].

Apart from genetic predispositions and a higher probability of having a diabetes diagnosis at an older age, several risk factors of type 2 diabetes are lifestyle-related, such as physical inactivity; malnutrition; and, correspondingly, overweight and obesity [4]. Therefore, several clinical practice guidelines on the treatment of type 2 diabetes focus not only on pharmacological interventions but also on a comprehensive self-management regimen that includes theory-based behavior change [4-7]. Measures for the latter warranted by the so-called Diabetes Self-Management and Education (DSME) regimen defined by the American Diabetes Association (ADA) include education on symptoms, etiology of and coping with diabetes, the adoption of a healthy (ie, high fiber- and fruit- and vegetable-based) diet, and the uptake of regular physical activity (PA) as a means to achieve weight loss [4,6]. Apart from the education component, continuous monitoring of blood glucose values, food intake, and frequency and intensity of PA is a requirement of DSME [6].

The potential of digital health applications, such as telemedicine, for supporting patients regarding DSME is well documented for patients with a more recent diabetes diagnosis, especially for applications that enable continuous glucose self-monitoring or health care provider feedback on the values recorded [8].

Recently, interest has spiked in digital health applications containing game components as they are expected to offer aid in behavior change [9], which, for many patients, is a necessary precondition for successful DSME [10]. Game components such as scoring systems, trophies, and leaderboards have been shown to be effective in increasing the motivation for uptake of healthy behaviors in a number of chronic conditions [11] as well as a measure of health promotion. However, the methodological quality of the evidence is still moderate to low [12]. Educational games often rely on storytelling elements such as coherent narratives and episodes, which generate a so-called transportation effect where players immerse themselves completely in the narrative world, which loosens reluctance toward behaviors perceived as laborious or unpleasant, such as PA [13,14]. Exergames stimulate PA by challenging the players' abilities and rewarding success [15].

A moderating role of the regulatory mode can be assumed in the relationship between gaming and behavior change. According to theory, either individuals can assess the situation they are in and then develop the most adequate strategy to reach a behavioral aim (assessment) or they can just initiate the behavior for which they strive (locomotion). Locomotion is associated with higher intrinsic motivation, whereas assessment is associated with anticipating failure and, therefore, procrastination [16].

In 2016, a meta-analysis including both types of game-based interventions (educational games and exergames) for patients with diabetes (type 1 and 2) showed no effect on blood glucose values (glycated hemoglobin [HbA_{1c}]) but showed an effect on quality of life, balance, and muscle strength [17]. Theng et al [18] found that videogames were useful tools for diabetes education independent of diabetes type. However, the analyses are outdated (both searches were conducted in 2014) given the substantial increase in the availability of gamified health interventions, as evidenced by a recent overview of gamified interventions used in the context of diabetes [19], half of which were launched after 2016. The median survival time of reviews is 5.5 years before they are outdated [20]. In addition, patient populations and the measures taken to deal with type 1 and type 2 diabetes differ greatly [7], and so do the effective components of digital health applications [8]. Therefore, targeted game-based interventions are necessary as well. Furthermore, given the complex requirements of DSME, focusing the analysis solely on clinical outcomes and neglecting behavioral outcomes as well as patient-reported outcomes (PROs), as did Martos-Cabrera et al [21] and Kaihara et al [22], is limited in perspective.

Objectives

Therefore, the questions to be answered were as follows: (1) *Do digital game-based interventions have an effect on the health behavior of patients with type 2 diabetes?* and (2) *Do digital game-based interventions have an effect on clinical outcomes and PROs in patients with type 2 diabetes?*

Methods

The protocol for this systematic review was published beforehand in PROSPERO (CRD42020209706) and followed during the conduct of the review. Reporting of the results adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [23].

Study Inclusion and Exclusion

The inclusion and exclusion criteria were defined according to the population, intervention, control, outcome, and study design scheme (Textboxes 1 and 2). For this purpose, digital health interventions containing game components were defined as the intervention group, whereas usual care or the use of digital health interventions without a game component were defined as the control group.

Textbox 1. Study inclusion criteria.

Population

- Participants with type 2 diabetes (no age restriction)

Intervention

- Use of digital health applications containing game components identified in previous reviews [12,17] (such as virtual reality, serious gaming, or exergaming)

Comparison

- Use of digital health applications without game components or standard or usual care

Outcome

- Primary outcomes:
  - Behavioral outcomes such as physical activity or dietary behavior
- Secondary outcomes:
  - Patient-reported outcomes such as self-efficacy, patient empowerment, and quality of life
  - Clinical parameters such as glycated hemoglobin (blood sugar value), BMI, and systolic blood pressure or diastolic blood pressure

Study design

- Randomized controlled trials
- Nonrandomized studies (only when n>10)

Textbox 2. Study exclusion criteria.

Population

- Participants without diabetes or with type 1 or gestational diabetes

Intervention

- No treatment or intervention

Comparison

- No treatment or intervention

Outcome

- Neither behavioral outcomes nor patient-reported outcomes or clinical parameters studied

Study design

- Cross-sectional studies, qualitative studies, reviews, and meta-analyses

Only studies published in English or German were included.

Database Search

An electronic database search was conducted in MEDLINE (via PubMed) and PsycINFO to cover both medical and psychological research. The initial search was conducted in April 2020 and updated in April 2022 with no restrictions on start time. The search string (Multimedia Appendix 1) included terms covering type 2 diabetes (population), including Medical Subject Heading terms and synonyms for *game* and *gaming* (intervention) as well as game components, and was piloted in previous research [24]. Population and intervention terms were linked with the operator *AND*. No restrictions were imposed on the outcome category of the search string to avoid accidentally excluding relevant effects of gamified interventions.

Additional searches were conducted within the references of the included studies (backward citation tracking) as well as on Google Scholar and Web of Science, where publications citing the included studies were checked (forward citation tracking) in July 2022.

Screening and Data Extraction

The screening of relevant records was a 2-step process. First, 2 independent reviewers screened the titles and abstracts of all records found by the database and hand searches. If deemed relevant by at least one reviewer, the full text was assessed for eligibility by both reviewers as well. The reference manager EndNote (Clarivate Analytics) was used for both screening and duplicate removal.

Data were extracted according to the population, intervention, control, outcome, and study design scheme, aiming at allowing for a comparison of the effects of different gamified intervention types on the aforementioned outcome domains. In addition, the following information was extracted from each study: (1) bibliographic information, (2) population characteristics, (3) the allocation of the study participants to the intervention and control group or control groups, (4) treatment or interventions applied to the control group (as a means to account for plausible confounding factors), (5) inclusion and exclusion criteria of each applicable study (as a means to account for plausible confounding factors), and (6) outcome measures (to inform quality assessment).

The data extraction sheet was piloted by 2 researchers on 2 of the included studies, which were randomly selected, and subsequently slightly adjusted by including the category “outcome measures.” Data extraction was performed using a Microsoft Excel (Microsoft Corp) spreadsheet.

For a visual representation, HbA_{1c} values at baseline and after intervention completion were extracted in percentage or mmol/mol depending on the data available in the included studies, along with the SD. Δ HbA_{1c} was computed, and statistical significance was extracted from the included studies. The threshold for statistically significant effects was set at $P<.05$. No assumptions were made if information was missing; this was labeled as “not reported” instead. All study results were tabulated. Apart from the tabulation and visualization of HbA_{1c} results, the presentation of the results is narrative.

Quality Assessment

The randomized controlled trials (RCTs) found were assessed for study quality by applying the Cochrane risk-of-bias tool version 2 (RoB 2) [25], whereas cohort studies, if included, were assessed using the corresponding Critical Appraisal Skills Programme (CASP) cohort study checklist [26]. Case-control studies were assessed using the corresponding checklist also provided by the CASP [27]. The RoB 2 covers bias within an outcome resulting from the randomization process (selection bias); blinding of participants, assessors, and analysts; deviations from intervention delivery (performance bias); changes in participants’ adherence to the intervention (attrition bias); modalities of outcome measurement; or selective reporting (reporting bias). RoB 2 assessment was performed for each relevant study outcome according to our inclusion criteria. According to the RoB 2 manual, the overall risk of bias within a study was deemed high if 1 study outcome had a high risk of bias. Both records by Höchsmann et al [28,29] were treated as 1 study with several outcomes. CASP checklists for nonrandomized studies cover the same categories except for randomization and blinding while also putting an emphasis on practical implications of the study results. In contrast to the RoB 2, CASP checklists were applied to the entire study instead of to selected outcomes. The RoB 2 deems studies to be at a low risk of bias when a low risk of bias is detected for all relevant domains. Some concerns regarding the risk of bias within an outcome can be assumed when some concerns are raised for at least one domain. A high risk of bias can be assumed when multiple domains raise some concerns or a high risk of bias is detected for at least one domain [25]. With the CASP, overall risk of bias is assessed by answering the following question: “Do you believe the results?”

Quality assessment was performed for the effect of both assignment to the intervention (ie, the intention-to-treat effect) and adherence to the intervention (ie, the per-protocol effect).

All steps of the review—screening of titles and abstracts and full texts, data extraction, and quality assessment—were performed by at least 2 researchers independently (LO, LH, or PT in the first search period and LH and TH in the second search period) to minimize bias. Differences in inclusion, extraction, and quality assessment were resolved through discussion with a third person not involved in the screening process (SD).

Diversions From the Protocol

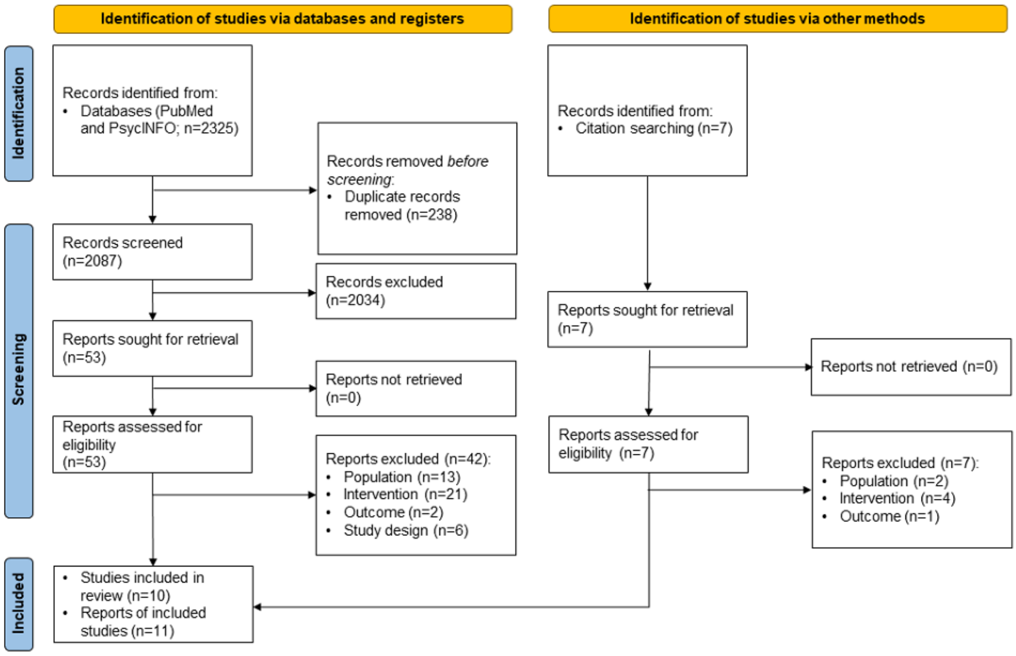
Contrary to the protocol registered with PROSPERO, research question 2 was adapted so that it clearly addressed PROs. Furthermore, we refrained from performing a search in key journals as these were all listed in MEDLINE.

Results

Results of the Search Process

Both database searches (2020 and 2022) taken together yielded 2325 results. A total of 7 additional potentially relevant publications were identified via additional searches, but excluded after full text assessment. In total, 2087 publications remained after duplicates were removed, 2034 (97.5%) of which were removed after title and abstract screening. The full texts of the remaining 53 publications were assessed for eligibility. This process led to the exclusion of 25% (13/53) of the studies as they addressed a population outside this review’s scope, such as patients with type 1 or prediabetes [30-42]. Another 40% (21/53) of the studies were excluded as the interventions studied did not have a game component [43-63]. A total of 15% (8/53) of the studies were excluded as they used 1-armed designs or did not study any of the prespecified outcomes but solely patient experiences, such as satisfaction with the application [64-71]. A complete list of the excluded studies with reasons for exclusion can be found in Multimedia Appendix 2 [30-71]. Finally, 10 studies were included in the qualitative data analysis [28,29,72-80]. Höchsmann et al [28,29] reported results from the same study in 2 records. The process of study selection is depicted in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram depicting study inclusion.



Descriptive Statistics of the Populations Studied

All the included studies (10/10, 100%) were RCTs. However, Kempf and Martin [78] and Brinkmann et al [72] applied a crossover design in which participants in the control group received the intervention later during the study period. The study samples ranged from 8 participants [72] to 465 participants [76]. The lowest mean age was 44 (SD 7.9) years [79] and the highest mean age was 68 (SD 5.8) years [73]. Brinkmann et al [72] only reported the age span of the study participants, which was 67 to 75 years. Overall, 533 female participants and 1061 male participants were included. The intervention duration ranged from 30 minutes (exergame) [72] to 36 weeks (self-management app with quiz component) [74]. In total, 30% (3/10) of the RCTs performed follow-up analyses after the intervention period, with follow-up times ranging from 7 days [72] to 48 weeks [77]. A complete overview of the population characteristics of the included RCTs can be found in Table 1.

Table 1. Study and population characteristics of the included randomized controlled trials.

Study, year, title, journal, and country	Study design	Study duration	Follow-up time	Population characteristics				
				Sample size, n	Age (years)	Sex	Inclusion criteria	Exclusion criteria
Brinkmann et al [72], 2017, "Effects of Cycling and Exergaming on Neurotrophic Factors in Elderly Type 2 Diabetic Men—A Preliminary Investigation"/Experimental and Clinical Endocrinology & DiabetesExp Clin Endocrinol Diabetes, Germany	Individually randomized crossover trial	30 min once	None	8	Ranging from 67 to 75	8 male participants	• Not reported	• Nonsmoking • Absence of diabetic retinopathy, neuropathy, nephropathy, or cardiovascular complications
Dugas et al [73], 2018, "Individual Differences in Regulatory Mode Moderate the Effectiveness of a Pilot mHealth trial for Diabetes Management among older Veterans"/PLOS ONE[a], United States	Individually randomized controlled trial	13 weeks	None	27	Mean 67.8 (SD 6.1)	Not reported	• Veteran patients with type 2 diabetes • Affiliated with a Veterans Affairs medical center • Aged >60 years • Poorly controlled diabetes (HbA_{1c}[b] >7.9%)	• Blindness • Deafness • Serious mental illness • Homelessness
Glasgow et al [74], 2010, "Outcomes of Minimal and Moderate Support Versions of an Internet-Based Diabetes Self-Management Support Program"/Journal of General Internal Medicine, United States	Individually randomized controlled trial	16 weeks	None	463	Mean 58.4 (SD 9.2)	233 male and 230 female participants	• Aged 25 to 75 years • Type 2 diabetes diagnosis • BMI >25 kg/m^2 • At least one or more risk factor for CVD[c] • Telephone access • Internet access at least twice a week	• None

Study, year, title, journal, and country	Study design	Study duration	Follow-up time	Population characteristics				
				Sample size, n	Age (years)	Sex	Inclusion criteria	Exclusion criteria
Grewal et al [75], 2015, "Sensor-Based Interactive Balance Training with Visual Joint Movement Feedback for Improving Postural Stability in Diabetics with Peripheral Neuropathy: A Randomized Controlled Trial"/Gerontology, United States	Individually randomized controlled trial	45 min twice a week for 4 weeks	None	39	Mean 63.7 (SD 8.2)	20 male and 19 female participants	• Ability to walk on one's own for 20 meters • Type 2 diabetes • Peripheral neuropathy	• Diagnosis of cognitive, vestibular, or central neurological dysfunction • Diagnosis of musculoskeletal abnormality • Active foot ulcers • Charcot joints • History of balance disorder
Höchsmann et al [28,29], 2019, "Effectiveness of a Behavior Change Technique–Based Smartphone Game to Improve Intrinsic Motivation and Physical Activity Adherence in Patients With Type 2 Diabetes: Randomized Controlled Trial"/JMIR Serious Games and "Novel Smartphone Game Improves Physical Activity Behavior in Type 2 Diabetes"/American Journal of Preventive Medicine, Switzerland	Individually randomized controlled trial	24 weeks	None	36	Mean 57 (SD 5.5)	19 male and 17 female participants	• Physically inactive (<150 min of moderate-intensity PA[d] per week) • BMI >25 kg/m² • Type 2 diabetes • Non–insulin-dependent • Aged 45 to 70 years • Having used a smartphone regularly for 1 year before the study	• Health risks counterindicating PA • Impaired mobility • Acute infections • Injuries
Kempf and Martin [78], 2013, "Autonomous Exercise Game Use Improves Metabolic Control and Quality of Life in Type 2 Diabetes Patients—a Randomized Controlled Trial"/BMC Endocrine Disorders, Germany	Crossover individually randomized controlled trial	30 min per day for 12 weeks	None	220	Mean 62 (SD 11; [intervention group]) and 60 (SD 9; [control group])	119 female and 101 male participants	• Type 2 diabetes • Diagnosis>5 years ago • Aged 50 to 75 years • BMI >27 kg/m² • Included in disease management program for diabetes	• Regular PA • Pharmacological therapy (except metformin and DPP-4[e] inhibitors)
Kerfoot et al [76], 2017, "A Team-Based Online Game Improves Blood Glucose Control in Veterans With Type 2 Diabetes: A Randomized Controlled Trial"/Diabetes Care, United States	Individually randomized controlled trial	24 weeks	48 weeks	465	Mean 59.5 (SD 9.9)	28 female and 428 male participants	• Type 2 diabetes • Inadequate glucose control • Taking oral diabetes medication • Insulin- and non–insulin-dependent	• Not reported

Study, year, title, journal, and country	Study design	Study duration	Follow-up time	Population characteristics				
				Sample size, n	Age (years)	Sex	Inclusion criteria	Exclusion criteria
Koohmareh et al [79], 2020, "Effect of Implementing a Mobile Game on Improving Dietary Information in Diabetic Patients"/Medical Journal of The Islamic Republic of Iran, Iran	Individually randomized controlled trial	15 min per day for 6 weeks	None	60	Mean 44.1 (SD 7.9; control group) and 43.9 (SD 9.0; intervention group)	32 female and 28 male participants	• Type 2 diabetes diagnosis confirmed by a specialist • Aged >18 years • Minimal literacy • Android-run smartphone • Smartphone skills • Willingness to participate	• Not reported
Maharaj et al [80], 2021, "Comparing Two Commercially Available Diabetes Apps to Explore Challenges in User Engagement: Randomized Controlled Feasibility Study"/JMIR Formative Research, Australia and New Zealand	Individually randomized controlled trial	2 weeks	None	89	Mean 53.2 (SD 11.1; control group) and 52.6 (SD 13.0; intervention group)	31 female and 58 male participants	• Type 2 diabetes diagnosis confirmed by a specialist • Aged >18 years • Fluent in spoken and written English • iOS- or Android-run smartphone • Written consent	• Not reported
Turnin et al [77], 2021, "Impact of a Remote Monitoring Programme Including Lifestyle Education Software in Type 2 Diabetes: Results of the Educ@dom Randomised Multicentre Study"/Diabetes Therapy, France	Individually randomized controlled multicenter study	48 weeks	None	263	Mean 59.6 (SD 9.6)	57 female and 166 male participants	• Type 2 diabetes diagnosis confirmed by a specialist • Aged >18 years • Insulin- and non–insulin-dependent • HbA_{1c} of 6.5% to ≤10% • Active internet connection	• Active severe comorbidities • Reduced mobility • Eating disorders • Bariatric surgery

[a]PLOS ONE: Public Library of Science ONE.

[b]HbA_{1c}: glycated hemoglobin (blood sugar value).

[c]CVD: cardiovascular disease.

[d]PA: physical activity.

[e]DPP-4: dipeptidyl peptidase 4

Results of the Quality Assessment

Applying the RoB 2, a high risk of bias was detected in 90% (9/10) of the included RCTs [28,73-80]. A total of 10% (1/10) of the studies had a low risk of bias [72]. For 40% (4/10) of the RCTs, multiple reasons for a high risk of bias were detected [73,74,79,80], whereas for 30% (3/10) of the studies, only 1 reason was found [75,77,78]. The allocation sequence was random in all but 10% (1/10) of the cases [79]. Major sources of bias were the blinding of study participants and personnel to the allocation to either the intervention or the control group [73,74,76,77,79,80] and, to a smaller degree, inadequate (ie, nonreliable or nonvalidated) measures for outcome assessment [28,73-75,79,80], both of which translate to detection bias. Most of the included RCTs (7/10, 70%) conducted per-protocol analyses [28,29,72,73,75,77,78,80], whereas another study did not specify the type of analysis [79]. As such, the effect estimate was potentially biased by dropouts in all but 20% (2/10) [74,76] of the included RCTs (attrition bias). Glasgow et al [74] and Kerfoot et al [76] performed an intention-to-treat analysis, whereas the remaining authors all performed per-protocol analyses except for Koohmareh et al [79], for whom the type of analysis could not be discerned. Bias because of selective reporting was detected by comparing the outcomes described in the Methods sections and those reported in the Results sections [75,76]. The results of the quality assessment can be found in Figure 2.

Figure 2. Results of the quality assessment applying the Cochrane risk-of-bias tool version 2 [28,29,72,-80].

	Generation of randomization sequence	Covered assignment to study groups	Blinding of study participants and personnel	Incomplete outcome data	Outcome assessment	Selective reporting
Brinkmann et al (2017) [72]	+	+	+	+	+	+
Dugas et al (2018) [73]	+	-	-	+	-	+
Glasgow et al (2010) [74]	+	-	-	-	-	+
Grewal et al (2015) [75]	+	+	?	+	?	-
Höchsmann et al (2019) [28, 29]	+	+	?	+	-	+
Kempf and Martin (2013) [78]	+	+	+	-	+	+
Kerfoot et al (2017) [76]	+	-	+	+	+	-
Koohmareh et al (2021) [79]	?	-	-	+	?	?
Maharaj et al (2021) [80]	+	-	-	-	?	?
Turnin et al (2021) [77]	+	-	?	+	+	+

Game Types and Components Analyzed in the Included RCTs

Of the 10 included RCTs, 4 (40%) focused on an exergame [28,29,72,75,78], one (25%) of which reported first behavioral and then clinical results of the same exergame intervention studied with the same population [28,29]. A total of 20% (2/10) of the studies reported on the effects of game components within digital self-management applications for diabetes [73,80]. In 40% (4/10) of the RCTs, the authors analyzed quiz games with DSME content [74,76,77,79]. The digital intervention studied by Brinkmann et al [72] combined an exergame with a game for cognitive problem-solving.

Within the exergames, virtual reality components such as virtual race tracks were used [72,75,78]. Scoring systems awarding trophies to winners or when individualized scores were achieved were used in 60% (6/10) of the interventions [28,29,73,74,76,79,80]. Storytelling features were part of 20% (2/10) of the interventions studied [28,79], and 10% (1/10) of the interventions applied a team-based approach to the game [78].

Among the 4 RCTs in which the authors reported on the matter [72,75,78,79], intervention intensity varied between 30 minutes once (equal to intervention duration) [72], 15 minutes per day for 6 weeks [79], 30 minutes per day for 12 weeks [78] and 45 minutes twice a week for 4 weeks [75].

A complete overview of the intervention types and game components studied in the included RCTs can be found in Table 2.

Table 2. Intervention characteristics of the included randomized controlled trials.

Study, year	Intervention group	Control group	Intervention	
			Duration	Intensity
Brinkmann et al [72], 2017	• Exergaming: interactive video games using Wii Fit Plus combining physical activity and cognitive challenges (n=8) aiming to improve neurotrophic factors	• Cycling on stationary bicycle (n=8)	30 minutes	30 minutes
Dugas et al [73], 2018	• Using self-management app with game elements (point reward system for achieving target values in clinical and behavioral outcomes) aiming to improve diabetes outcomes in 4 randomized conditions: • App use only (n=5) • App use including provider communication features (n=5) • App use including team engagement features (n=6) • App use including team engagement and provider communication features (n=6)	• Usual care (n=5)	13 weeks	Not reported
Glasgow et al [74], 2010	• Self-management website allowing for goal setting in medication adherence, nutrition, and exercise, including quiz component (n=169) • Augmented with (1) follow-up calls with a member of the study staff to ask questions about the study and receive help in handling the website and (2) group meeting with other study participants (n=162)	• Enhanced usual care (automated feedback on health risks based on patient-provided disease-relevant parameters; recommendation of preventive behaviors; n=132)	16 weeks	Not reported
Grewal et al [75], 2015	• Virtual obstacle-crossing task with audio and video feedback on a virtual reality interface • Ankle-reaching task with virtual representation and feedback onscreen (n=16)	• Usual care (n=18)	4 weeks	45 minutes twice a week
Höchsmann et al [28,29], 2019	• Smartphone game "Mission: Schweinehund" based on self-determination theory and including behavioral or motivational elements as well as a storyline where users restore a garden with resources gained through individualized in-game workouts tracked via phone sensors (n=18)	• 1-time lifestyle counseling and structured exercise plan (n=18)	24 weeks	Not reported
Kempf and Martin [78], 2013	• Wii Fit Plus including balance board (n=120)	• Routine care (n=100)	12 weeks	>30 minutes per day for 12 weeks
Kerfoot et al [76], 2017	• Team-based mobile DSME[a] quiz with scoring system plus booklet on civic issues (n=227)	• Team-based mobile quiz on civic issues plus DSME booklet (n=229)	24 weeks	Not reported
Koohmareh et al [79], 2020	• Amoo mobile game—glycemic index and calorie training game (n=30)	• Educational content similar to the game through a brochure (n=30)	6 weeks	15 minutes per day for 6 weeks
Maharaj et al [80], 2021	• mySugr—self-monitoring and self-management app with nudging and game component (point reward system for certain behaviors; n=44)	• Glucose Buddy—self-monitoring and self-management app (n=45)	2 weeks	Not reported
Turnin et al [77], 2021	• DSME software including quiz components (n=135)	• Usual care (n=128)	48 weeks	Not reported

[a]DSME: Diabetes Self-Management and Education.

Effects of Gamified Health Interventions on Health Behavior

Exercise intensity and adherence were studied in 50% (5/10) of the included studies [28,29,73-75,78]. A total of 40% (4/10) of the studies reported on nutritional behavior [73,74,79,80], and 20% (2/10) of the studies reported on medication adherence [73,74].

Positive effects on behavioral PA outcomes were reported in several of the included RCTs (4/10, 40%). A total of 50% (2/4) of the exergames studied led to an increased intensity of PA (measured as step count, caloric expenditure, and self-report) in the study participants [28,29,78], and so did the quiz component nested within the DSME website studied by Glasgow et al [74]. However, the latter was only effective when the website was supplemented with follow-up calls by study staff as a supportive measure in handling the website and group meetings with other study participants [74]. Only Höchsmann et al [28] reported on PA adherence and found no substantial effect of their exergame on PA adherence, where PA exercises were nested within a coherent narrative. However, the intervention statistically significantly increased intrinsic motivation for PA ($P<.001$), whereas intrinsic motivation decreased in the control group (1-time lifestyle counseling and structured exercise plan) during the study period. Between-group effects were significant. The authors also found a significant positive relationship between time spent doing the in-game exercises and PA motivation (P=.01) [28].

Dugas et al [73] found no overall intervention effect of any of the intervention arms studied on adherence as a whole (quantified using an in-app rating system; Table 3), but they found a statistically significant interaction effect (in regression analysis) of time spent using the self-management app with game elements and assessment (P=.01). They also found a statistically significant interaction effect of time and locomotion on weekly exercise adherence ($P<.05$) [73].

In 40% (4/10) of the RCTs, the authors found significant positive effects on *nutrition behavior*. Glasgow et al [74] reported a significant decrease in fat intake in the intervention group compared with that in the control group (P value for intergroup differences=.006). Koohmareh et al [79] found that participants using their educational game on glycemic index and calorie intake paid significantly more attention to the glycemic levels and calorie count of their food (P value for intergroup differences=.001). Maharaj et al [80] showed that participants using the mySugr app with the reward system could significantly reduce their high-fat food consumption, whereas no significant changes were found in the control group using a self-management app without a game component (P value for intergroup differences=.052). Interaction effects of time and assessment as well as of time and locomotion were found by Dugas et al [73] for nutrition adherence (quantified using an in-app rating system) as well. The authors also found a significant positive effect of locomotion on nutritional adherence ($P<.05$) but none of assessment (P value not reported) [73].

Glasgow et al [74] found no significant effect of the intervention on medication adherence or on eating habits other than fat intake (P value for intergroup differences=.006). Dugas et al [73] found an interaction effect of time spent using the intervention and assessment on medication adherence (P=.04).

A total of 40% (2/5) of the exergames studied had no effect on PA intensity [75,78]. Overall, positive effects of digital health interventions with game components could be found on motivation for and intensity of PA as well as on eating habits.

Table 3. Results of the included randomized controlled trials according to all relevant outcomes and overall study quality.

Study, year	Outcome (outcome measure)	Results		Study quality according to RoB 2[a]
		Statistically significant	Nonsignificant	

Brinkmann et al [72], 2017	• BDNF[b], VEGF[c], and IGF-1[d] (all measured using an enzyme-linked immunosorbent assay)
	• Heart rate
	• Lactate values
		• Clinical parameters:
		  • Significantly better lactate values in intervention group (*P*=.04)
			• Clinical parameters:
			  • Insignificant lower heart rate in intervention group (*P*>.05)
			  • Insignificant increase in BDNF in intervention group (*P* value not reported)
			  • Insignificant increase in VEGF in intervention group (*P* value not reported)
			  • Insignificant increase in IGF-1 in intervention group (*P* value not reported)
				• High

Dugas et al [73], 2018	• HbA_{1c}[e]
	• Regulatory mode (locomotion and assessment scales developed by Kruglanski et al [81])
	• Adherence to healthy behaviors (glucose, medication, and nutrition tracking entered manually into app; PA[f] tracked via Fitbit or manually; and recorded app use, all quantified using in-app point rating system)
		• Behavioral outcomes:
		  • Significant positive causal relationship between locomotion and weekly adherence score (*P*<.05)
		  • Significant positive causal effect of interaction between time and assessment during intervention time on adherence (*P*=.01)
		  • Significant positive causal effect of interaction between time and locomotion for app use, including provider communication features, on adherence (*P*=.04)
		• Clinical parameters:
		  • Significant positive causal effect of app use, including provider communication features, on HbA_{1c} (*P*<.01)
		  • Significant positive causal effect of interaction between time and adherence on HbA_{1c} (*P*<.01)
			• Behavioral outcomes:
			  • No treatment effect of any intervention arm on total adherence (*P* value not reported)
			• Clinical parameters:
			  • No significant between-group differences in HbA_{1c} during intervention time (*P* value not reported)
				• Low

Study, year	Outcome (outcome measure)	Results		Study quality according to RoB 2[a]
		Statistically significant	Nonsignificant	

Glasgow et al [74], 2010	• Health literacy (brief questionnaire by Chew et al)
	• Dietary behavior ("Starting the Conversation Scale" by Ammerman et al)
	• Adherence to medication for diabetes, blood pressure, and cholesterol (medication-taking items of the Hill-Bone Compliance Scale)
	• Fat intake (National Cancer Institute Percent Energy from Fat Screener)
	• Total weekly caloric expenditure (Community Healthy Activities Model Program for Seniors Questionnaire)
	• HbA_{1c}
	• BMI[g]
	• Lipid ratio
	• Mean arterial pressure
		• Behavioral outcomes:
		  • Significant improvement in eating habits in intervention group but not in control group (*P* value for intergroup differences ≤.001)
		  • Significant decrease in fat intake in intervention group but not in control group (*P* value for intergroup differences=.006)
		  • Significant increase in PA in intervention group but not in control group (*P* value for intergroup differences=.04)
			• Behavioral outcomes:
			  • No significant improvement in medication adherence in intervention group vs control group (*P* value for intergroup differences=.29)
			  • No significant differences in eating habits (*P* value for intergroup differences=.08), fat intake (*P* value for intergroup differences *P*=.46), PA (*P* value for intergroup differences=.63), and medication adherence (*P* value for intergroup differences=.86) between intervention groups
			• PROs[h]:
			  • No interaction effect of health literacy on any of the outcomes measured (P not reported)
			• Clinical parameters:
			  • No significant improvement of HbA_{1c} (*P* value for intergroup differences=.42), BMI (*P* value for intergroup differences=.19), lipid ratio (*P* value for intergroup differences=.90), and mean arterial pressure (*P* value for intergroup differences=.83) in any study arm
				• Low

Grewal et al [75], 2015	• Postural stability (FES-I[i] and postural stability)
	• Diabetes peripheral neuropathy (VPT[j])
	• Daily PA (time spent sitting, standing, and walking and total step count) measured via shirt-worn sensor
	• Quality of life (SF-12[k])
		• PROs:
		  • Significant improvement in mental health component of SF-12 in intervention group but not in control group (*P* value for intergroup differences=.04)
		• Clinical outcomes:
		  • Significant reduction in average center of mass sway area (in degrees) in intervention group but not in the control group (*P* value for intergroup differences=.009)
		  • Significant reduction in medial-lateral center of mass sway area in intervention group but not in the control group (*P* value for intergroup differences=.008)
		  • Significant reduction of hip and ankle sway in the intervention group but not in the control group (*P* value for intergroup differences=.008)
		  • Significant reduction of ankle sway degree in intervention group but not in control group (with and without blindfold; *P* value for intergroup differences=.02)
				• Low

Study, year	Outcome (outcome measure)	Results		Study quality according to RoB 2[a]
		Statistically significant	Nonsignificant	

			• Behavioral outcomes:
			  • No significant differences in time spent sitting (*P*=.62), standing (*P*=.36), or walking (*P*=.08) in intervention and control group
			• PROs:
			  • No significant differences in physical component of SF-12 in intervention and control group (*P* value for intergroup differences=.64)
			  • No significant differences in FES-I in intervention and control group (*P* value for intergroup differences=.31)
			• Clinical outcomes:
			  • No significant reduction in anterior-posterior center of mass sway area in intervention or control group (*P* value for intergroup differences=.38)
			  • No significant reduction in average center of mass sway area in intervention or control group when blindfolded (*P* value for intergroup differences=.18)
			• No effects on VPT reported	

Höchsmann et al [28,29], 2019	• Intrinsic PA motivation (12-item version of the Intrinsic Motivation Inventory)
	• PA adherence (step count, stride cadence, completed vs canceled in-game workouts, and duration and patterns of game use)
	• HbA_{1c}
	• Aerobic capacity (cardiorespiratory fitness [maximum oxygen uptake and first ventilatory threshold])
	• Daily PA (step count via accelerometer wristband)
	• Total cholesterol
	• LDL-C[l]
	• HDL-C[m]
	• Triglycerides
	• Resting heart rate
	• SBP[n]
	• DBP[o]
			• Behavioral outcomes:
			  • Nonsignificant increase in intrinsic PA motivation after intervention on the subscale for value/usefulness (*P*>.05) but significant between-group differences (*P*<.05)
			• Only descriptive reporting of PA adherence
			• Clinical parameters:
			  • No changes in resting heart rate (*P*=10), SBP (*P*=.38), and DBP (*P*=.18) in any of the study groups
			  • No changes in skeletal muscle mass in any of the study groups (*P*=.71)
			  • No changes in total cholesterol (*P*=.55), HDL-C (*P*=.46), LDL-C (*P*=.74), and triglycerides (*P*=.95) in any of the study groups
				• Low [28]
				• Moderate [29]

Study, year	Outcome (outcome measure)	Results		Study quality according to RoB 2[a]
		Statistically significant	Nonsignificant	

		• Behavioral outcomes:
		  • Significant increase in intrinsic PA motivation in the intervention group (*P*<.001) and nonsignificant decline in the control group (*P*>.05)
		  • Significant between-group differences in intrinsic PA motivation after intervention (*P*<.05)
		  • Significant between-group differences in intrinsic PA motivation after intervention on the subscales for interest or enjoyment (*P*<.05) and perceived competence (*P*<.05) (significant increase in intervention group (*P*<.001)
		  • Significant increase in intrinsic PA motivation after intervention on the subscale for perceived choice in the intervention group (*P*<.05) but no between-group differences (*P*>.05)
		  • Significant relationship between in-game exercise (measured in minutes) and changes in intrinsic PA motivation (total score) (*P*=.01)
		  • Daily PA increase in the intervention and control group with a significant difference between groups (*P*<.001)
		• Only descriptive reporting of PA adherence
		• Clinical parameters:
		  • Significantly higher increase in step count in intervention group than in control group (*P*<.001)
		  • No changes in HbA_{1c} in the intervention group but increase in the control group (significant between-group differences) (*P*=.02)
		  • Significant increase in aerobic capacity in the intervention group and decrease in the control group (significant between-group differences) (*P*<.001)
		  • Significantly higher decrease in body fat mass in intervention than in control group (*P*=.045)		

Kempf and Martin [78], 2013			• Clinical parameters: • No significant differences in DBP, SBP, total cholesterol, HDL-C, LDL-C, triglycerides, metformin or DPP-4[t] inhibitor treatment, or physical well-being in any of the study groups (*P* value not reported)	• Low

Study, year	Outcome (outcome measure)	Results		Study quality according to RoB 2[a]
		Statistically significant	Nonsignificant	

	• HbA_{1c}
	• BMI
	• FPG[p]
	• Total cholesterol
	• LDL-C
	• HDL-C
	• Triglycerides
	• Self-reported PA
	• SBP
	• DBP
	• Self-assessed diabetes-related impairment using PAID[q]
	• Self-assessed physical and mental well-being using SF-12
	• Subjective well-being using WHO-5[r]
	• Quality of life using ADS-L[s]
		• Behavioral outcomes:
		  • Significant increase in PA in both groups (*P* value for intergroup differences <.001)
		• PROs:
		  • Significant decrease in diabetes-related impairment in both groups (*P* value for intergroup differences=.03)
		  • Significant improvement in subjective well-being in the intervention group but not in the control group (*P* value for intergroup differences=.004)
		  • Significant improvement in mental health in the intervention group but not in the control group (significant between-group effects; *P* value for intergroup differences=.02)
		  • Significant improvement in quality of life in the intervention group but not in the control group (significant between-group effects; *P* value for intergroup differences <.001)
		• Clinical parameters:
		  • Significant reduction in HbA_{1c} in the intervention group, but not in the control group (*P* value for intergroup differences<.001)
		  • Significant reduction in BMI in both groups (*P* value for intergroup differences=.008)
		  • Significant reduction in weight in both groups (*P* value for intergroup differences <.001)
		  • Significant decrease in FPG in both groups (*P* value for intergroup differences=.008)		

Kerfoot et al [76], 2017	• HbA_{1c}
	• Oral diabetes medication PPR[u]
	• Urine microalbumin to creatinine ratio
	• Diabetes Empowerment Scale-Short Form
	• Self-assessed diabetes-related impairment using PAID
		• PROs:
		  • Significant increase in empowerment in the intervention group but decrease in the control group during intervention time (significant between-group differences; *P* value for intergroup differences=.01)
		• Clinical parameters:
		  • Significantly higher reduction in HbA_{1c} in the intervention group than in the control group both after the intervention and at follow-up (significant between-group differences; *P* value for intergroup differences=.048)
		  • Significantly higher reduction in HbA_{1c} in the intervention group for patients with baseline HbA_{1c} of >75 mmol/mol (*P*=.03)
			• Behavioral outcomes:
			  • No significant differences in PPR in any group (*P* value not reported)
			• PROs:
			  • No significant differences in diabetes-related impairment during intervention time in any study group (*P* value not reported)
			  • No significant differences in diabetes-related impairment and empowerment at follow-up in any study group (*P* value not reported)
			• Clinical parameters:
			  • No significant differences in urine microalbumin to creatinine ratio in any study group (*P* value not reported)
				• Low

Study, year	Outcome (outcome measure)	Results		Study quality according to RoB 2[a]
		Statistically significant	Nonsignificant	

Koohmareh et al [79], 2020	• FPG
	• Knowledge of diabetes diet (self-developed Amoo[v] test)
	• Attention to food glucose levels and food calories
		• Behavioral outcomes:
		  • Significantly more attention to food glucose levels and food calories in intervention group but not in the control group (*P* value for intergroup differences=.001)
		• PROs:
		  • Significantly higher Amoo test scores in the intervention group but not in the control group (*P* value for intergroup differences=.001)
			• Clinical outcomes:
			  • No significant differences in FPG (*P* value for intergroup differences=.63)
				• Low

Maharaj et al [80], 2021	• Self-care behaviors (SD-SCA[w])
	• Illness beliefs (Brief Illness Perception Questionnaire)
		• Behavioral outcomes:
		  • Borderline significant median difference in high-fat food consumption (lower in mySugr group; *P* value for intergroup differences=.052)
			• Behavioral outcomes:
			• No significant median differences in self-care behaviors in any study group (*P* value for intergroup differences=.64) PROs:
			  • No significant median differences in illness beliefs in any study group (*P* value for intergroup differences=.05)
				• Low

Turnin et al [77], 2021	• HbA_{1c}
	• BMI
	• Waist circumference
		• Clinical outcomes:
		  • Significant reduction in waist circumference in intervention group but not in control group (*P* value for intergroup differences=.04)
		  • Stronger intergroup differences in frequent users (*P*=.008)
			• Clinical outcomes:
			  • No significant differences in HbA_{1c} between intervention and control group after adjustment for risk factors (*P* value for intergroup differences=.12)
			  • No significant differences in BMI between intervention and control group after adjustment for risk factors (*P* value for intergroup differences=.08)
				• Low

[a]RoB 2: Cochrane risk-of-bias tool version 2.

[b]BDNF: brain-derived neurotrophic factor.

[c]VEGF: vascular endothelial growth factor.

[d]IGF-1: insulin-like growth factor–1.

[e]HbA_{1c}: glycated hemoglobin (blood sugar value).

[f]PA: physical activity.

[g]BMI: body mass index

[h]PRO: patient-reported outcome.

[i]FES-I: Falls Efficacy Scale–International.

[j]VPT: vibration perception threshold.

[k]SF-12: Short Form Health Survey.

[l]LDL-C: low-density lipoprotein cholesterol.

[m]HDL-C: high-density lipoprotein cholesterol.

[n]SBP: systolic blood pressure.

[0]DBP: diastolic blood pressure.

[p]FPG: fasting plasma glucose.

[q]PAID: Problem Areas in Diabetes Scale.

[r]WHO-5: 5-item World Health Organization Well-Being Index.

[s]ADS-L: *Allgemeine Depressionsskala* long version (German).

[t]DPP-4: dipeptidyl peptidase 4.

[u]PPR: patient-pill ratio.

[v]Amoo: diabetes test designed by Koohmareh et al [79].

[w]SDSCA: Summary of Diabetes Self-Care Activities.

Effects of Gamified Health Interventions on PROs

In the included RCTs, data were provided on health literacy in general [74,79,80], quality of life [75,78], diabetes-related impairment [76,78], and subjective well-being [78].

Concerning *health literacy*, Koohmareh et al [79] found a significant positive effect of their educational game on knowledge concerning a diet adequate for patients with diabetes (measured on a self-developed scale; *P*=.001). Maharaj et al [80] found no significant median differences in illness beliefs (measured using the Brief Illness Perception Questionnaire) between the gamified mySugr and the self-management app without any game components (*P* value for intergroup differences=.05). Glasgow et al [74] used health literacy as a moderating variable in a multivariate analysis of covariance to measure the effects of their self-management website with quiz elements but found no interaction effects (*P* value not reported).

In the domain of *quality of life*, Grewal et al [75] found a significant improvement in mental well-being because of the virtual balance training they studied (*P* value for intergroup differences=.04) but no effect of said intervention on physical well-being (*P* value for intergroup differences=.64; both measured using the Short Form 12 Health Survey). The same effect was demonstrated by Kempf and Martin [78], who studied Wii Fit Plus games, using both the Short Form 12 Health Survey and a German depression scale. *Subjective well-being*, measured using the 5-item World Health Organization Well-Being Index scale, improved significantly in the study by Kempf and Martin [78] as well (*P* value for intergroup differences=.004).

Grewal et al [75] and Kempf and Martin [78] studied the effects of gamified interventions on *diabetes-related impairment* both using the Problem Areas in Diabetes Scale. Although the latter found a positive effect of the Wii Fit Plus games (*P* value for intergroup differences=.03) [78], the former found no effect of virtual balance training (*P* value not reported) [75]. In terms of impairment, Grewal et al [75] found no effect of the virtual balance training on fear of falling (*P* value for intergroup differences=.31).

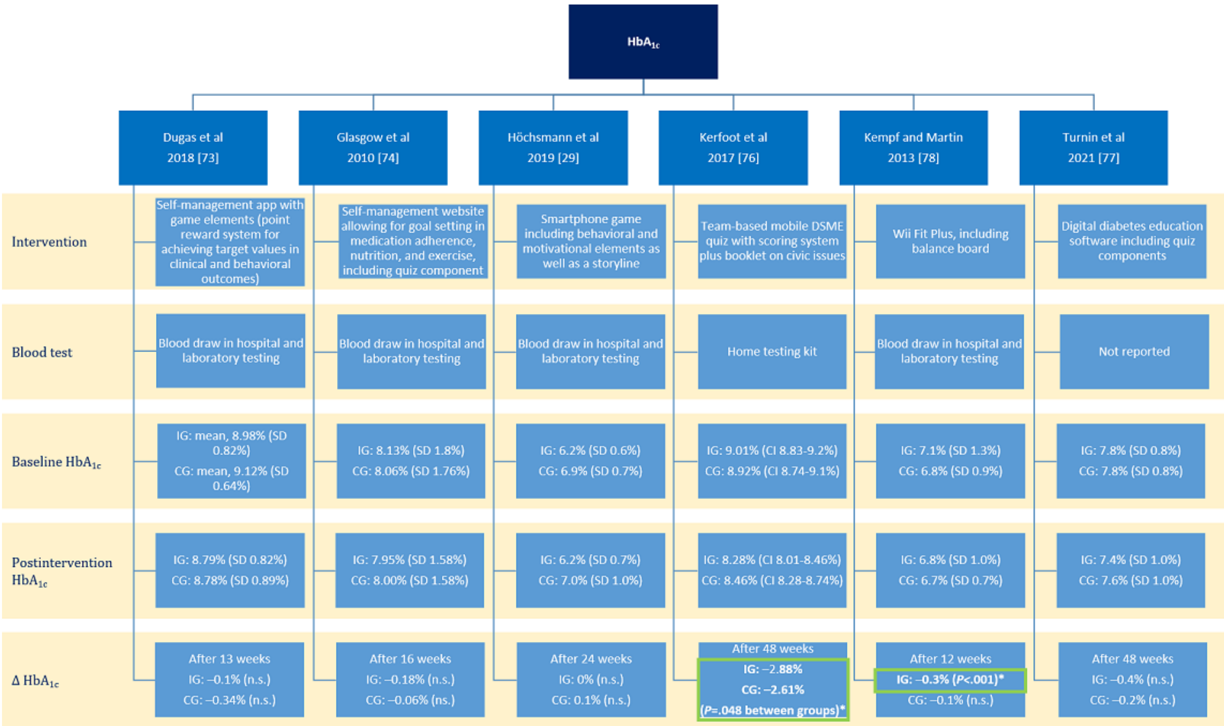
Overall, sparse positive effects of digital health interventions with game components could be found on health literacy and diabetes-related impairment, whereas substantial evidence was found for the improvement of subjective mental well-being.

Effects of Gamified Health Interventions on Clinical Outcomes

The clinical outcome studied most often in the included RCTs was HbA_{1c} [29,73,74,76-78]. Furthermore, 30% (3/10) of the included studies analyzed changes in BMI [74,77,78], whereas Höchsmann et al [28], Glasgow et al [74], and Kempf and Martin [78] also analyzed lipid outcomes and blood pressure values. Fasting plasma glucose (FPG) was studied twice [78,79], and so was the heart rate of the participants [28,72]. Brinkmann et al [72] studied cognitive parameters in conjunction with lactate values, and Grewal et al [75] analyzed postural stability.

The effects of the gamified interventions on HbA_{1c} levels studied in 60% (6/10) of the RCTs are depicted in Figure 3, where asterisks mark significant changes in HbA_{1c}. Only Kerfoot et al [76] (*P* value for intergroup differences=.048) and Kempf and Martin [78] (*P* value for intergroup differences<.001) found significant positive effects of a mobile, team-based DSME quiz and Wii Fit Plus games, respectively, on HbA_{1c} levels in terms of a reduction in the intervention group and significant between-group effects. Dugas et al [73] found a significant effect of time spent using the self-management app with an award system on HbA_{1c} levels in a regression analysis (*P*<.01), as well as an interaction effect of total adherence score (additive score of exercise, nutrition, and medication adherence; *P*<.01).

Figure 3. Effects of the interventions studied on glycated hemoglobin (HbA_{1c}) levels. *Significant. Δ HbA_{1c}: difference in HbA_{1c} between pre- and postintervention measurement; CG: control group; DSME: Diabetes Self-Management and Education; IG: intervention group; n.s.: not significant [29,73,74,76-78].



Kempf and Martin [78] also found significant positive effects of the intervention on *BMI* (*P* value for intergroup differences=.008); however, Glasgow et al [74] (*P* value for intergroup differences=.20) and Turnin et al [77] (*P* value for intergroup differences=.08), also studying DSME software with quiz components, did not. Significant effects on *FPG* after using the same software were also reported by Kempf and Martin [78] (*P* value for intergroup differences=.008) but not by Koohmareh et al [79] (*P* value for intergroup differences=.63), who studied the same intervention type. Significant effects were not found on lipid outcomes and blood pressure values [29,74,78] or on cognitive outcomes and lactate values [72]. Grewal et al [75] found their exergame, including a virtual obstacle course, to have a positive effect on postural stability when compared with usual care (*P* value for intergroup differences=.009).

Turnin et al [77] found a significant reduction in *waist circumference* in the intervention group when compared with the control group both before and after adjusting for confounding factors such as baseline HbA_{1c} levels, age, sex, or obesity (*P* value for intergroup differences=.04). The authors also reported an increased effect on waist circumference in those with a higher frequency of use (*P*=.008).

No significant effects were found on *heart rate* [29,72], *blood pressure* (systolic or diastolic) [29,78], or *lipid values* (ie, on total cholesterol, triglycerides, low-density lipoprotein cholesterol, or high-density lipoprotein cholesterol) [29,78] in any of the RCTs that reported on these values.

Brinkmann et al [72] studied the vascular endothelial growth factor as an indicator of *diabetes retinopathy* but found no effect of the Wii Fit exergame they studied (*P* value not reported). Furthermore, they found no effect of the intervention on insulin-like growth factor–1 as a proxy for *poorly adjusted diabetes* (*P* value not reported).

Brinkmann et al [72] found improved lactate values in the intervention group (*P*=.04) but not in the control group (*P* value not reported), which used a stationary bicycle, thus indicating higher *fitness* levels owing to the exergame. Improved fitness because of an exergame was also demonstrated by Höchsmann et al [29] using aerobic capacity as an indicator (*P*<.001). Grewal et al [75] found improved postural stability to be an effect of the virtual balance training they studied (*P*=.009).

As Brinkmann et al [72] aimed to also improve *cognitive functioning* of the study participants by adding cognitive challenges to the exergame, they studied the brain-derived neurotrophic factor as an indicator of learning and memory capacity and found no significant effect of the intervention (*P* value not reported).

Overall, sparse positive effects of digital health interventions with game components could be found on clinical outcomes, with fitness-related outcomes improving the most.

A complete overview of the effects found in the included RCTs can be found in Table 3. If not stated otherwise, differences in outcomes are reported between the intervention and control group(s) before and after the study in Table 3.

Discussion

Principal Findings

Despite heterogeneity in the effects of the gamified applications studied in this review on behavioral, clinical, and patient-reported outcomes, certain patterns emerged. Exergames had the tendency to improve fitness-related and, to a smaller extent, clinical values (as shown in 4/10, 40% of the RCTs [73,76-78]), whereas educational games affected disease-related knowledge and especially nutrition behavior (as shown in 4/10, 40% of the RCTs [73,74,79,80]). In addition, exergames had a potential to improve outcomes related to self-reported well-being such as quality of life and diabetes-related impairment (as shown in 2/10, 20% of the RCTs [75,78]).

Comparison With Prior Work

The results confirm those of a meta-analysis by DeSmet et al [82], who showed significant positive effects of serious games on health behavior independent of any diagnosis and its theory-based determinants and significant but much smaller effects on various clinical outcomes. As for nutrition behavior, which improved according to 40% (4/10) of the RCTs included in this review solely because of self-management applications with quiz elements, Ledoux et al [83] found similar effects of a serious game for young patients with type 1 diabetes.

Somewhat surprisingly, self-efficacy was not among the outcomes studied in the included RCTs despite existing evidence that both exergames and serious games can increase the feeling of being able to actively affect one’s health outcomes [65,84]. A precondition derived from behavior change theories is the option for goal setting by the intervention participants themselves as opposed to behavioral goals predefined by the intervention developers [85]. This precondition was met by all the gamified interventions studied in this review that used a reward or scoring system as these game components allow for the autonomous setting of target values that the users aim to achieve and, thus, generate intrinsic motivation [12].

A coherent narrative as an instrument of storytelling was used in only 20% (2/10) of the included interventions; however, it aided in producing positive effects on behavioral, knowledge-related [28,79], and clinical outcomes [29]. As such, the results confirm observations made for narrative health communication messages when delivered in a digital manner [86].

Physical fitness because of an increase in PA owing to interventions with game components is an especially promising result as PA is one of the primary target behaviors of diabetes self-management. The same is true for dietary behavior [6]. As such, these results underline once more the potential of digital interventions for DSME, acknowledged also by the ADA and the European Association for the Study of Diabetes in a joint statement [87].

The relatively high mean age of the study participants is surprising insofar as the traditional target group for digital health applications of all sorts is usually younger people [88]. Christensen et al [17], in sensitivity analyses, also found a positive effect of game-based interventions only for people aged <18 years. Especially regarding exergaming, the positive effects for older people because of high engagement have already been proven elsewhere [89]. Given the fact that most of the gamified interventions studied in this review (7/10, 70%) were designed for mobile devices, the high penetration of such devices in all age groups might play an important role in overcoming the digital health divide because of age [90]. Therefore, the results need to be considered in light of demographic changes and a rise in the demand for health care, especially for chronic diseases [91].

With intervention duration varying widely (Table 2), statements on its relevance have to be made with caution. However, the results show that effects on clinical outcomes can be achieved via digital health interventions with game components after at least 12 months [76,78], which corresponds to the concept of DSME as a continuous, long-term intervention [4,6]. However, even 36 weeks of intervention duration did not guarantee significant effects on BMI and HbA_{1c} [74], hinting at a washout in intervention fidelity common in digital health applications [92].

The fact that generally positive effects of digital health interventions of any kind are biased because of low overall study quality also mirrors findings of recent evidence syntheses [22,93]. The methodological issues concerning the quality of obtainable evidence raised in the joint statement by the ADA and the European Association for the Study of Diabetes [87] persist in this review even though all the included studies (10/10, 100%) were RCTs or had adaptive RCT designs. The issue of blinding of study participants and personnel to the allocation is common in digital health trials as the fact that one did not receive a gamified health application is easily uncovered [8]. Therefore, the study conducted by Maharaj et al [80] is a positive example of comparing 2 digital health applications whereby one is augmented with game components. The issue of missing outcome data because of dropouts, well known to researchers in multiple fields, is also common in digital health research [94] and is linked to the issue of intervention fidelity. The reasons as to why trial participants may lose interest in the use of digital health applications can be numerous [92]. Therefore, participatory design is an important precondition for gamified applications as well [95]. Nonvalidated outcome measures, another major source of bias in the included RCTs, point to the need to develop core outcome sets for digital health applications with or without game components.

Strengths and Limitations

Robust and reproducible systematic review methods were used to identify the best available evidence, and the results were reported according to the PRISMA checklist (Multimedia Appendix 3 [23]). Owing to the fact that all steps taken in this review were performed by 2 researchers independently and checked by a third researcher, it is highly unlikely that relevant records were overlooked or incorrectly discarded as irrelevant. The same is true for information in the included records relevant to the quality assessment.

The focus on research published in German or English is a limitation. Owing to the diverse intervention types (with intervention durations varying widely) and outcomes studied in the rather large number of included RCTs (compared, eg, with the meta-analysis by Christensen et al [17]), a meta-analysis especially of clinical outcomes was not deemed feasible. Rather, the broad realm of outcomes studied allows for a holistic overview of the potential effects of digital health interventions with game components.

Some of the included RCTs (3/10, 30%) had a considerable loss to follow-up, which would have required intention-to-treat analyses. However, most studies (7/10, 70%) conducted per-protocol analyses instead. Furthermore, the reasons for dropout were not always reported.

Little to no follow-up time after the intervention period limits the comparability of the gamified interventions studied in the included RCTs with other digital or analog behavior change interventions that have demonstrated sustainable effects over time [96]. However, according to both theory and evidence, sustainable and long-lasting behavior change over a time span of at least 6 months is necessary to achieve improved health outcomes and still not easily achieved [85]. Owing to limited reporting of intervention intensity, no discernible patterns regarding effectiveness could be found. Moreover, effective components of gamified health interventions regarding both clinical outcomes and behavior change have not been identified yet [97].

Conclusions

This systematic review provided a thorough analysis of the effectiveness of digital health interventions with game components for the self-management of type 2 diabetes. The included RCTs analyzing exergames showed positive effects on fitness-related outcomes and, albeit only in 1 case, also on HbA_{1c}. Educational games improved dietary habits and subjective mental health and well-being. However, the evidence base was ambiguous and further limited because of the considerable risk of bias in the study designs of most of the included RCTs (9/10, 90%). Nevertheless, the results imply that digital health interventions with game components can help improve PA, dietary habits, and well-being. Therefore, these applications, when developed based on theory and evaluated rigorously, can help achieve the behavioral goals mentioned in several guidelines for DSME. Given the mostly low quality of the included RCTs, the presented evidence allows for nothing more than the suggestion of digital health interventions with game components as a supplement to traditional DSME, which corresponds to the statement by Fleming et al [87]. The main results of this review are summarized in Textbox 3.

Textbox 3. Main results of the review.

- The variety of game components used in digital health interventions for type 2 diabetes ranges from quiz components over storytelling elements to full-scale exergames.
- Digital health interventions containing game components might improve the health behavior patterns, quality of life, and clinical outcomes of patients with type 2 diabetes.
- The methodological quality was low in most of the included randomized controlled trials.

Further research should compare digital health interventions that contain game components with those that do not rather than comparing the former with usual care and, as such, risking bias because of high dropout rates. Furthermore, longer follow-up assessments are crucial to detect whether the effects of gamified interventions are sustainable. Adaptive study designs such as microrandomization, where individuals are randomized to several intervention components or treatments for the study duration [98], could be used to determine which game components have an effect on which outcome domain (behavioral, PROs, or clinical). Larger sample sizes would allow for more detailed subgroup analyses [99] to determine which user groups, in addition to those defined by age, profit the most from digital health interventions containing game components. Finally, but importantly, a comparison of the effects of digital health interventions with game components for patients with type 1 and 2 diabetes is bound to provide further insights.

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Authors' Contributions

LO and LH devised the study design and conducted the literature search, study selection process, quality assessment, and data extraction together with TH. SD and PT were involved in the consensus process during study selection, data extraction, and quality assessment. PT, OS, and MS analyzed the extracted data and derived points for discussion and implications. LH drafted the manuscript, which was critically revised for important intellectual content and approved by all the authors.

Conflicts of Interest

Unrelated to this study, OS served as a consultant for Novartis. Unrelated to this study, JS reports institutional grants for investigator-initiated research from the German Federal Joint Committee, Federal Ministry of Health, Federal Ministry of Education and Research, European Union, Federal State of Saxony, Novartis, Sanofi, Allergologisk Laboratorium København (ALK), and Pfizer. He also participated in advisory board meetings as a paid consultant for Sanofi, Lilly, and ALK. JS serves the German Ministry of Health as a member of the Sachverständigenrat Gesundheit und Pflege (expert advisory board on health and care).

Multimedia Appendix 1
Database-specific search strings for PubMed and PsycINFO.
[DOCX File , 71 KB - games_v11i1e44132_app1.docx]

Multimedia Appendix 2
List of excluded studies with reasons.
[DOCX File , 19 KB - games_v11i1e44132_app2.docx]

Multimedia Appendix 3
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File , 314 KB - games_v11i1e44132_app3.docx]

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Abbreviations

ADA: American Diabetes Association
CASP: Critical Appraisal Skills Programme
DSME: Diabetes Self-Management and Education
FPG: fasting plasma glucose
HbA_{1c}: glycated hemoglobin
PA: physical activity
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRO: patient-reported outcome
RCT: randomized controlled trial
RoB 2: Cochrane risk-of-bias tool version 2

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Review

Comparison of Exergames Versus Conventional Exercises on the Health Benefits of Older Adults: Systematic Review With Meta-Analysis of Randomized Controlled Trials

Xi Chen[1*], MD; Lina Wu[1*], MD; Hui Feng[1,2,3], Prof Dr, PhD; Hongting Ning[1], PhD; Shuang Wu[1], PhD; Mingyue Hu[1], PhD; Dian Jiang[1], BSc; Yifei Chen[1], MD; Yu Jiang[4], BSc; Xin Liu[5], MD

[1]Xiangya School of Nursing, Central South University, Changsha, China

[2]Xiangya-Oceanwide Health Management Research Institute, Central South University, Changsha, China

[3]National Clinical Research Center for Geriatric Disorders, Xiangya Hospital, Changsha, China

[4]Changsha Xingsha Hospital, Changsha, China

[5]Department of General Practice, 921 Hospital of Joint Logistics Support Force, The Chinese People's Liberation Army, Changsha, China

[*]these authors contributed equally

Corresponding Author:
Xin Liu, MD
Department of General Practice
921 Hospital of Joint Logistics Support Force
The Chinese People's Liberation Army
No.1 Hongshan Bridge
Changsha, 410008
China
Phone: 86 13308490423
Email: 281039313@qq.com

Abstract

Background: Conventional exercises (CEs) can provide health benefits for older adults, but the long-term exercise adherence rate is low. As an emerging, stimulating, and self-motivating strategy, exergames (EGs) are defined as combinations of exercises and games that users carry out through physical actions. They can promote exercise, but the health effects of EGs versus CEs on the physical function and mental health (cognitive function, depression, and quality of life) of older adults remain controversial.

Objective: The aim of the study is to compare the health benefits of EGs versus those of CEs for the physical function and mental health of older adults.

Methods: A comprehensive search was conducted from the earliest available date to February 2023 in the following 6 databases: PubMed, Web of Science, Embase, Cochrane, CINAHL, and PsycINFO. All English-language randomized controlled trials comparing the effects of EGs versus those of CEs on the physical function and mental health of older adults, with nearly same physical activity between the 2 interventions, were included. Risk of bias was independently evaluated by 2 authors using the Cochrane risk of bias in randomized trials tool. Two authors independently extracted data. We followed the *Cochrane Handbook of Systematic Reviews of Interventions* to process and analyze the data for meta-analysis. Standardized mean differences (SMDs) and 95% CIs were used for continuous data, and random models were used for analyses.

Results: We included 12 studies consisting of 919 participants in total. Of these, 10 studies were eventually included in the meta-analysis. The results showed that EGs versus CEs exhibited no significant differences in physical (P=.13; τ^2=0.31; χ^2_6=26.6; I^2=77%; SMD=0.37; 95% CI –0.11 to 0.86) or cognitive function (P=.63; τ^2=0.01; χ^2_3=3.1; I^2=4%; SMD=0.09; 95% CI –0.27 to 0.44) effects.

Conclusions: Our findings indicate no significant difference between EGs and CEs in improving the physical function and cognitive function of older adults. Future studies are required to compare the effects of EGs versus those of CEs on cognitive function according to cognitive status, quantify the “dose-effect” relationship between EGs and health benefits, and evaluate the effects of different types and devices of EGs with regard to the health benefits of older adults.

Trial Registration: PROSPERO CRD42022322734; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=322734

(JMIR Serious Games 2023;11:e42374) doi:10.2196/42374

KEYWORDS

exergame; exergaming; older adult; elder; geriatric; gerontology; physical function; mental health; systematic review; meta-analysis; meta-analyses; review methodology; RCT; randomized; cognitive function; depression; QOL; quality of life

Introduction

Background

With fertility rates declining and life expectancies rising, the global population is aging [1]. The number of adults older than 65 years has tripled over the past 50 years and, by 2050, older adults will make up a quarter of the global population [2-4]. Aging can lead to degenerative changes in the physical and cognitive function of older adults, resulting in impaired daily life functions and reducing the independence of older adults, thereby affecting their mental health and increasing the burden of health care [5]. Physical dysfunction is increasingly common at end of life [6], and the global pooled incidence rate of older adult frailty in communities is 43.4 per 1000 person-years [7]. Mental health problems are also common among older adults in China, and it is reported that 21,129 out of 88,417 older adults (23.6%) have these problems [8].

The physical and mental decline of older adults may eventually have serious social and economic consequences for an aging society [9]. For physical decline, frail older people (97/177, 54.5%) needs more health care services than nonfrail older people (30/987, 2.2%) [10,11], and the median hospitalization cost of frail patients is more than twice that of healthy patients (US $44,408 vs US $18,660) [12]. Furthermore, frail people also require continuous care at 5.82-fold the rate of healthy people after discharge [13]. Regarding mental health, studies predict that worldwide care costs for dementia, which is associated with cognitive decline, will increase to US $2 trillion by 2030 [14]. At the same time, the global economic burden of mental disorders in 2010 was similar to that of cardiovascular diseases, higher than that of cancer, and is expected to more than double by 2030 (US $2.5 trillion vs US $6.1 trillion) [15]. Thus, measures must be taken to promote healthy aging. A proven effective strategy is regular physical exercise [16].

Exercise is defined as "planned, organized and repetitive physical activity" [17]. Several studies have shown that conventional exercises (CEs), such as aerobic, resistance, and combined exercise, can improve the physical function and mental health of older adults [18-23]. However, older adults may not exercise due to lack of access to sports venues (eg, the COVID-19 pandemic), inconvenience, or lack of motivation [24]. In addition, the long-term exercise adherence rate for CEs among older adults seems to be low [25,26]. Therefore, an increasing number of studies have considered possible alternatives to CEs.

Exergames (EGs) are a combination of exercise and gaming that allows people to physically interact with a web-based game scene on a screen [27]. It requires the player's physical performance, as the technology used in the game system tracks the player's movements to control those in the game, thus immersing the player [28]. For example, in a Kinect-based EG [29], the game uses infrared light and cameras in the Kinect system to capture and track the player's movements and creates a full-body 3D web-based map, which is rendered by the screen in front of the player. Participants stand in front of the screen, imitate the actions of digital characters on the screen, and adjust their movements in real time based on instant visual and auditory feedback. It can be implemented in community centers, retirement institutions, long-term care facilities, assisted living, nursing homes, burn centers, hospitals, and homes [30,31].

EGs are an interesting strategy for active aging and good mental health [32]. They have been proven to be acceptable, feasible, safe, enjoyable, stimulating, and self-motivating tools [30,33-35]. EGs can be carried out at home, alone, or in groups, which may make it easier for older adults to participate in exercise [35]. In terms of physical function and mental health, in some studies, it is found that the EGs are better than CEs [36-38]; some have reported that EGs are as effective as CEs [39,40]; yet others have concluded that the effects of CEs are better [41]. In short, there is controversy regarding the effects of EGs and CEs on the physical function and mental health of older adults.

Research Gap and Aim

While 2 systematic reviews have compared the impacts of EGs and CEs on older adults, the results were inconclusive [42,43]. One compared balance and prevention of falls for EGs versus CEs in healthy older adults, and 20 randomized controlled trials (RCTs) were included [42]. EGs were found to have greater improvements in posture control and dynamic balance than CEs [42]. The other review compared the impact of EGs versus CEs on the cognitive function of older adults; it included 13 studies for systematic review and 11 studies for meta-analysis [43]. The results showed no statistical difference between the EGs and CEs in cognitive function [43]. However, these systematic reviews (1) did not distinguish sedentary video games from EGs; (2) searched only PubMed, Web of Science, and Cochrane databases; (3) included non-RCTs and quasi-experiments; (4) did not consider inconsistencies in exercise content between EGs and CEs; and (5) failed to distinguish the effects of EGs alone from the effects of EGs combined with other interventions, such as CEs.

Therefore, a systematic review should be conducted examining all the evidence, using quantitative analysis to compare the impacts of EGs versus CEs on older adults. Our study aims to compare the health benefits of EG versus CE programs for older adults' physical function and mental health (cognitive function, depression, and quality of life [QOL]). The comprehensive research results may provide a basis for the choice of rehabilitation strategy for the healthy aging of older adults.

Methods

The PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) was used to report this review [44].

Search Strategy

PubMed, Web of Science, Embase, Cochrane, CINAHL, and PsycINFO were searched using subject headings and keywords from their inception up to February 2023. We limited the publication language to English. Search strategies are shown in Multimedia Appendix 1. The references of all included studies were reviewed for further relevant research. If more information about relevant research was needed, we contacted the first author.

Criteria for This Review

Types of Studies

Published peer-reviewed reports of RCTs were included. We considered trials in which randomization was implied with at least 2 intervention arms (ie, EGs and CEs). Quasi-randomized studies were excluded. Abstracts, systematic reviews, case reports, and registered trial reports were also excluded.

Participants

Studies focused on older adults, where all participants aged 60 years or older, were included. Studies with a hybrid sample (ie, younger and older adults) and older adults with hemiplegia or other paralysis were excluded.

Types of Interventions

Activities carried out under sitting conditions and controlled by handheld devices (ie, sedentary video games) were excluded. There must be a group where the only intervention is EGs not combined with any other intervention, such as CEs or cognitive training.

Studies comparing EGs with CEs (eg, aerobic and endurance training, resistance or strength training, multicomponent training, balance training, high-intensity interval training, Tai Chi, yoga, dance, Otago, physical therapy exercises, ball exercise, and treadmill) were included. The CEs performed precisely the same physical activity as the EGs but did not involve web-based feedback.

Types of Outcomes

Primary Outcomes

Physical function is defined as the ability to perform and complete objectively measured performance-based tasks that assess cardiovascular fitness, muscle strength, flexibility, mobility, and balance [45]. Physical function was measured by the gait speed test, Berg balance test, sit-to-stand test, or 30-second chair stand test.

Secondary Outcomes

Cognitive function is defined as a broad set of thinking abilities that can be measured using performance-based tasks [23]. Cognitive function was measured by the Montreal Cognitive Assessment (MoCA) or Mini-Mental Status Exam (MMSE). If a study used both MoCA and MMSE to measure cognitive function, we extracted only the data measured by MoCA because a previous study has shown that MoCA is a better cognitive function measurement method and can detect cognitive heterogeneity well [46].

Depression was measured by the Geriatric Depression Scale. QOL was measured by SF-36 (36 health survey questionnaire).

Screening Process and Data Extraction

Screening Process

Two reviewers (XC and LW) independently conducted literature screening, first screening titles and abstracts to determine whether the research met the inclusion criteria.

Then the full text was obtained to determine whether the study was eligible for inclusion. If 2 reviewers had disagreements, a third reviewer was to be consulted to decide whether to include it. If disagreements could not be resolved through discussion, we would attempt to contact the corresponding author of the study for clarification.

Data Extraction

Two authors extracted data independently. The extracted data included first author, age, sample size (female %), population type, dosage of intervention, types of intervention, types of control, outcome, device, and results for the review objectives. We extracted data presented in figure and graph form when 2 review authors independently obtained the same results. Disagreements were resolved by a third reviewer. If data were missing, we would contact authors.

Quality Assessment

Methodological quality was assessed independently by 2 authors using the Cochrane risk-of-bias tool [47], which includes the following seven contents items: (1) random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) incomplete outcome data, (5) selective reporting, and (6) other bias.

Statistical Analysis

We followed the *Cochrane Handbook of Systematic Reviews of Interventions* to process and analyze data for meta-analysis [47]. The results of EGs and CEs were compared after the intervention. All results are continuous variables. Meta-analysis was performed using Review Manager 5.4 software (Cochrane). Standard mean difference and 95% CIs were used for continuous data. Subgroup analyses based on gender distribution were performed. The results were regarded as statistically significant when $P<.05$ [47]. The heterogeneity test was quantified using the I^2 statistic and the chi-square P value. The I^2 statistic was considered low, moderate, or large at 25%, 50%, or 75%, respectively [48]. A chi-square P value of .05 or less suggests heterogeneous meta-analyzed studies [47]. The random model was selected because the included studies from different populations were heterogeneous. Publication bias was assessed by examining funnel plots.

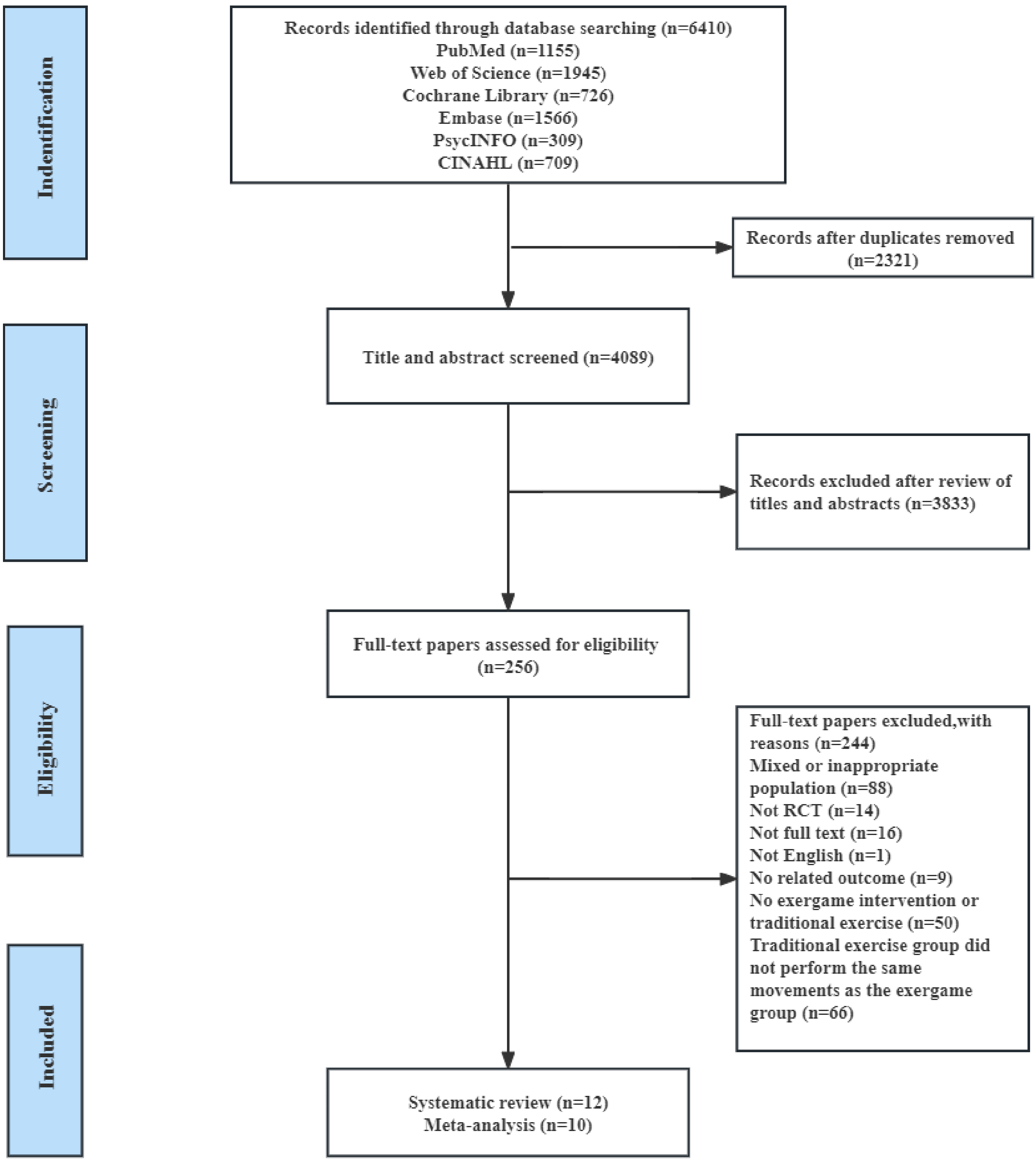
Results

Selected Studies

In total, 6410 potentially relevant studies were identified through database searching. After deduplication, the titles and abstracts of 4089 records were screened by checking the inclusion criteria; 256 studies were further screened by viewing the full texts for eligibility; 12 papers were included for the systematic review, and 10 papers were included for meta-analysis. Figure 1 shows the PRISMA flow diagram for paper selection.

Five studies focused on community-dwelling older adults [38,49-52], 3 studies recruited older adults from care facilities [29,40,53], 1 study was conducted in hospital and home [54], 1 study recruited older adults in a clinical physical rehabilitation unit [55], and 2 studies did not report the research setting [56,57]. Multimedia Appendix 2 [29,38,40,49-57] presents the characteristics of the included studies.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) flowchart of the study selection process. RCT: randomized controlled trial.



Characteristics of Participants and Interventions

The 12 included studies had a total sample size of 919 participants, with individual studies ranging from 18 to 282 participants. One study only recruited women [56], 1 study had an equal proportion of female and male participants [55], 6 studies recruited more female participants [29,40,49,52,53,56], and 5 studies recruited more male participants [38,50,51,54,57]. In total, 6 studies focused on older adults with Parkinson disease [38,50,51,54,55,57], 1 on older adults with mild cognitive impairment [49], and 1 on frailty [29]; 4 investigated older adults without special conditions [40,52,53,56].

A 2-arm design was used in 11 studies, including an intervention arm and a control arm [29,38,40,50-57]; 1 study used a 3-arm design, including 2 intervention arms and a control arm [49]. The intervention duration ranged from 5 to 12 weeks, and the most widely used duration was 6 weeks. The frequency was 2 or 3 times per week, and the length of each session was 30 to 90 minutes. The older people in 2 studies only participated in a single session of exercise training [52,53]. In total, 4 studies used Nintendo Wii for the intervention [53,54,56,57], 5 studies used Kinect for the intervention [29,38,49-51], 1 study used Tymo for the intervention [55], 1 study used GRAIL for the intervention [52], and 1 study did not report the intervention device [40].

Among the control group exercises, 1 study consisted of squats, postural displacements, dance, and sports (volleyball and boxing) [53]; 1 included resistance exercise, aerobic exercise, Tai Chi, and balance exercises [29]; 1 included global exercises and balance exercises [57]; 1 used Tai Chi [49]; 1 included task-oriented exercise, walking, stretching, balance training, flexibility exercises, and coordination exercises [55]; 1 included passive range of motion for lower extremities, active free exercises, stretching exercises, strength training, resisted exercise, and balance training [54]; 2 included strength exercises and core training [40,56]; and 4 studies used treadmill training in the control group [38,50-52].

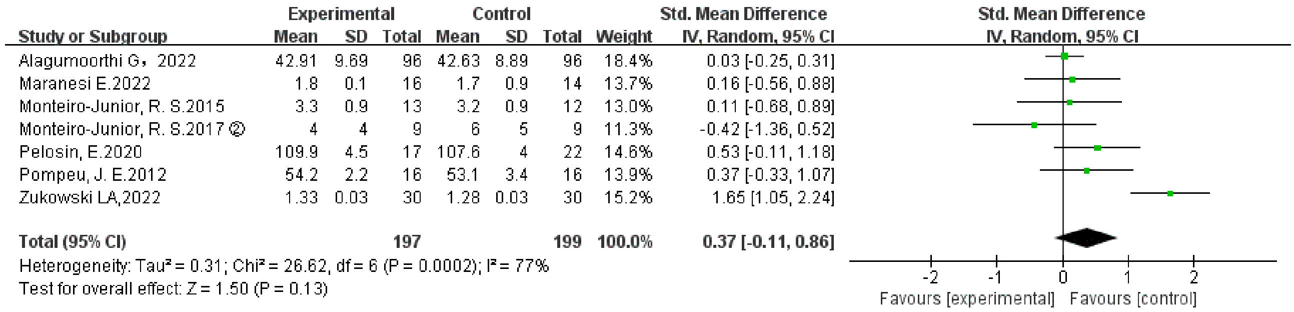
Meta-Analysis Results

Due to the lack of original data, we did not perform a meta-analysis of 2 papers [38,50].

Primary Outcome

Seven studies reported physical function according to the 30-second chair stand test, gait assessment (GaitRite, CIR Systems, United States), the sit-to-stand test, or the Berg balance test [40,51,52,54-57]. There was no significant difference between EGs and CEs (*P*=.13; τ^2=0.31; χ^2_6=26.6; I^2=77%; standardized mean difference [SMD]=0.37; 95% CI –0.11 to 0.86), more details in Figure 2.

Figure 2. Meta-analysis of the effect of exergames versus conventional exercises on physical function [51-57].

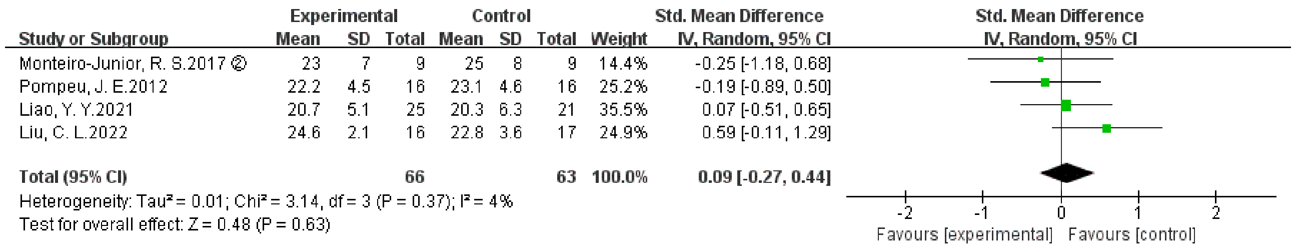


Secondary Outcome

Cognitive Function

Four studies reported cognitive function according to the MoCA or MMSE [29,40,49,57]. No significant difference was observed between EGs and CEs in MoCA or MMSE (*P*=.63; τ^2=0.01; χ^2_3=3.1; I^2=4%; SMD=0.09; 95% CI –0.27 to 0.44), more details in Figure 3.

Figure 3. Meta-analysis of the effect of exergames versus conventional exercises on cognitive function [29,49,53,57].



Depression

A single study reported depression and found no significant difference between EGs and CEs [40].

Quality of Life

Only 1 study reported QOL [38]. The results show that the SF-36 scores of the EG group improved more than those of the CE group.

Subgroup Analysis

To further compare the effects of EGs versus CEs on physical and cognitive functions in different gender distributions, the results of subgroup analysis are shown in Figures 4 and 5. No significant difference was observed in physical function between EGs and CEs when the percentage of females <50% (P=.23; τ^2=0.02; χ^2_2=2.4; I^2=18%; SMD=0.18; 95% CI –0.12 to 0.49) and when the percentage of females ≥50% (P=.40; τ^2=0.79; χ^2_3=19.5; I^2=85%; SMD=0.41; 95% CI –0.54 to 1.36). No significant difference was observed in cognitive function between EGs and CEs when the percentage of females <50% (P=.59) and when the percentage of females ≥50% (P=.42; τ^2=0.02; χ^2_2=2.3; I^2=13%; SMD=0.18; 95% CI –0.26 to 0.62).

Figure 4. Subgroup analysis of the effects of exergames versus conventional exercises on physical function [51-57].

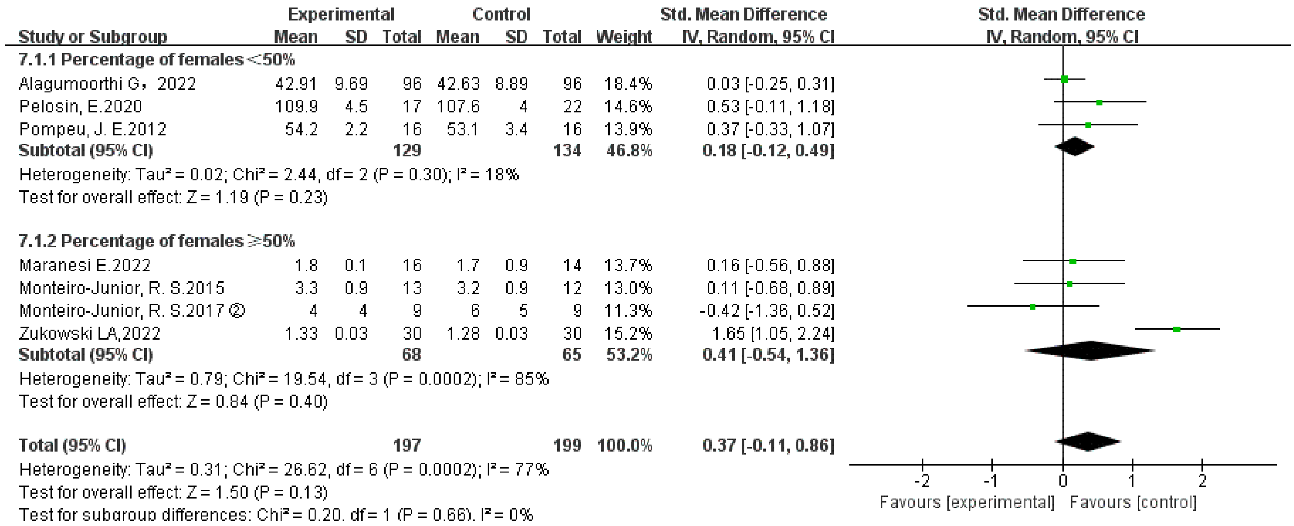
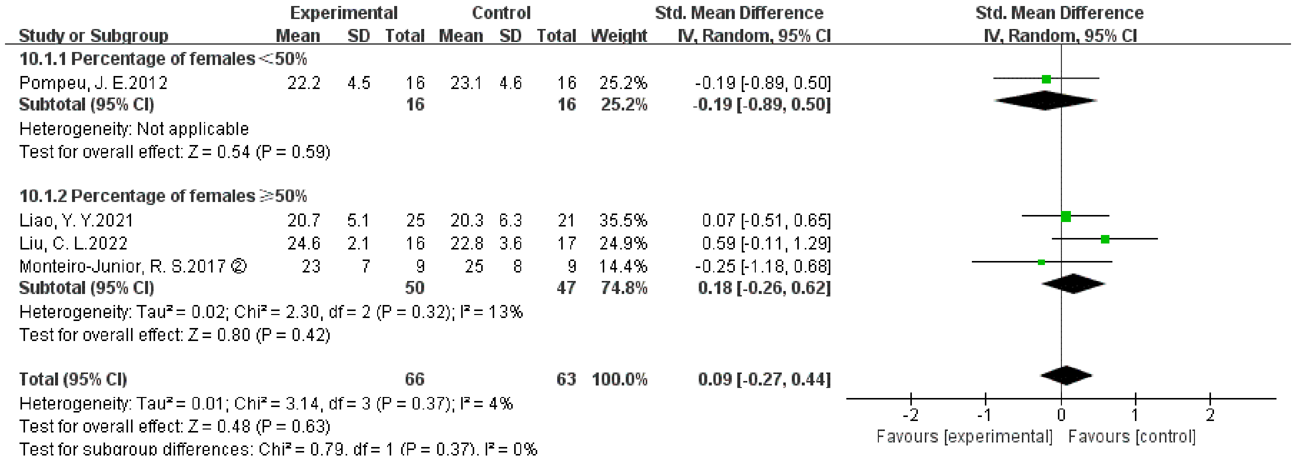


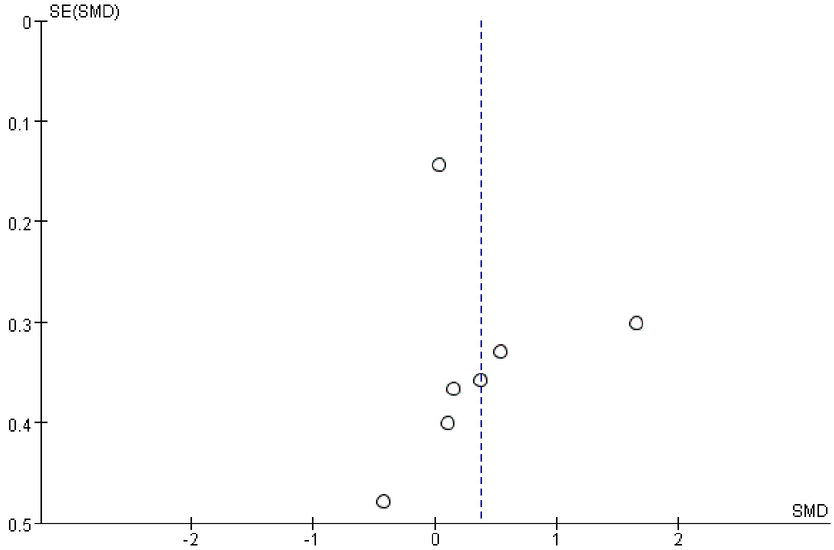
Figure 5. Subgroup analysis of the effects of exergames versus conventional exercises on cognitive function [29,49,53,57].



Publication Bias

The funnel plot did not show a clear funnel shape in physical function (Figure 6). The reason may be that some small studies with negative results may not favor the EG intervention.

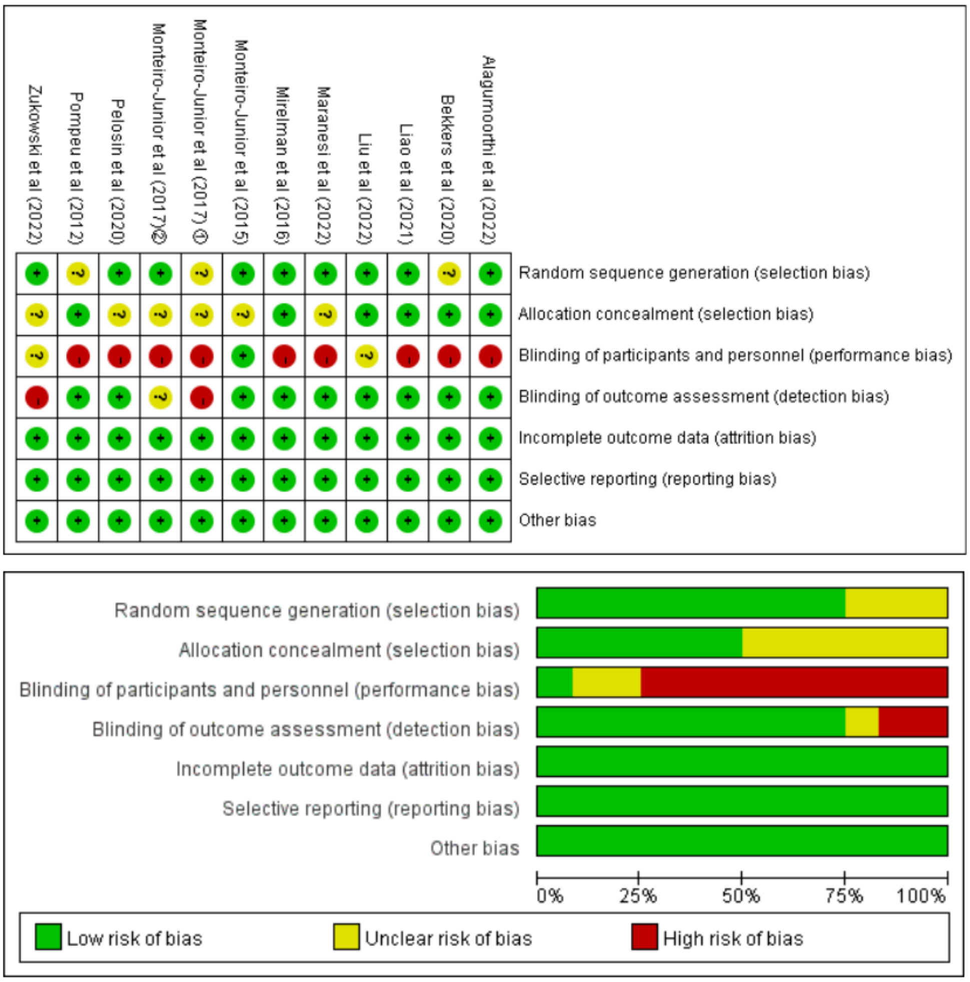
Figure 6. Funnel plot for publication bias assessment. SMD: standardized mean difference.



Quality Assessment

Figure 7 shows the results of the methodological quality assessment. The quality of the included studies was found to be acceptable. Regarding the risk-of-bias assessment [47], we found that 9 studies showed a high risk of performance bias [29,38,40,50,51,53,57], while 2 studies had unclear bias risk [49,56]. In total, 11 studies used a single-blind protocol [29,38,40,49-55,57], and 1 used a double-blind protocol [56]. Due to the EGs and CEs, it was not possible to blind patients or study personnel to the group allocation. High risk studies may overestimate the effect of EGs compared to CEs.

Figure 7. Analysis of the risk of bias in accordance with the Cochrane risk-of-bias tool [29,38,40,49-57].



Discussion

Principal Findings

By ensuring that EG and CE groups in the reviewed studies performed the same physical activity, this study is the first to compare the health benefits of EGs and CEs for older adults. We observed that EGs show potential as a novel approach for enhancing physical and cognitive function in older adults. The results of the meta-analysis show no significant difference in physical function or cognitive function between EGs and CEs after intervention. This means that EGs may replace CEs in these aspects. Our findings provide evidence of the beneficial effects of EGs, which may offer a promising strategy for promoting healthy aging in older adults. Given that EGs are an innovative, fun, and relatively safe form of exercise [58], this review presents timely evidence that suggests EGs could be a valuable tool for health professionals, such as physical therapists and occupational therapists.

The results show no significant difference in cognitive function between EGs and CEs. This supports the findings of previous studies [49,59,60]. One RCT with older individuals with dementia showed no significant difference in executive function, episodic memory, or working memory between EGs and aerobic training groups [60]. The other RCT suggested that the Kinect adventures training group and conventional physical therapy group had no significant difference in cognitive function after intervention, and both had positive effects on cognitive function in older adults [59]. In addition, EGs are inexpensive [61], safe [30,62], and easy to use [63], and healthy older adults living in the community can use them without supervision [64,65]. Therefore, the application of EGs in the cognitive rehabilitation of older adults should be promoted, especially for those with mild cognitive impairment or dementia.

However, our findings are inconsistent with a previously published systematic review and meta-analysis that compared the effects of EGs versus CEs on cognitive skills [43]. Based on that study, EGs seem to be more effective than conventional physical training for global cognitive performance. A possible reason is the potential ceiling effect [66]. The previous systematic review and meta-analysis included more patients with mild cognitive impairment or dementia, while our study included more older adults with normal cognitive function. Therefore, even before the intervention, the cognitive function of older adults in our study was quite good, which may make the improvement of cognitive function following EGs and CEs not obvious, resulting in a small difference in the improvement of cognitive function between the 2 groups. Thus, it is suggested that subsequent studies compare the effects of EGs and CEs on cognitive function according to the classification of the cognitive status of older adults.

Furthermore, EGs and CEs showed no significant difference in physical function. This is in accordance with previous findings [67,68]. This may be related to the impact of EGs on heart rate and energy expenditure similar to CEs [69]. Due to a lack of studies, we cannot analyze the impact of potential moderators (intervention time, intensity, and type of EG) on physical function. First, a subgroup analysis of the relationship between intervention time and effect shows that a weekly intervention affects physical function [42]. In that regard, there was no consensus on the duration of weekly interventions in the studies we included. Second, the intensity of EGs must be at least moderate to achieve the effect [69], while the included studies rarely measured the intensity of EGs. Finally, the types and devices of EGs will also affect the intervention effect. It is suggested that future studies explore the impact of different types and devices of EGs on the physical function of older adults. Subsequent studies should quantify the "dose-effect" relationship between EGs and health benefits in older adults, derive optimal intervention doses for EGs (eg, program period, weekly intervention duration, frequency, and intensity), and determine how different types and devices of EGs affect physical function in older adults.

Since gender distribution was very different among the studies, we performed subgroup analysis based on gender but found no difference in physical or cognitive function between groups at different distributions.

Only 1 study compared EGs versus CEs for depression, and only 1 paper compared the effects of EGs and CEs on QOL. The number of such studies is too small to conduct a meta-analysis. Therefore, future research needs to focus more on older adults' mental health and further explore and compare the effects of EGs versus CEs on depression and QOL.

According to the literature review, in addition to physical function and mental health, the included studies also compared adherence, motivation, cost-effectiveness, fall rates, accessibility, enjoyment, and attractiveness. One study showed no significant difference in adherence between EGs and CEs [38]; one study showed that the adherence of EGs was significantly higher than that of CEs [56]; and another study showed that EGs can improve the motivation and adherence of older adults in the long-term rehabilitation process [57]. One study found that EGs increased participants' motivation to do more repetitive movements with minimal or no instruction [54]; another study showed that the presence of motivating stimuli and the novelty aspect of EGs can be particularly important in patients with Parkinson disease who have reduced motivation [57]. One study reported that the extra cost of EGs is minimal compared to CEs (the costs of the computer, screen, safety harness, and platform are relatively low for medium-income countries) [38]. Three studies showed that the fall rate of older adults in the EG group was significantly lower than that in the CE group after the training [38,50,54]. Two studies reported that the advantages of accessibility, enjoyment, and attractiveness of EGs for older adults can further enhance the training effect of CEs [29,49]. However, the number of studies was small enough that a meta-analysis could not be done. We recommend that future research compares these outcomes between EGs and CEs because this information would be invaluable to establishing the added value of EGs versus CEs.

It is worth noting that while EGs may replace CEs in improving physical and cognitive function, it should be considered that not everyone is interested in EGs and not all EGs are suitable for older adults. A recent systematic review and qualitative meta-synthesis conducted by our group explored older adults' experiences of implementing exergaming programs [70]. We found that a small number of older adults were not interested in EGs, which may be due to age- or health-related factors (eg, vision, hearing, motor skills, or cognitive impairment). At the same time, most older adults have no experience with EGs and worry about whether they can understand and play such games correctly. In addition, people in East Asian countries (such as China, Japan, and South Korea) are more likely to feel embarrassed when using EGs because they feel uncomfortable being observed or judged by others. Finally, most existing EGs are not fully suitable for older adults due to a lack of flexibility and adaptability. However, most of these obstacles can be overcome, for example, by designing older people–friendly EGs for different target groups and giving older adults enough time to train and familiarize themselves with EGs.

This paper has limitations. Since we only included English-language studies, information deviations may occur. As exergaming is a fairly new field, there are few papers on this topic, and the number of studies included (and the total sample size) was not very large; thus, the results should be interpreted with caution. The overall methodological quality of the included studies ranged from medium to excellent, so our findings need to be interpreted with caution. Due to the heterogeneity of intervention types, intervention settings, intervention objects, and measurement tools for some outcome indicators, we were unable to conduct a comprehensive meta-analysis. The existence of publication bias resulted in heterogeneity (eg, differences in the intervention protocol) among the included studies, which reduced the quality of evidence. Finally, it must be acknowledged that the conclusions of this systematic review and meta-analysis may have been influenced by the professional backgrounds of the authors.

Conclusions

Our findings suggest that EGs are a novel and effective strategy for improving physical and cognitive function in older adults. There is no significant difference between EGs and CEs in improving the physical function and cognitive function of older adults, and EGs may replace CEs in these aspects. Our results confirm the effectiveness of EGs in rehabilitation programs for older adults and indicate that EGs may be a novel and feasible alternative to CEs. Future studies should compare the effects of EGs and CEs on cognitive function according to classification of the cognitive status of older adults. Subsequent studies should also quantify the "dose-effect" relationship between EGs and health benefits in older adults, derive optimal intervention doses for EGs, and explore the effects of different types and devices of EGs on physical function in older adults. More high-quality studies with more accurate outcome indicators are needed to further explore and compare the health benefits of EGs versus CEs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Literature retrieval strategy for the PubMed database.

[DOCX File , 14 KB - games_v11i1e42374_app1.docx]

Multimedia Appendix 2

Characteristics of studies included in this review.

[DOCX File , 20 KB - games_v11i1e42374_app2.docx]

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Abbreviations

CE: conventional exercise
EG: exergame
MMSE: Mini-Mental Status Exam
MoCA: Montreal Cognitive Assessment
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QOL: quality of life
RCT: randomized controlled trial
SF-36: 36 health survey questionnaire
SMD: standardized mean difference

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Original Paper

Virtual Reality Technology in Nursing Professional Skills Training: Bibliometric Analysis

Chengang Hong[1], BSc; Liping Wang[1], PhD

School of Nursing, Hangzhou Normal University, Hangzhou, China

Corresponding Author:
Liping Wang, PhD
School of Nursing
Hangzhou Normal University
2318 Yuhang Tang Road, Yuhang District
Hangzhou, 311100
China
Phone: 86 15356641080
Email: wangliping111@126.com

Abstract

Background: Nursing professional skills training has undergone significant transformation due to the exponential growth of computer and medical technology. The innovative use of virtual reality (VR) in nursing education has emerged as a cutting-edge technical support technique that has gained attention as a highly effective method for improving nurse training quality.

Objective: This study aims to review the current status of VR technology in nursing professional skills training, research hotspots, and emerging trends in the last 15 years.

Methods: The Web of Science Core Collection database was used to search for literature on VR technology in nursing professional skills training covering the period from 2006 to 2022. Biblioshiny (K-Synth Srl) was used to import and convert the records to Bibliometrix (K-Synth Srl) for analysis, and R (R Core Team) was used for descriptive bibliometric analysis. VOSviewer (Leiden University) was used to cluster co-occurring keywords, and Scimago Graphica (version 1.0.16; Scimago Lab) was used to generate a geographical visualization of published countries and regions.

Results: A total of 1073 papers were analyzed, indicating a surge in research on the application of VR in nursing professional skills training in recent years, as evidenced by a positive trend in annual publication of relevant literature. The majority of studies were from the United States (n=340) and Canada (n=107), and Margaret Verkuyl was the most prolific author, leading the way with 9 publications. Furthermore, “Computerized Virtual Patients in Health Professions Education: a Systematic Review and Meta-Analysis” was the most frequently cited reference. Keywords such as *education*, *simulation*, *skills*, *students*, and *care* were most commonly used by researchers.

Conclusions: The bibliometric analysis provides a comprehensive overview of the use of VR in nursing professional skills training, indicating that VR-based training is an effective means of improving the skills and competencies of nursing students and professionals alike. The COVID-19 pandemic has reinforced the importance of developing VR-based distance education, despite challenges such as integrating virtual and real-world training and mitigating safety risks.

(JMIR Serious Games 2023;11:e44766) doi:10.2196/44766

KEYWORDS

virtual reality; VR; nursing professional skills; bibliometric analysis; visual content analysis; extended reality; XR; augmented reality; AR; mixed reality

Introduction

Background

Nursing work holds a crucial position in health care. Nursing students, serving as a valuable pool of talent for the clinical nursing team, are essential figures in the advancement of nursing practice. They play a pivotal role in promoting the growth and development of the nursing profession and are a crucial component of the health care workforce [1]. Nursing educators face a significant challenge in cultivating the necessary expertise and skills among nursing students to provide effective patient care [2]. Considering the low efficiency of traditional nursing professional skills training methods, it can be challenging to motivate nursing students to engage with enthusiasm [3]. To ensure that nursing students possess sufficient expertise and are qualified to work in hospitals, many nursing educators use a variety of teaching strategies, including using VR, to enhance the quality of nursing professional skills training.

A virtual reality (VR) system can be defined as a highly interactive 3D digital media environment that generates a simulated reality and creates an immersive experience through the user's senses of vision, hearing, and touch. Essentially, it provides users with the feeling of being present in a separate virtual environment. The characteristics of VR systems can be summarized into 3 pivotal elements: immersion, interactivity, and sensory perception [4]. VR technology has been extensively applied in nursing theory teaching, nursing skills training, and clinical nursing teaching, both domestically and internationally. Yang and Huang [5] found that traditional nursing skills teaching fails to replicate the actual clinical environment. Students often lack the opportunity to gain genuine sensory experience of nursing operations and may learn various nursing procedures in a conventional and generic manner. This may hinder their ability to effectively transition into clinical work in the early stages of their career. Chu et al [6] showed that a VR-based immersive experiential learning model could be implemented for teaching and that situational learning was achieved through virtual laboratory and simulation training. Gao and Yao [7] provided a new idea for a method to teach endoscopic retrograde cholangiopancreatography to nurses by combining a VR endoscopic simulation system with microteaching. Jung and Park [8] built a head-mounted VR platform to enable students to observe the process of intravenous catheter implantation by modeling the angiography room. These examples provide a compelling argument for the potential of VR technology in enhancing the professional skills of nurses and nursing students.

Research Problem and Aim

The concept of "bibliometrics" was proposed by Pritchard in 1969, and it is defined as "the application of mathematical and statistical methods to books and other knowledge dissemination media" [9]. Bibliometrics offers a highly efficient tool for analyzing the progress of scientific research. It enables quantification of information on a specific research topic derived from online scientific citation databases, such as details on authors working in a field, publication numbers, and the distribution of research institutions [10]. Bibliometrics is a powerful tool that can assist in identifying significant literature in a research field and provide valuable data, such as keywords, institutions, country linkages, and distribution characteristics, in the form of a knowledge map. By quantifying the current state and future trends of the research topic, bibliometrics serves as an essential aid in comprehending the development of a particular field [11]. Generally, the greater the number of references included in a bibliometric method, the better we can comprehend the landscape of a research field [12]. A scoping review conducted by Yang and Huang [5] outlines the applications of VR technology in nursing professional skills training. There has been limited research on the scientific output of this field using bibliometric and visualization analyses. As a result, it is critical to comprehend the research status and hot spots of this field to aid in the advancement of nursing professional skills for nurses and nursing students. This study strives to offer a comprehensive analysis of the research field using the Web of Science (WOS) Core Collection as a basis and to serve as a valuable reference for future research.

Methods

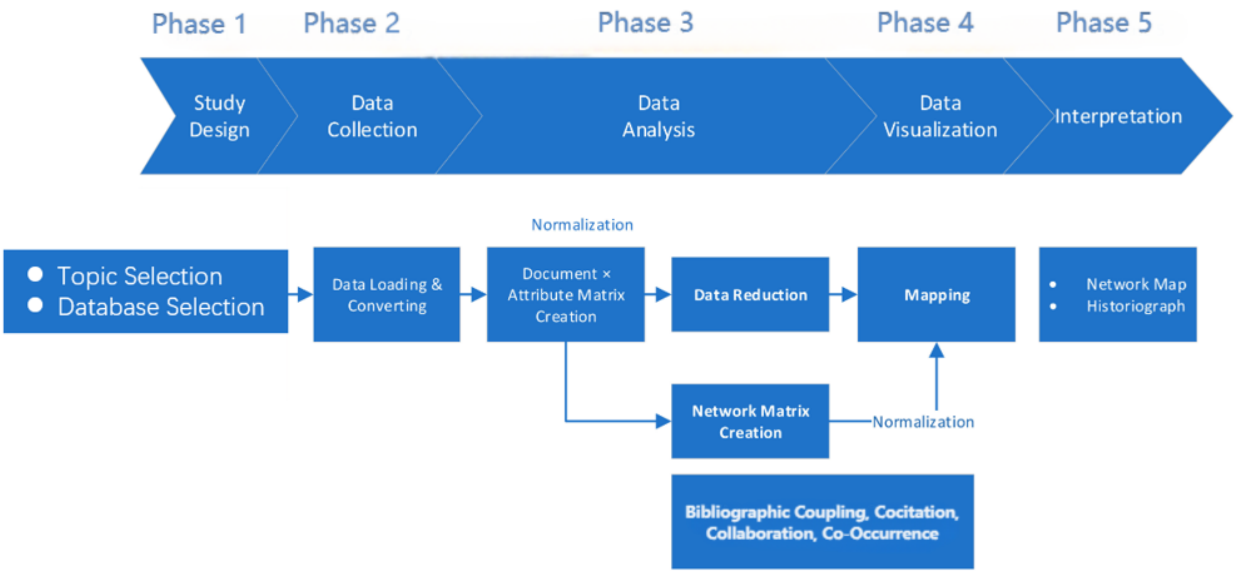
Data Sources and Search Strategy

For this study, articles and reviews that were published in English between 2001 and 2021 were included, using the WOS Core Collection database as the primary data source: (1) the retrieval expression was constructed using a formula that used a Boolean logic operator: TS=(virtual reality OR VR OR virtual medicine OR augment reality OR mixed reality OR virtual simulation) AND TS =(nursing* OR nursing practice OR nursing training OR academic training OR serious game), and the scope of literature was restricted to only articles and reviews; (2) the English language was selected; (3) there were 1073 documents retrieved in the search of WOS (as updated on 11 November 2022); and (4) all records were exported to plain text files, including the full record and cited references.

Bibliometric Analysis

A description of the bibliometric analysis method can be found in Aria and Cuccurullo [13]. Five rigorous steps, namely study design, data collection, data analysis, data visualization, and interpretation, were included in the analysis [14]. The complete methodology is schematically illustrated in Figure 1. The initial stage was the study design phase; nursing professional skills training was selected as the study topic. The research data resource chosen was the WOS Core Collection database, from which literature retrieval returned 1242 documents during the data collection phase. The review followed the structured approach outlined by Kable et al [15] for researching and evaluating literature. In this study, 2 reviewers (CH and LW) conducted an independent screening of the search results, with cross-checking used to resolve any disagreements. Training in document retrieval and screening was received by all researchers based on the textbook *Medical Literature Information Retrieval* [13]. A document-type filter was applied to the WOS, and articles and data papers were included, resulting in a sample of 1073 papers published between 2006 and 2022. All records were imported to Biblioshiny (K-Synth Srl) and converted to Bibliometrix (K-Synth Srl) for subsequent analysis. In the third stage, R (R Core Team) was used for descriptive bibliometric analysis and to develop a matrix of all documents. Biblioshiny, the Tidyverse package ggplot2 (Hadley Wickham), and VOSviewer (Leiden University) were used in the fourth stage to create a keyword cluster map. Scimago Graphica (version 1.0.16; Scimago Lab) was used to generate geographic visualization maps of the countries or regions. To identify influential sources, the Bradford law was used to unveil the journal distribution. The Methods section presents an interpretation of the data analysis and visualization outcomes.

Figure 1. Diagram illustrating the methodology of the bibliometric analysis, adapted with consent from the work of Aria and Cuccurullo [13] and Secinaro et al [14].



Ethical Considerations

An ethical approval application was not filed for this paper. The Chinese Hospital Association has stated that an ethics review is unnecessary for secondary analyses of published data.

Results

Descriptive Bibliometric Analysis

Each period's publication count is a reflection of the research field's development trends. Figure 2 presents the scientific output over the course of the study. There were 3 periods based on the number of publications: 2006 to 2013, 2014 to 2019, and 2019 to 2022. As seen in Figure 2, no relevant papers were released before 2006. From 2006 to 2013, the number of published articles increased annually, but at a relatively sluggish pace. The quantity of publications in 2019 (n=76) surpassed 75 for the first time. The number of articles published between 2019 and 2021 increased significantly, indicating that more scholars were focusing on the potential of VR in the nursing professional skills training field. Table 1 provides essential details on the 1073 research papers published in the WOS Core Collection database from 2006 to 2022. The annual average number of published research papers was 61.29, with each paper having an average citation count of 11.52. These papers had 4369 authors, with 59 of them being single-author papers. The average number of authors for each research paper was 2 (2.33). The collaboration index, which is the total number of authors of multi-authored papers divided by the total number of multi-authored papers, was 2.38. These papers also produced a total of 2388 author keywords.

Figure 2. The production of research on virtual reality–based nursing professional skills training in the scientific domain between 2006 and 2022.

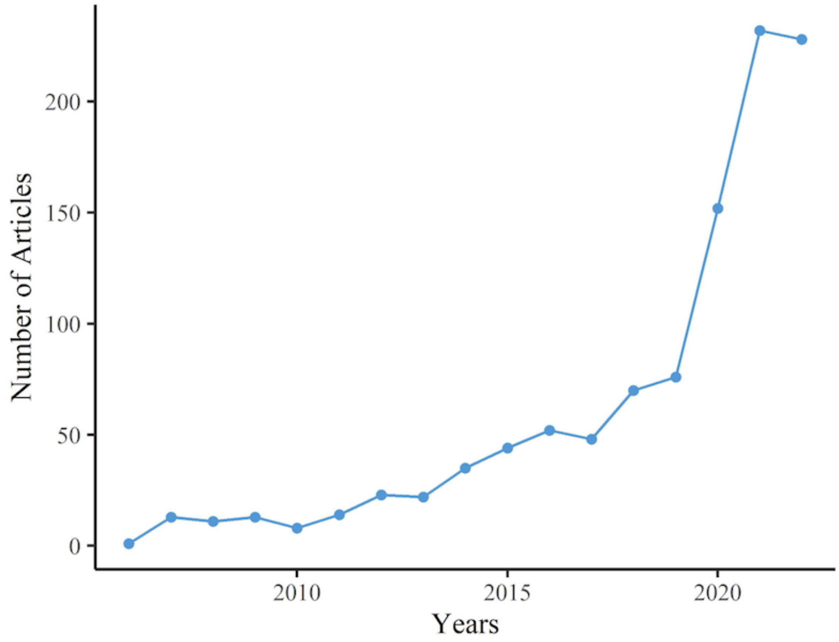


Table 1. Crucial information on virtual reality–based nursing professional skills training literature determined by the bibliometric analysis.

Information	Values
Documents, n	1073
Sources[a] (frequency distribution), n	300
Timespan (years)	2006-2022
References, n	30,766
Author keywords, n	2388
Keywords Plus[b], n	1469
Authors, n	4369
Authors' appearances (frequency distribution), n	5283
Authors of single-authored documents, n	59
Authors of multi-authored documents, n	1014
Documents per author (average), n	0.246
Coauthors per document (average), n	4.92
Citations per document (average), n	11.52
Collaboration index	0.23

[a]Sources include journals and books.

[b]Total number of phrases that frequently appear in the title of an article's references.

The WOS Research Areas

One or more subject categories (SCs) are linked to each publication indexed in the WOS. In this study, the number of research areas covered by VR-based nursing professional skills training education literature increased from 2 in 2006 to 22 in 2022 (Figure 3). Figure 4 displays the annual changes in productivity in the top 10 areas of VR-based nursing professional skills training education, which illustrates changes in the focus areas of VR-based nursing professional skills training education. The most popular research area was nursing, followed by education and educational research and health care sciences and services. With the increasing maturity of VR technology and stable production of VR equipment, the explosive growth in publications in the field of nursing professional skills training can be attributed to the use of various teaching strategies, including VR, by many nursing educators to enhance the quality of education.

Figure 3. The count of Web of Science research areas included in the literature of VR-based nursing professional skills training.

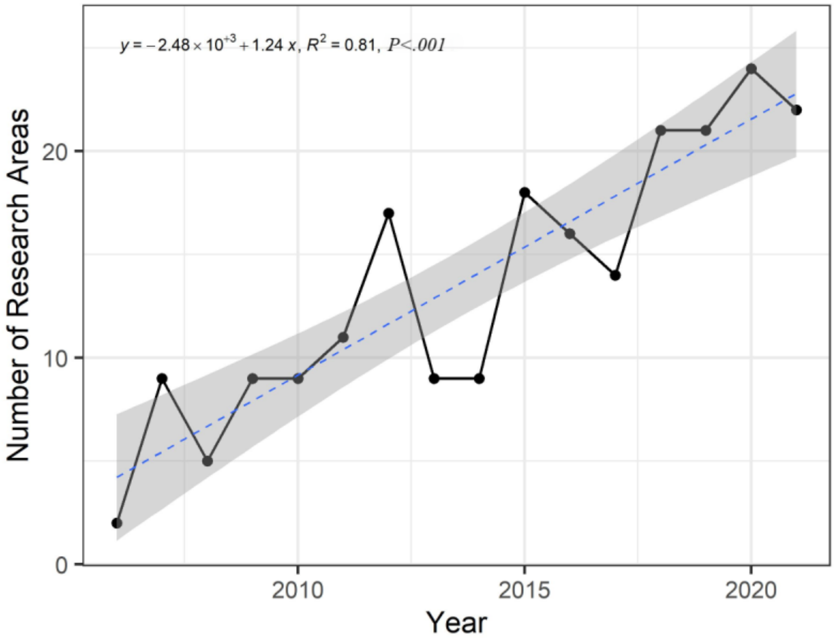
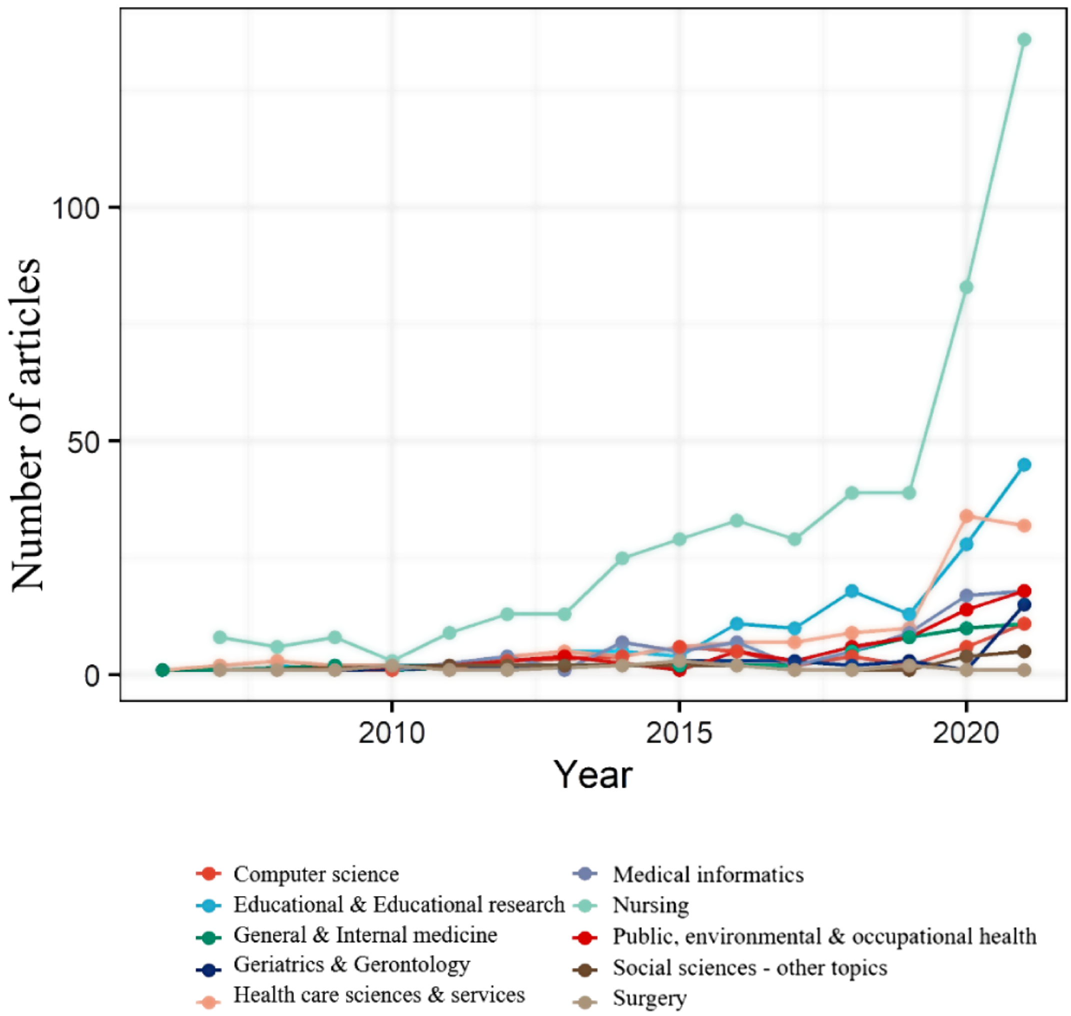


Figure 4. Yearly variations in the productivity of the top 10 Web of Science research areas in specific fields.



Research Countries and Institutions

Table 2 highlights that the United States has contributed the highest number of publications (340/1042, 32.63%) in the domain of VR-based nursing professional skills training, followed by Canada (107/1042, 10.27%), China (89/1042, 8.54%), Australia (71/1042, 6.81%), and the United Kingdom (51/1042, 4.89%). Of the total number of articles, 64.65% (658/1042) were published in these 5 countries. To generate a geographic visualization map (Figure 5), countries with more than 5 publications were analyzed using Scimago Graphica. The lines on the map indicate the degree of cooperation between different countries, with the thickness of the lines reflecting the extent of cooperation. It is evident from the map that the United States, Canada, Australia, China, and other countries have actively collaborated with other countries. Additionally, several scholars from Europe have shown interest in VR-based nursing professional skills training education and have conducted joint research projects to a certain extent. Table 3 highlights that while the United States has the highest number of publications, Canada's top 10 institutions rank higher in total citations, suggesting that both countries have robust support and funding for VR-based nursing professional skills training research.

Table 2. Countries with the highest total citation count for virtual reality–based nursing professional skills training research, ranked by the top 10.

Ranking	Country	Articles, n	Citations, n
1	United States	340	4215
2	Canada	107	1186
3	China	89	867
4	Australia	71	1145
5	United Kingdom	51	1027
6	Brazil	49	227
7	Korea	42	181
8	Spain	35	309
9	Singapore	30	489
10	Turkey	28	115

Figure 5. Map displaying research collaboration between countries.

Table 3. The institutions ranked in the top 10 based on the total number of citations for virtual reality–based nursing professional skills training.

Institution	Country	Articles, n
University of Toronto	Canada	42
National University of Singapore	Singapore	38
Université de Montréal	Canada	23
Toronto Metropolitan University	Canada	22
Centennial College	Canada	20
Johns Hopkins University	USA	20
University of Ottawa	Canada	19
University of São Paulo	Brazil	19
Nanyang Technological University	Singapore	18
University of Almeria	Spain	18

Most Influential Source Journals

Table 4 shows that *Clinical Simulation in Nursing* was the most cited journal with 1401 of 30,766 total citations (4.55%), while the *Journal of Medical Internet Research*, with an impact factor of 7.077, was the most impactful among the top 10 academic journals. Half of the journals in the table were ranked in the top quartile position. We also analyzed the distribution of research papers among leading sources and found that the top 5 journals accounted for 304 of 1042 (29.17%) of the total number of papers. The top 5 journals with the highest numbers of papers published were *Clinical Simulation in Nursing* (n=125), *Nurse Education Today* (n=93), *Journal of Nurse Education* (n=32), *Journal of Medical Internet Research* (n=27), and *Nurse Education in Practice* (n=27), with *Clinical Simulation in Nursing* having the most local citations (Table 4). According to the Bradford law, the source journals of VR-based nursing professional skills training papers were widely scattered, and the top 10 most influential journals were selected based on the number of local citations. Journals that were identified as core source journals in the field of VR-based nursing professional skills training according to the Bradford law are marked in Figure 6. These included *Clinical Simulation in Nursing*, *Nurse Education Today*, *Journal of Nurse Education*, *Journal of Medical Internet Research*, *Nurse Education in Practice*, *CIN-Computers Informatics Nursing*, and *Journal of Advanced Nursing*. These journals played a crucial role in the development of VR-based nursing professional skills training during the study period.

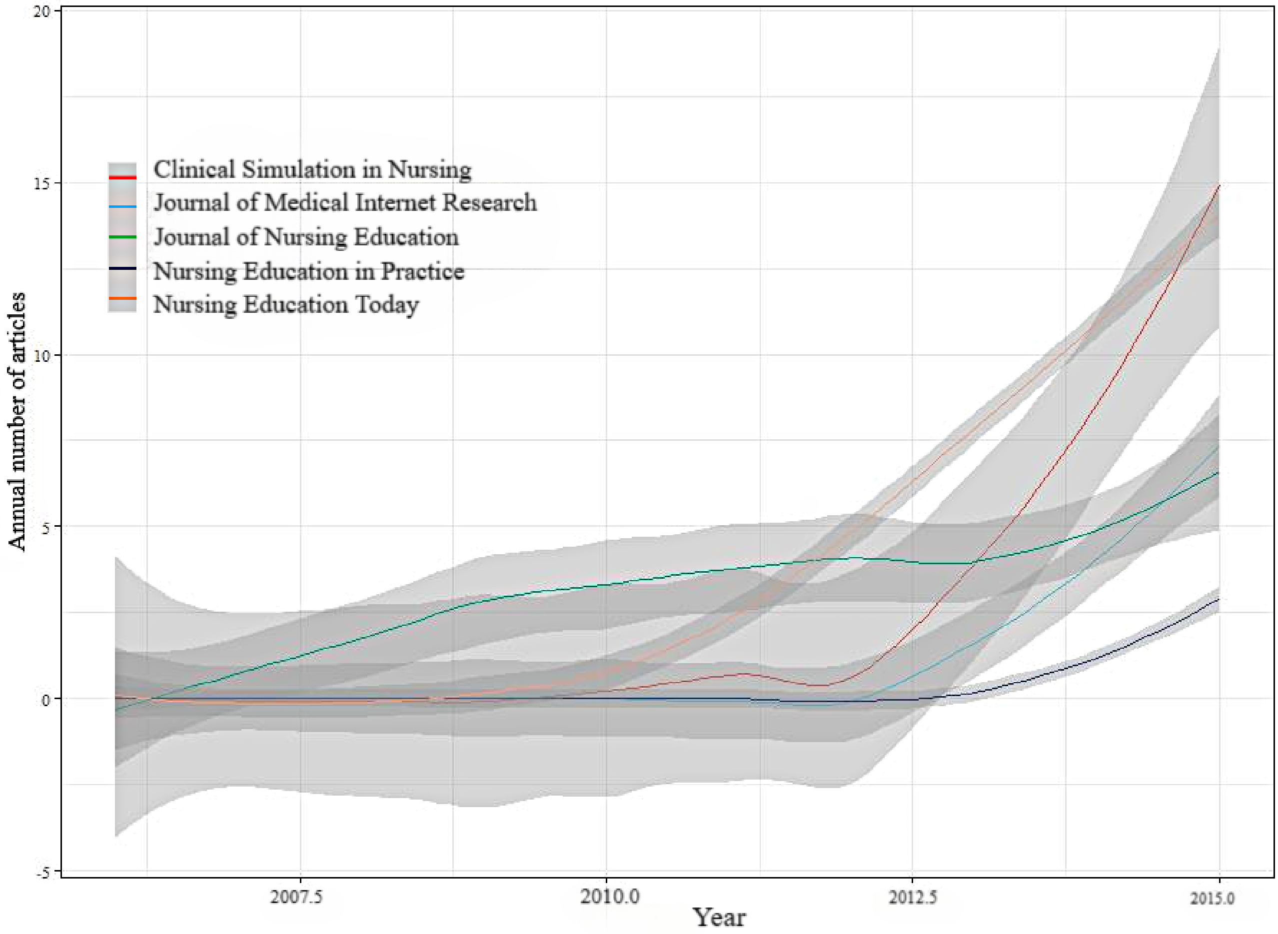
Table 4. Ranking of the top 10 journals in VR-based nursing professional skills training based on the number of local citations.

Journal	Local citations, n	Documents, n	Impact factor[b]	Rank (quartile)
Clinical Simulation in Nursing [a]	1401	125	2.856	Q1
Nurse Education Today [a]	1397	93	3.906	Q1
Journal of Nursing Education [a]	526	32	2.381	Q2
Journal of Medical Internet Research [a]	470	27	7.077	Q1
Nurse Education In Practice [a]	440	27	3.43	Q1
CIN-Computers Informatics Nursing [a]	421	25	2.146	Q3
Journal of Advanced Nursing [a]	407	19	3.057	Q1
Nurse Educator	385	18	2.791	Q1
JMIR Serious Games	382	18	3.364	Q2
Nursing Education Perspectives	343	17	0.59	Q3

[a]Journals classified as core resources in virtual reality–based nursing professional skills training according to the Bradford law.

[b]Impact factor in 2021.

Figure 6. Temporal analysis of the publication sources of virtual reality–based nursing professional skills training.



Most Influential Authors

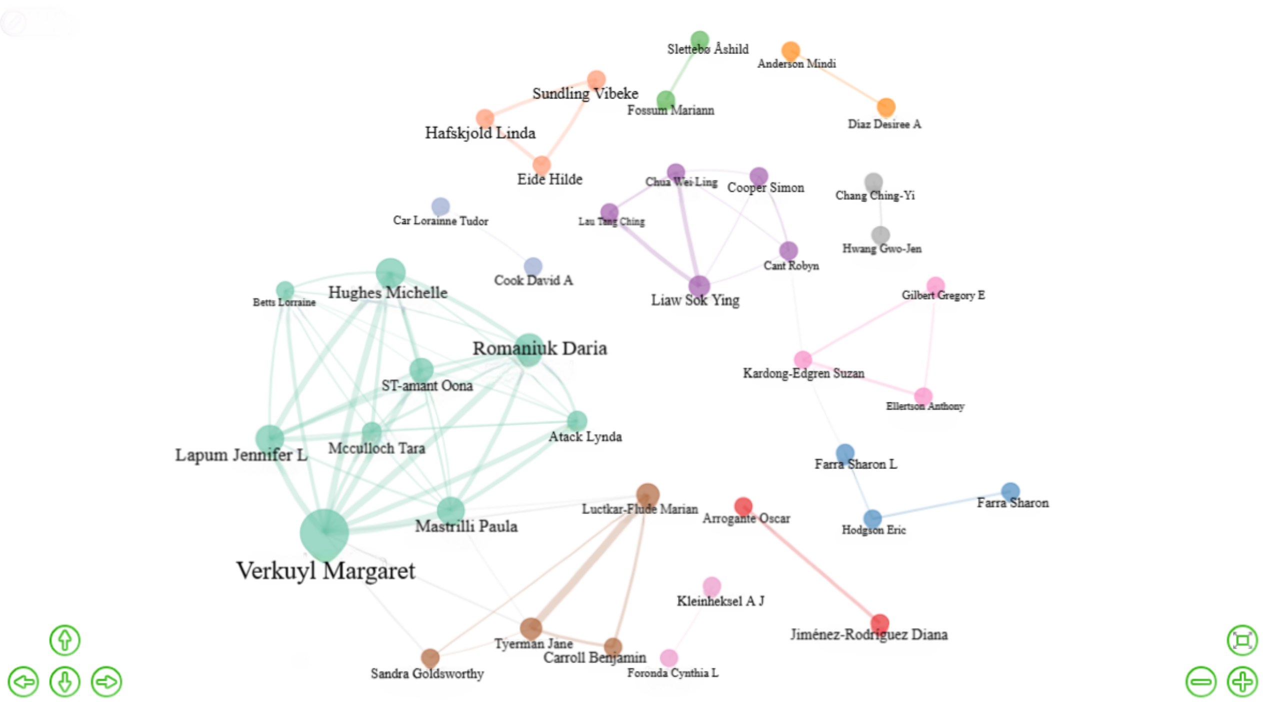
The H index is a widely accepted measure of scientific performance based on the number of citations received by a scientist's published papers [16]. Table 5 shows the top 10 authors with the largest H index: Margaret Verkuyl (H index 9), Shujuan Liao (H index 7), Daria Romaniuk (H index 7), Hilde Eide (H index 6), Sharon L Farra (H index 6), Michelle Hughes (H index 6), Paula Mastrilli (H index 6), Michelle Aebersold (H index 5), Lynda Atack (H index 5), and Luciana Mara Monti Fonseca (H index 5). The researcher with the highest number of citations, indicating significant influence, was Margaret Verkuyl. She is also the author with the highest density of collaboration (Figure 7). The top 10 most influential researchers included researchers from Canada (n=5), China (n=1), Norway (n=1), Brazil (n=1), and the United States (n=2). The 1073 papers involved 4369 authors. In total, 59 authors published 65 documents as sole authors, with an average of 4.92 co-authors per document and a collaboration index of 0.23. Each author contributed an average of 0.246 documents to the field, and on average, each document had 1.1 authors and 4.92 coauthors. These findings suggest that VR-based nursing professional skills training research is often a collaborative effort involving multiple authors.

Table 5. Authors ranked by the H index, with the top 10 being the most influential.

Author	H Index	G Index	Times cited[a], n	Scientific productions, n	First year published	Country
Margaret Verkuyl	9	16	268	21	2016	Canada
Shujuan Liao	7	13	250	13	2014	China
Daria Romaniuk	7	9	183	9	2016	Canada
Hilde Eide	6	10	124	10	2011	Norway
Sharon L Farra	6	7	114	7	2013	United States
Michelle Hughes	6	9	147	9	2017	Canada
Paula Mastrilli	6	10	165	10	2016	Canada
Michelle Aebersold	5	5	126	5	2015	United States
Lynda Atack	5	7	137	7	2016	Canada
Luciana Mara Monti Fonseca	5	8	68	8	2014	Brazil

[a]Web of Science Core Collection times cited count.

Figure 7. Visualization map of author collaboration in research on virtual reality–based nursing professional skill training.



Most Influential Papers

This section provides a list of the most influential papers (based on the number of citations) published between 2006 and 2022. Cocitations within a group of authors suggest that certain documents may include concept symbols. It is noteworthy that Tables 6 and 7 show a difference between the local citation score (LCS), which reflects the number of citations within the field, and the global citation score (GCS), which represents the total number of citations in WOS. The paper with greatest influence according to LCS was "Clinical Virtual Simulation in Nursing Education: Randomized Controlled Trial" (n=49). The paper with greatest influence according to GCS was "Computerized Virtual Patients in Health Professions Education: a Systematic Review and Meta-Analysis" (n=273). The papers in question may encompass theories that form the foundation of the field, early works that lay groundwork, and methodological principles [17].

Table 6. Top 10 papers ranked by the local citation score.

Paper	Year	Journal	Local citation score	Global citation score
Padilha et al [18]	2019	*J Med Internet Res*	49	108
Foronda et al [19]	2020	*Simul Healthc*	49	87
Cobbett and Snelgrove-Clarke [20]	2016	*Nurs Educ Today*	43	62
Cant and Cooper [21]	2014	*Nurs Educ Today*	39	94
Butt et al [22]	2018	*Clin Simul Nurs*	35	74
Cook et al [23]	2010	*Acad Med*	33	273
Padilha et al [24]	2018	*Clin Simul Nurs*	27	48
Duff et al [25]	2016	*Clin Simul Nurs*	26	50
Verkuyl et al [26]	2017	*Clin Simul Nurs*	26	50
Kidd et al [27]	2012	*J Psychosoc Nurs Men*	26	60

Table 7. Top 10 papers ranked by the global citation score.

Paper	Year	Journal	Local citation score	Global citation score
Cook et al [23]	2010	*Acad Med*	33	273
Cook et al [28]	2013	*Acad Med*	3	193
Zendejas et al [29]	2013	*J Gen Intern Med*	1	173
Foronda et al [30]	2016	*Nurse Educ Pract*	3	166
Gentry et al [31]	2019	*J Med Internet Res*	22	135
Kipping et al [32]	2012	*Burns*	6	130
Triola et al [33]	2006	*J Gen Intern Med*	13	123
Padilha et al [18]	2019	*J Med Internet Res*	49	108
Robert et al [34]	2014	*Front Aging Neurosci*	1	107
Manera et al [35]	2015	*Front Aging Neurosci*	3	106

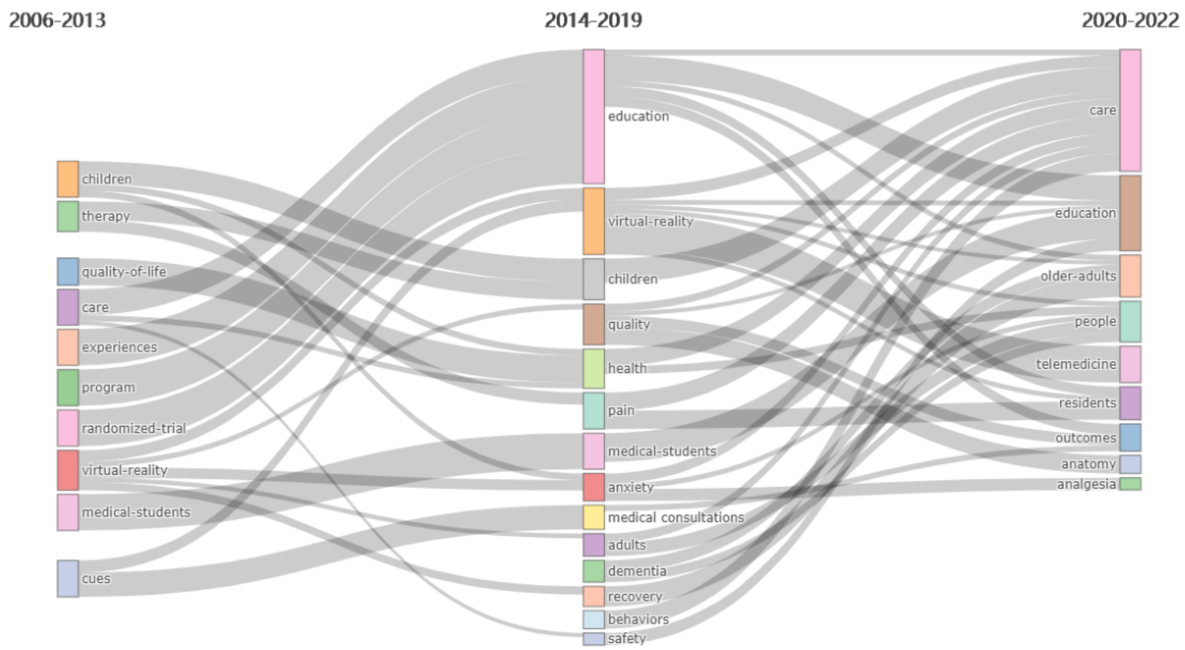
Distribution of Keywords

By conducting data cleaning to eliminate coding errors that could arise from different articles using varying keywords to introduce the same concept, we identified 2388 author keywords in 1073 published papers on VR-based nursing professional skills training between 2006 and 2022. The keyword analysis enables summary of the study's topics in the field and exploration of hotspots. For instance, *nursing* and *nurses* were recorded as *Nurses* to prevent discrepancies. *Education* had the highest frequency of 178 among the keywords, with other high-frequency keywords being *Simulation* (n=148), *Skills* (n=95), *Students* (n=84), *Care* (n=77), *Impact* (n=64), *Knowledge* (n=64), *Nurses* (n=62), *Virtual-reality* (n=58), and *Technology* (n=47), as shown in Table 8. Additionally, Multimedia Appendix 1 shows a keyword cluster map created using VOSview, while Figure 8 depicts the thematic evolution of the keywords.

Table 8. Top 10 keywords related to the application of virtual reality in nursing professional skills training.

Ranking	Keyword	Frequency	Centrality
1	*Education*	178	0.06
2	*Simulation*	148	0.05
3	*Skills*	95	0.04
4	*Students*	84	0.03
5	*Care*	77	0.05
6	*Impact*	64	0.06
7	*Knowledge*	64	0.05
8	*Nurses*	62	0.02
9	*Virtual-reality*	58	0.03
10	*Technology*	47	0.05

Figure 8. Map showing thematic evolution of keywords.



Discussion

General Information

Based on the annual number of publications, the publication years can be divided into 3 phases: 2006 to 2013, 2014 to 2019, and 2019 to 2022. The first phase, spanning from 2006 to 2013, saw an increase in the number of articles, albeit at a relatively slow growth rate. The second phase, from 2014 to 2019, was marked by significant advancements in VR device and software technology. This was exemplified by the launches of Project Glass by Google in 2012 and the first generation of the Oculus Rift VR headset by Oculus. These improvements resulted in an increase in the availability and quality of VR components [17]. In the period between 2014 and 2021, there was a noticeable increase in interest among scholars in computer science, as evidenced by periods 2 and 3. In the most recent phase, from 2019 to 2021, the number of publications exceeded 75 for the first time, with 76 articles published. This trend indicates an expanding interest among scholars in exploring the potential of VR technology in the field of nursing professional skills training.

Contributions to VR-based nursing professional skills training came from various countries worldwide, including the United States, Canada, China, Australia, the United Kingdom, Brazil, Korea, Spain, Singapore, and Turkey, with some taking a more prominent role. Notably, China is one of the few Asian countries to contribute to this field, indicating a lack of research emphasis on this topic among Asian scholars. In contrast, Canadian institutions and scholars have demonstrated continued interest in research in this area. A bibliometric analysis of VR and nursing professional skills training revealed Canada to have the highest contribution among all countries [23].

The frequency of cocitation can serve as a reflection of a journal's quality and influence. Among the ten journals with the highest cocitation frequency, half were found to be ranked in the top quartile. This suggests significant impact and recognition in the international community, indicating that the application of VR in nursing professional skills training has gained worldwide attention.

Following the analysis of cocited papers, it was found that "Clinical Virtual Simulation in Nursing Education: Randomized Controlled Trial" (n=49) was the most influential paper in terms of LCS. This study may contain foundational theories, pioneering early work, and methodological principles in the field. Similarly, "Computerized Virtual Patients in Health Professions Education: a Systematic Review and Meta-Analysis" (n=273) was deemed the most influential paper in terms of GCS. These works demonstrate how innovative research can impact an academic discipline for years to come and continue to inform contemporary research in the field.

Research Hot Spots and Frontiers

By using a combination of high-frequency keyword statistics, visualization analysis, and including relevant literature, this study indicates that an overwhelming majority of both domestic and international researchers have concentrated their efforts on exploring the application of VR technology in nursing education with a particular emphasis on nursing professional skills training.

Owing to variations in technological advancement, each country and region has conducted research to its own specifications with regards to the use of VR in nursing education. As an illustration, the VR nursing skills training system can provide a significant contribution to ensuring the proficiency of nursing students by enabling them to learn essential operational skills without the need for physical attendance, thereby providing them with the opportunity to review training materials anywhere at any time [23]. International research in this field commonly uses desktop VR system software to enhance students' clinical thinking skills. This type of software emphasizes immersive patient scenarios presented on the computer screen in which students are "placed" in a simulated clinical setting to observe and address the patient's discomfort and pain. The aim is to develop students' proficiency in making informed clinical decisions based on complex patient conditions [36]. The VR system can be improved in a short time according to teaching and learning needs, quickly meeting the skills training and teaching needs of various courses and improving the training effect. In order to give full play to the maximum benefit of the virtual system, it is suggested that schools and hospitals with suitable conditions choose VR technology to carry out skills training for students and promote their early adaptation to clinical practice.

In the field of nursing education, there are notable technical issues that exist with the application of VR technology at present. Caylor et al [37] pointed out that VR systems are faced with the problem of unclear navigation mechanisms within the operation interface. Poor experiences among nursing students during simulation learning are attributed to the confusing nature of the navigation interface within VR software platforms. Wilson et al [38] suggested that in future research on VR technology more attention be given to creating a simulation system with high fidelity, increasing the complexity of the cases presented within VR and reproducing challenging clinical case scenarios to enhance subjects' diagnostic reasoning abilities. Moreover, the development level and quality of VR software must be improved. This improvement is necessary due to the lack of understanding among VR technicians of the medical care field, which leads to failures to accurately reflect the key points and difficulties that teachers aim to emphasize. Additionally, it is vital to combine the advantages of VR teaching with existing nursing practices to ensure that VR technology is used effectively in nursing education [39]. To maximize the potential of VR technology in nursing education, researchers must consider providing a more comprehensive VR technology intervention, emphasizing multidisciplinary cooperation, and enhancing the familiarity of software technology developers with the nursing field. Additionally, teachers' proficiency in the operation of the virtual teaching process must be improved. To better explore the efficacy of VR technology in nursing education, it is crucial to enhance the VR teaching environment to improve nursing students' ability to apply the skills learned in virtual settings to clinical practice.

Applications and Development Trends in Research

Over the last 15 years, VR technology has been extensively implemented in nursing professional skills training. As mobile computing and sophisticated software programs continue to develop, highly immersive VR systems have become increasingly affordable and accessible [40]. Popular VR systems currently used in nursing professional skills training include Kinect from the United States, Nintendo Wii from Japan, HTC Vive from Taiwan, China, and Samsung Gear VR from South Korea. By integrating these VR systems into nursing education, we aim to facilitate the development of students' initiative and promote self-directed learning abilities, ultimately enhancing their clinical practice acumen.

As COVID-19 continues to impact the world, students' access to skills training may be limited. However, VR technology offers a viable solution to this problem. VR-based nursing skills training immerses students in a simulated environment, offering an opportunity to develop critical skills despite the pandemic. According to research, the use of a VR immersive experiential learning model for teaching fosters situational teaching through virtual laboratory and simulation training [6]. Furthermore, Gao and Yao [7] combined use of a VR endoscopic simulation system with the microteaching method to provide a new idea for teaching nurses endoscopic retrograde cholangiopancreatography. Jung and Park [8] developed a head-mounted VR platform for observing the process of intravenous catheter implantation in a highly realistic sensory scenario. This platform enabled students to view the entire arterial and venous system of the body, strengthening their theoretical and practical operation skills. Zhang et al [41] developed a highly realistic scenario simulation system for improving teachers' teaching ability and cultivating students' initiative, enthusiasm, and autonomous learning ability.

To establish VR technology as a reliable tool for improving nursing professional skills training, researchers must integrate knowledge from various fields, including nursing, computer science, neuroscience, psychology, social cognition, multisensory perception, and multimedia development. This requires an interdisciplinary approach that takes into account the needs of all stakeholders, including students, teachers, nurses, and software developers [42]. Thus, research on VR-based nursing professional skills training must involve a broad range of individuals to create effective teaching strategies that meet the unique needs of every student. High-quality research is necessary to explore the full potential of VR technology across various disciplines.

Strengths and Limitations

This is the first bibliometric analysis of VR-based professional skills training in nursing, providing a comprehensive understanding of the current state of VR in nursing education. Through analyzing keywords, countries or regions, institutions, authors, journals, and references, we have gained valuable insight into the research landscape. In the future, longitudinal in-depth studies on current hot topics or large, multicenter, high-quality randomized controlled studies guided by research trends can further enhance this field. At present, research in this field is predominantly limited due to technology and cost. To promote growth, policy and financial support should be provided to encourage researchers to learn from foreign advanced experience and enhance VR technology. Nursing staff must participate in program design from a nursing education perspective to create more suitable VR equipment and procedures. By vigorously developing the application of VR in the field of nursing education, we can better prepare our students for clinical practice.

However, it is important to note that this study used only one database (WOS), which may have excluded high-quality papers in the field. Additionally, the current word segmentation algorithm used in bibliometrics lacks necessary intelligence, leading to inaccurate extraction of some keywords. Thus, future bibliometric studies must strive to enhance the semantic understanding of citation data to facilitate accurate word segmentation and intelligent extraction of bibliometric knowledge. To ensure a more comprehensive and precise theoretical basis, future research should expand the database and source high-quality papers both domestically and internationally. This will better promote the advancement of nursing education and practice to new levels.

Conclusions

To review the application of VR technology in nursing professional skills training, this study used the WOS database, R, Scimago Graphica, and VOSview to provide a scientific and intuitive analysis. Bibliometric analysis indicates that research on VR-based professional skills training in nursing has experienced rapid development over the past 15 years. This is evident from the rising number of publications in core journals and increased collaboration between authors and countries or regions. Although this paper demonstrates an exponential growth trend in VR-based nursing professional skills training and positive feedback in the field's advancement, further investigation is required to understand the feedback mechanism.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Map showing research collaboration between keywords.
[PNG File , 857 KB - games_v11i1e44766_app1.png]

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Abbreviations

GCS: global citation score
LCS: local citation score
SC: subject category
VR: virtual reality
WOS: Web of Science

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Review

Dimensions of Interactive Pervasive Game Design: Systematic Review

Liu Kai[1,2*], PhD; Wee Hoe Tan[3,4*], PhD; Erni Marlina Saari[5*], PhD

[1]School of Art and Design, Henan University of Engineering, Zhengzhou, China

[2]Faculty of Art, Sustainability and Creative Industry, Sultan Idris Education University, Tanjong Malim, Malaysia

[3]De Institute of Creative Arts and Design, UCSI University, Kuala Lumpur, Malaysia

[4]Serious Games Association, Singapore, Singapore

[5]Faculty of Computing and Meta-Technology, Sultan Idris Education University, Tanjong Malim, Malaysia

[*]all authors contributed equally

Corresponding Author:
Liu Kai, PhD
School of Art and Design
Henan University of Engineering
No. 1, Xianghe Road, Xinzheng
Zhengzhou, 451191
China
Phone: 86 13298339393
Fax: 86 62503826
Email: liukai@haue.edu.cn

Abstract

Background: As the gaming industry grows around the world, playing pervasive games is becoming an important mode of entertainment. A pervasive game is one in which the game experience extends into the actual world or where the fictive world of the game merges with the physical world. How pervasive games can adapt to the ever-changing nature of technology and design in current society requires a comprehensive review.

Objective: In this systematic review, we aimed to measure and analyze 4 dimensions of pervasive games through development, technology, experience, and evaluation. Moreover, we also aimed to discover and interpret their relationship with game, interaction, experience, and service design.

Methods: We first chose 3 well-known databases, Web of Science, Scopus, and EBSCO, and searched from 2013 to April 2022. A strictly thorough Boolean search for research keywords such as "pervasive game," "design," and "interactive" resulted in 394 relevant articles. These articles were identified, screened, and checked for eligibility to find valid and useful articles, which were then categorized and analyzed using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) method.

Results: The systematic selection was finally left with 40 valid and valuable articles. After categorization and analysis, all articles were classified according to 4 main themes, which were design and development (11/40, 28%), interaction and technology (15/40, 38%), users and experience (9/40, 23%), and evaluation and service (5/40, 13%). These 4 main areas can be subdivided into several smaller areas.

Conclusions: In the 4 areas of game design, interaction design, experience design, and service design, many scholars have studied pervasive games and made contributions. Although the development and technology of pervasive games have evolved with the times, there is still a need to strengthen emerging design concepts within pervasive games.

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KEYWORDS

interactive; pervasive game; systematic review; design; mobile phone

Introduction

Background

During the global COVID-19 pandemic, people from all walks of life played video games to find joy, connection, and a sense of belonging. A game is a source of entertainment and comfort for millions of people in all countries, and it transcends age, race, gender, platform, and political party. In 2021, according to the Entertainment Software Association survey, 90% of gamers agreed that video games bring joy and strongly agreed that they can inspire (79%), provide mental stimulation (87%), and relieve stress (87%) [1]. Sensor Tower released its *Mobile Gaming 2022* report, which provides insight into how challenges affect different regions and game genres and which markets continue to grow in the face of these challenges. The biggest game opportunity is in China, as can be interpreted from the data. China currently leads the mobile game industry in terms of revenue and downloads and is expected to maintain its dominant position in the coming years [2]. Multiplayer online battle arena has proven to be one of the most challenging but rewarding game genres in the mobile game market, bringing a series of huge successes and painful failures. The latest high-profile multiplayer online battle arena to be released on cell phones is *Pokémon Unite*, developed by Pokémon Company in partnership with Tencent's TiMi Studio. *Pokémon GO* was downloaded more than 15 million times in the first 2 days of its release, making it the biggest release ever. By the end of the first week, the game had reached approximately 30 million downloads in 7 days [3].

Pervasive games are a very important subfield among the many game classifications. As early as 2009, Montola et al [4] wrote in their book that pervasive games were defined as having *one or more salient features that expand the contractual magic circle of play spatially, temporally, or socially.* Initially, pervasive games were relatively simple to play. Game players with other players and nonplayer characters communicate via phone, email, or MSN Messenger [4]. However, now, pervasive games are a whole new game style that extends game experiences into the actual world, weaving into the fabric of players' real-life settings [5]. According to some researchers, a pervasive game is when the player's experience is extended to the actual world, achievable because of the device's sensors [6]. These games are a relatively new type of entertainment that takes the game experience out of the device and into the actual environment, merging virtual and physical realities [7].

Pervasive games use mobile devices' data collection, geotagging, e-commerce, internet cookies, and social media capabilities [8]. Pervasive games rose to popularity with the release of Niantic's *Pokémon GO* in 2016. Two games now dominate the pervasive games market: *Pokémon GO* and *Ingress* [9]. Ingress has a rather simple core loop and low polish, but its dynamics seem to be tailored to enforce team socializing and collaboration [10]. After the successor to *Ingress*, *Pokémon GO* offers a more complicated primary gameplay loop. The mechanics of *Pokémon GO*'s main gameplay loop are more intertwined than those of *Ingress*; nonetheless, the game focuses significantly more on the individual's experiences in the Pokémon world and far less on social connections and collaboration [11].

Objectives

On the basis of the abovementioned background retrospect, it can be seen that further research on pervasive games is necessary. As design continues to evolve, many new concepts are being added. There is a need to add more current design factors in the game design industry. For example, interaction design, experience design, service design, and branding design are popular design concepts that constantly influence game design. In addition, the existing systematic review articles fail to provide detailed information on the review process. This includes keyword identification, article screening, and article eligibility. Moreover, because of this situation, prospective researchers could not reconstruct the survey, authorize interpretation, or assess the breadth of the data. Furthermore, this study is important because it provides researchers with an understanding of peer literature reviews and helps researchers better understand pervasive game design issues that may require academic attention. The current systematic analysis was conducted to answer the primary research question: Does the pervasive game embody other conceptions of thinking in the design field? The survey's primary focus was on perceptions of pervasive game design, including perceptions of design thinking in interaction design, experience design, service design, and branding design.

The *Methods* section describes the procedure used to answer the research topic of this study. The *Results* section conducts a systematic review and synthesis of the scientific literature to identify, select, and analyze the research needed on pervasive game design within design thinking situations. Finally, the *Discussion* section discusses the steps that must be followed, emphasizing the importance of aspiring academics understanding the issues.

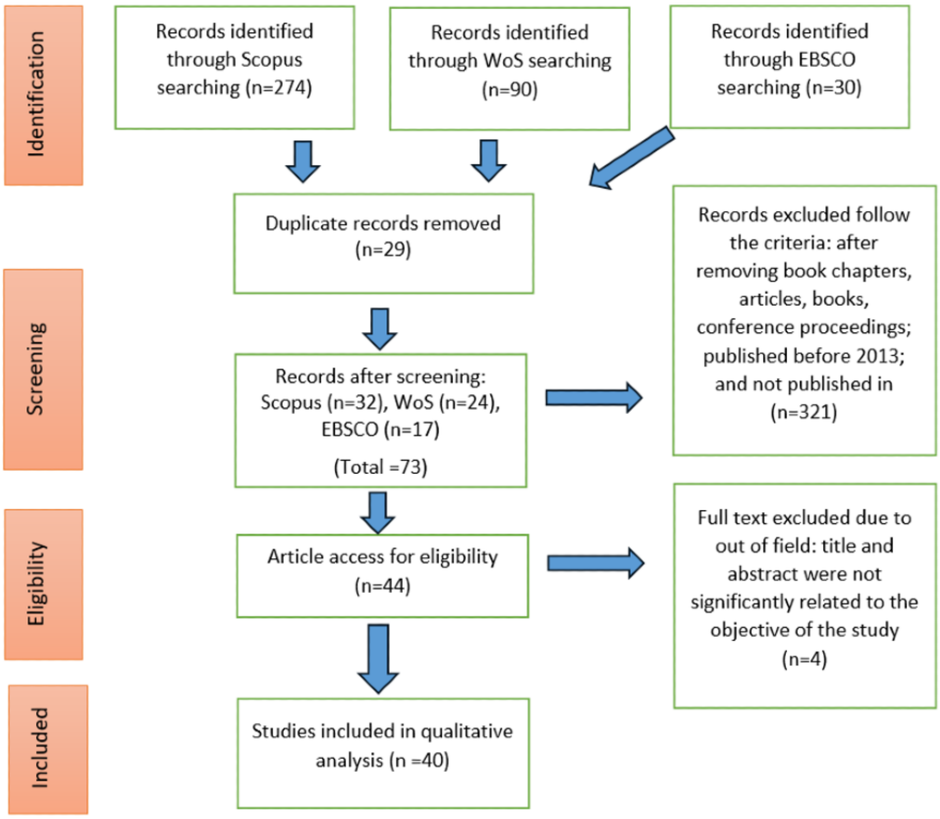
Methods

Overview

Several studies related to system evaluation have been conducted globally. However, only a few studies have focused on the design thinking connotations of pervasive games in the context of design thinking [4-8]. This section describes the need for a systematic analysis of the design thinking connotations of pervasive games. In contrast, the following section presents the methodology used to find the research answers formulated by this study. This literature analysis is divided into four sections: (1) design and development, (2) interaction and technology, (3) user and experience, and (4) evaluation and service. Furthermore, this section systematically reviews and synthesizes the scientific literature to distinguish, screen, and analyze important pervasive game research. Finally, reflecting on potential scholars suggests what actions should be taken to address the issues raised. The prerecording systematic reviews and meta-analysis (PRISMA [Preferred Reporting Items for Systematic Reviews and Meta-Analyses]) approach was used in this analysis, a documented standard for conducting a systematic literature review. In general, publication rules are required to aid writers in assessing and reviewing the quality and rigor of a review with relevant and necessary details. PRISMA also emphasizes the randomized study evaluation survey, an important feature in systematic analysis reports for various study types [12] (Figure 1).

In terms of instruments, the resilient character of 3 electronic databases, Scopus, Web of Science, and EBSCO, was used to evaluate this research methodology. This review's electronic database search included articles relevant to education, information technology, and social science. However, similar to Scopus, no database is perfect and detailed [13]. They mainly cover various fields, such as business and industry, economics, information technology, humanities, social sciences, communication and dissemination, education, arts, literature, medicine, and general science. This section also provides an overview of the 4 major subsections: identification, screening, eligibility, and data abstraction.

Figure 1. Flow diagram of the proposed search study. WoS: Web of Science.



Identification

The systematic review process can be divided into 3 main phases, each of which is responsible for selecting several appropriate papers for this report. The first step is the identification of keywords, followed by a search for related and analogous terms using resources such as the thesaurus, dictionaries, encyclopedias, and earlier research. Consequently, after determining all pertinent keywords, search strings for the databases Scopus, Web of Science, and EBSCO (Textbox 1) were formulated. This review successfully retrieved 394 papers from 3 databases during the first step of conducting a systematic review.

Textbox 1. Search strings.

Scopus

- TITLE-ABS-KEY ("pervasive gam*" AND design* AND (interaction OR interactive)) AND (LIMIT-TO (PUBYEAR, 2022) OR LIMIT-TO (PUBYEAR, 2021) OR LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2016) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2013)) AND (LIMIT-TO (PUBSTAGE, "final")) AND (LIMIT-TO (DOCTYPE, "ar")) AND (LIMIT-TO (SRCTYPE, "j"))

Web of Science

- ALL= ("pervasive gam*" AND design* AND (interaction OR interactive)) and Articles (Document Types) and 2022 or 2021 or 2020 or 2019 or 2018 or 2017 or 2016 or 2015 or 2014 or 2013 (Publication Years)

EBSCO

- ALL= ("pervasive gam*" AND design* AND (interaction OR interactive)) and Articles (Document Types) and 2022 or 2021 or 2020 or 2019 or 2018 or 2017 or 2016 or 2015 or 2014 or 2013 (Publication Years)

Screening

During the preliminary screening, duplicate papers were eliminated from consideration. In the first phase, we decided not to include 29 articles. In the second phase, we used several inclusion and exclusion criteria developed to screen 73 articles. The first criterion was the literature, which consisted of research articles, as this is the most important source of useful information. Publications in the form of systematic reviews, reviews, meta-analyses, meta-syntheses, book series, books, chapters, and conference proceedings were excluded in the current investigation. In addition, the review focused solely on papers written in English. It is essential to remember that the plan was to select publications across 10 years, from 2013 to 2022. Thus, 321 publications were disregarded because they did not meet certain criteria.

Eligibility

A total of 44 articles were prepared for the third step, which is referred to as eligibility. At this stage, the titles of all the articles and the primary content they contained were subjected to a comprehensive review to verify that the inclusion requirements had been reviewed and that the articles were suitable additions to this study following the research goals. Consequently, 4 reports were excluded because they did not consist of pure scientific articles based on empirical evidence. Finally, 40 articles were included in the final analysis (Textbox 2).

Textbox 2. Selection criteria.

Inclusion criteria

- Language: English
- Timeline: 2013-2022
- Literature type: journal (only research articles)

Exclusion criteria

- Language: non-English
- Timeline: <2013
- Literature type: journal (book chapter and conference proceeding)

Data Abstraction and Analysis

An integrative analysis, which is one of the examination techniques used to analyze and synthesize different research designs, was conducted in this study. This technique was used to integrate qualitative, quantitative, and mixed methods. The primary focus of the specialists' research was on the formulation of pertinent topics and subtopics. The data collection phase was the initial step in developing the theme. We thoroughly combed through a collection of 40 papers, searching for statements or information that responded to questions raised by this study. The second step involved the expert and us analyzing the situation regarding pervasive games within design thinking, determining meaningful groups to form. The 4 primary themes that emerged from the design and development, interaction and technology, user and experience, and evaluation and service need to be overcome. We reviewed every developed theme from this point onward, including any themes, concepts, or ideas that have any connection. We established themes based on the findings of the study within the framework of this research. In this instance, a log was kept during the data analysis to document any analyses, opinions, puzzles, or other ideas pertinent to data interpretation.

We also compared the findings to resolve any inconsistencies that may have occurred while developing the theme. It is important to note that we discussed with academics any inconsistencies that may have occurred within the themes and tried to resolve the inconsistencies. In conclusion, the developed themes underwent minor adjustments to ensure coherence. Two specialists carried out the examinations: one specialized in the games industry and the other specialized in the game academic areas. This was performed to ensure that the problems were valid. By establishing domain validity, the expert review phase helped ensure that each subtheme was clear, important, and adequate. Adjustments were made at our discretion based on comments and feedback from industry professionals.

Results

Overview

By extending the game experience into the physical domain, pervasive games represent a new era of entertainment and interaction. Pervasive game design is one of the many issues that must be reconsidered. As the development of pervasive games becomes more and more successful, the need to incorporate new design concepts becomes increasingly urgent. There were 40 articles extracted and analyzed based on a searching technique. All articles were classified according to 4 main themes: design and development (11/40, 28%), interaction and technology (15/40, 38%), users and experience (9/40, 23%), and evaluation and service (5/40, 13%; Table 1).

Table 1. Detailed presentation of results based on the research criterion.

Study, year	Journal	Title	Available in the database?			Remarks
			Scopus	Web of Science	EBSCO	
Arango-López et al [14], 2021	*Universal Access in the Information Society*	GeoPGD: methodology for the design and development of geolocated pervasive games	Yes	Yes	No	Design and development
Arango-López et al [15], 2021	*Universal Access in the Information Society*	Using geolympus to create a pervasive game experience in the higher education context	No	Yes	No	Design and development
Costa et al [16], 2021	*Multimodal Technologies and Interaction*	An Interactive Information System that supports an augmented reality game in the context of game-based learning	Yes	Yes	No	Interaction and technology
Oliva-Maza et al [17], 2021	*IEEE Revista Iberoamericana de Tecnologias del Aprendizaje*	Mystery of the runaway letrabytes: inclusive assessment of phonological awareness with tangible gamification	No	Yes	No	Evaluation and service
Santos et al [18], 2021	*JMIR serious games*	Promoting physical activity in Japanese older adults using a social pervasive game: randomized controlled trial	Yes	Yes	No	Users and experience
Alavesa et al [19], 2020	*Multimedia Tools & Applications*	Embedding virtual environments into the physical world: memorability and co-presence in the context of pervasive location-based games	No	Yes	Yes	Interaction and technology
Bellotti et al [20], 2019	*IEEE Transactions on Games*	REAL: reality-enhanced applied games	Yes	No	No	Interaction and technology
Costa et al [21], 2020	*Information*	Design of a mobile augmented reality platform with game-based learning purposes	Yes	Yes	No	Interaction and technology
Bonillo et al [22], 2019	*Multimedia Tools & Applications*	Developing pervasive games in interactive spaces: the JUGUEMOS toolkit	Yes	Yes	Yes	Design and development
Eckstein et al [23], 2019	*Entertainment Computing*	Smart substitutional reality: integrating the smart home into virtual reality	Yes	Yes	No	Design and development
Leone [24], 2019	*IxD&A (Interaction Design and Architecture(s))*	U'Game—a toolkit for urban gaming	No	Yes	No	Interaction and technology
Santos et al [25], 2019	*JMIR serious games*	Effects of social interaction mechanics in pervasive games on the physical activity levels of older adults: Quasi-Experimental Study	Yes	Yes	No	Users and experience
Santos et al [26], 2019	*Journal of Rehabilitation and Assistive Technologies Engineering*	Pervasive game design to evaluate social interaction effects on levels of physical activity among older adults	No	Yes	No	Users and experience
Guo et al [27], 2018	*Information*	Ontology-based domain analysis for model driven pervasive game development	Yes	No	No	Design and development
Klaassen et al [28], 2018	*Sensors (Basel, Switzerland)*	Design and evaluation of a pervasive coaching and gamification platform for young diabetes patients	No	No	Yes	Evaluation and service
Valente et al [29], 2018	*Personal & Ubiquitous Computing*	A method to assess pervasive qualities in mobile games	Yes	No	Yes	Evaluation and service
Kasapakis and Gavalas [30], 2017	*Multimedia Tools and Applications*	Occlusion handling in outdoors augmented reality games	Yes	No	No	Interaction and technology
Maia et al [31], 2017	*Entertainment Computing*	LAGARTO: A LocAtion based Games AuthoRing TOol enhanced with augmented reality features	Yes	Yes	No	Design and development
Valente et al [7], 2017	*Requirements Engineering*	Mapping quality requirements for pervasive mobile games	Yes	No	No	Evaluation and service

Study, year	Journal	Title	Available in the database?			Remarks
			Scopus	Web of Science	EBSCO	
Jong [32], 2016	*British Journal of Educational Technology*	Teachers' concerns about adopting constructivist online game-based learning in formal curriculum teaching: the VISOLE[a] experience	No	No	Yes	Users and experience
Mora et al [33], 2016	*Journal of Ambient Intelligence & Smart Environments*	From interactive surfaces to interactive game pieces in hybrid board games	No	Yes	Yes	Interaction and technology
Sekhavat [34], 2016	*International Journal of Computer Games Technology*	KioskAR: an augmented reality game as a new business model to present artworks	No	No	Yes	Interaction and technology
Guo et al [35], 2015	*International Journal of Multimedia and Ubiquitous Engineering*	RealCoins: A case study of enhanced model driven development for pervasive games	Yes	No	No	Design and development
Kasapakis and Gavalas D [36], 2015	*Journal of Network & Computer Applications*	Pervasive gaming: status, trends and design principles	No	No	Yes	Design and development
Kasapakis et al [5], 2015	*Personal and Ubiquitous Computing*	Pervasive games field trials: recruitment of eligible participants through preliminary game phases	Yes	No	No	Evaluation and service
Lemcke et al [37], 2015	*Personal and Ubiquitous Computing*	RouteMe: a multilevel pervasive game on mobile ad hoc routing	Yes	No	No	Interaction and technology
Lv et al [38], 2015	*Personal & Ubiquitous Computing*	Touchless interactive augmented reality game on vision-based wearable device	Yes	No	No	Interaction and technology
Pløhn et al [39], 2015	*Electronic Journal of e-Learning*	Dynamic pervasive storytelling in long lasting learning games	Yes	Yes	No	Design and development
El-Nasr et al [40], 2015	*Entertainment Computing*	Data-Driven Retrospective Interviewing (DDRI): A proposed methodology for formative evaluation of pervasive games	Yes	No	No	Evaluation and service
Sra and Schmandt [41], 2015	*Personal & Ubiquitous Computing*	Expanding social mobile games beyond the device screen	Yes	Yes	No	Interaction and technology
Evans et al [42], 2014	*Personal & Ubiquitous Computing*	The Malthusian Paradox: performance in an alternate reality game	Yes	Yes	Yes	Interaction and technology
Maggiorini et al [43], 2014	*Multimedia Systems*	Opportunistic mobile games using public transportation systems: a deployability study	Yes	No	Yes	Interaction and technology
Schmitz et al [44], 2014	*Pervasive and Mobile Computing*	The impact of coupled games on the learning experience of learners at risk: an empirical study	Yes	No	No	Users and experience
Chamberlain et al [45], 2013	*Entertainment Computing*	Them and Us: an indoor pervasive gaming experience	Yes	Yes	No	Users and experience
Chen et al [46], 2013	*International Journal of Human-Computer Interaction*	Your way your missions: A location-aware pervasive game exploiting the routes of players	Yes	Yes	Yes	Interaction and technology
Coenen et al [47], 2013	*Journal on Computing and Cultural Heritage*	MuseUs: case study of a pervasive cultural heritage serious game	Yes	No	No	Interaction and technology
Kristiansen [48], 2013	*International Journal of Mobile Human Computer Interaction*	Design games for in situ design	Yes	Yes	No	Design and development
Neustaedter et al [49], 2013	*Personal & Ubiquitous Computing*	Creating scalable location-based games: lessons from Geocaching	Yes	Yes	Yes	Design and development
Papagiannakis et al [50], 2013	*Journal of Universal Computer Science*	A multimodal ambient intelligence environment for playful learning	Yes	Yes	No	Users and experience

Study, year	Journal	Title	Available in the database?			Remarks
			Scopus	Web of Science	EBSCO	
Soute et al [51], 2013	*Entertainment Computing*	Evaluating player experience for children's outdoor pervasive games	Yes	No	No	Users and experience

[a]VISOLE: Virtual Interactive Student-Oriented Learning Environment.

Design and Development

Development Mode

Pervasive games are a completely new game form that extends game experiences into the physical world by incorporating information and communication technologies into the fabric of players' real-world environments. This emerging game mindset makes it difficult for developers to explore technologies and methods for providing a high-quality interactive experience for users and designing novel and compelling forms of content [36].

Model-driven development and domain-specific modeling have succeeded in many open or in-house information system scenarios. However, its application to games is rare and immature. Guo et al [35] illustrated solutions by describing a pervasive game case's technical and procedural development, incorporating model-driven development into the game development process. Furthermore, Guo et al [27] proposed a lightweight domain analysis that can be incorporated into the pervasive game development process. The domain analysis process is based on a game ontology that provides game design and domain analysis. They introduced the ontology, demonstrated its application in the domain analysis procedure, and evaluated and discussed the quality of the ontology using a user acceptance survey. The test results indicated that most potential users found the ontology useful and simple to use.

Development Tool

When developing pervasive games, programmers must deal with high turnover, cheating, and heterogeneity of devices and platforms. LAGARTO is an authoring tool for constructing location-based mobile games with augmented reality (AR) capabilities. These games are a subclass of pervasive games in which the game's progression depends on the location of the players. Maia et al [31] gleaned requirements for designing the LAGARTO software architecture from a literature review and focus group meetings. The tool consists of a web-based application for creating and managing games and a mobile app for tracking players. Their primary objective is to develop software that enables nonprogrammers to design, construct, and run location-based mobile games. The development of pervasive games is slowing down because of the multiple challenges that these games present to their creators, such as the vast array of interaction paradigms and the complexity of developing applications where so many innovative technologies converge. Bonillo et al [22] introduced JUGUEMOS, a toolkit designed to assist developers in creating pervasive games for interactive spaces. The toolkit addresses 3 difficulties that arise during the development of pervasive games: integrating heterogeneous devices, managing multiple displays, and facilitating game coding. They conducted case studies exploring the toolkit's expressivity, its ability to support collaborative multidisciplinary experiences, and its potential to support interactive experiences outside our interactive space. With the addition of pervasive or narrative components, however, the complexity of construction and support increases, necessitating a tool to manage the information appropriately and dynamically. Space and the pervasiveness of social interaction collaborate to achieve objectives by exchanging data between multiple pervasive games to improve the game experience. Arango-López et al [15] described a platform (*Geolympus*) that enables the creation of game experiences based on the player's location.

Development Direction

In recent years, games' design and development incorporating web-based elements into real environments have expanded. Such games include pervasive games, which seek to enrich the game world by combining these 2 realities to immerse the player more deeply in the story. The implementation of pervasive games has increased player engagement and motivation. New technologies have enabled advancements in the design and development of video games. Pervasive games have not been an exception, and combining traditional game elements with real-world elements and scenarios has made it possible to enhance motivation and user experience. However, previous research has demonstrated the need for a procedure to guide the design and development of pervasive games. In light of this, Arango-López et al [14] developed GeoPGD, a methodology that integrates the design of geolocated narrative as the core of the game experience. This methodology guides designers and developers through the various stages of creating pervasive games and provides tools for defining narrative elements, locations, and user-pervasive game interactions. Furthermore, Pløhn et al [39] described the Dynamic Pervasive Storytelling (DPS) approach and the design of the pervasive game *Nuclear Mayhem*, which was created to support a course in web game development at Nord-Trndelag University College in Norway. *Nuclear Mayhem* runs alongside the course for 9 weeks and requires specific elements to become part of the players' everyday lives, reminding them of the game they are playing. The game DPS as a model aims to increase the universality of the game and support the player's ongoing level of awareness in the game by incorporating real-world events. DPS uses real-world events as a building block to create the entire game story before the game begins by incorporating current events into its design and increasing the universality of the experience and in-game awareness as the game unfolds. This paper concludes that DPS is a promising approach to developing game narratives because it increases the universality of the game and promotes in-game awareness.

Mobile culture has given rise to many context-based products such as location- and hashtag-based apps. This poses new challenges for designers. Design methodologies that recognize context and allow it to influence design concepts are required. Kristiansen [48] focused on a design problem where live design practices can enhance the early design process: designing a pervasive game. Pervasive games are computer games that use cities as playgrounds and cell phones with GPS capabilities. Some contextual design approaches already exist, but the authors propose an approach that requires designers to conceptualize and implement ideas in the field, that is, at the game's location. The challenge is to develop a creative approach that includes on-site design work and generates game concepts for pervasive games. The proposed design approach, called *site storming*, was based on games involving individual scenario exploration of the site and various types of game cards, followed by a collective evaluation of the ideas generated. A series of evaluations showed that designers enjoyed using this method, stimulated idea generation, and live design influenced their design concepts.

The pervasive game aims to take computer games out of the PC and into the "real world" of cities, streets, and parks. This real-world physicality makes for an enjoyable player experience but presents a unique challenge for designing and coordinating such games. Neustaedter et al [49] explored how location-based games can be designed to overcome this scalability challenge—using Geocaching to determine how it has maintained user engagement and growth over the past decade. The findings show that Geocaching benefits from direct player creation of simple and complex game content. Geocaching also simplifies game choreography by allowing players to monitor game content, other players, and even nonplayers. Recently, developments in virtual reality technology have allowed users to consume immersive content from the comfort of their living rooms. Alternate reality promises to enhance this experience by incorporating physical environments into the simulation. Smart substitute reality (SSR) is a novel approach that combines the passive haptics of substitute reality with the active capabilities of a smart home environment. SSR is intended to serve as the basis for serious games. Eckstein et al [23] discussed the concept of SSR while implementing a prototype in our Smart Lab. They created multiple web-based environments with varying degrees of mismatch to the real world and added selected objects to induce additional tactile and thermal stimuli to enhance immersion.

Interaction and Technology

Outdoor Location

With the rise of pervasive computing, location-aware pervasive games are increasing rapidly. Chen et al [46] presented the design and implementation of *Your Way Your Missions*. This location-aware pervasive game uses the player's route to combat the inefficiencies of location- and radius-based information adaptation. *Your Way Your Missions* provides the player with a Google Maps–based tool to predefine the route and relies on self-reporting to obtain the player's planned route. Such a design returns the task to the player based on the task's location attributes and the player's intended route. The results show that the route predefinition and self-reporting approach is an effective way to obtain the player's planned route. This adaptation of information based on the player's planned route can help them locate the task at any time and location. Leone [24] also described this location-based outdoor interaction in his article. He described this small community's view of the connection between the real world and the video game world using physical and digital support. The paper highlights 3 games produced through participatory processes and argues for the role of urban and popular games as tools to promote citizenship. Other scholars have also suggested that using augmented or web-based field trips and pervasive educational games can potentially transfer learning content to the real world outside the classroom. Lemcke et al [37] presented the pervasive educational game *RouteMe*, which contextualizes the rather abstract topic of routing in ad hoc networks. The game was designed for college-level courses as a motivational supplement to these courses to enhance the learning experience. Students take on the role of routing nodes or applications with routing requirements. In 3 successive levels of difficulty, they are introduced to game concepts, learn basic routing mechanics, and become aware of the general limitations and capabilities of routing nodes.

With the increasing popularity of personal communication devices, the demand for location- and environment-based mobile services is growing exponentially. The mobile game as a service is no exception. Unfortunately, unlike other services, location- and context-based games strictly require near-field communication to create teams and arenas with nearby players. As currently used technologies have scalability (Bluetooth) or energy (Wi-Fi) limitations, opportunistic networks are considered a viable solution to engage large numbers of players in a larger area. However, it remains unclear how the increased latency and probabilistic message forwarding introduced by opportunistic networks will affect the player experience. Maggiorini et al [43] addressed these issues by simulating the deployment of a connection-based game on opportunistic networks provided by public transportation systems in 3 cities: Milan (Italy), Edmonton (Alberta, Canada), and Chicago (Illinois, United States). Moreover, they studied an opportunistic cooperative version of a well-known independent game for playability and scalability reasons. The emphasis on this particular game promotes the use of public transportation systems. Emerging pervasive games use sensors, graphics, and web technologies to provide immersive gameplay interactions integrated with the real world. Existing pervasive games typically rely on the device screen to provide game-related information and ignore opportunities to include new types of contextual interactions such as jumping, punching gestures, or even voice as game input. Sra and Schmandt [41] presented the design of *Spellbound*, a team-based physical mobile game, to help us understand how to design pervasive games that foster a spirit of togetherness. Sra and Schmandt [41] also briefly discuss how solidarity and playfulness transform physical movements into an ideal activity. *Spellbound* is an outdoor, team-based physical game. It takes advantage of the aforementioned opportunities to combine real-world movements such as jumping and spinning with the web-based world. It also replaces touch-based input with voice interaction. It uses custom hardware to provide tactile feedback, embodying the true spirit of social play that characterizes traditional children's games.

They believe that *Spellbound* is a form of digital outdoor play anchoring enjoyment in physical movement, social interaction, and tangible feedback.

Industry Application

Pervasive games have also contributed in terms of industry domains. Coenen et al [47] presented a case study of *MuseUs*, a popular pervasive game for museums that operates as a mobile phone app. During the museum visit, players are encouraged to create their exhibits and are guided through the process by application. The aim was to provide a learning effect during a museum exhibit visit. The core of the *MuseUs* experience is that it does not require a predetermined path through the museum and does not interfere with the exhibit itself. In addition, the application encourages visitors to see elements of cultural heritage in a new light, enabling a personal narrative while building a personal exhibition. Moreover, Sekhavat [34] described the architecture of *KioskAR*, a pervasive AR game. This game introduces a new business model that enables players to use AR to display their artworks in a web-based kiosk while enjoying the game. In addition to the competition, this game requires social interaction between players to earn more points. A user study evaluated the presence and usability of the application. The experiment showed that *KioskAR* could achieve a high level of usability and presence.

Interaction Mode

Creating pervasive games using emerging interactive technologies is becoming increasingly popular. Lv et al [38] designed and evaluated a touchless motion interaction technique for developing interactive and AR games on vision-based wearable devices. Users interact with AR games by making dynamic hand or foot gestures in front of the camera, which triggers interactive events with objects in the scene. As evidence, 3 elementary AR games with 11 dynamic gestures were created using the proposed touchless interaction technique. Finally, they presented a comparative evaluation to demonstrate the social acceptability and usability of the touchless approach running on a hybrid wearable frame or Google Glass and assess workload, user sentiment, and satisfaction. Recently, developments in interactive surfaces and tangible user interfaces offer new opportunities for pervasive games that combine traditional board games' social affordances with the interactivity of video games. Mora et al [33] proposed a strategy centered on tokens, constraints, spatial representations, and interactive events in this research area. Rather than using interactive surfaces as the primary interaction medium, this approach relies on physically manipulating interactive, computer-enhanced game components on standard surfaces. Furthermore, AR in mobile game development, where computer-generated graphics are used to enhance the player's view of the physical world, is becoming increasingly common.

AR Overview

In AR applications, it is common for objects to be partially or completely obscured by physical objects; if not handled properly, the visualization of obscured objects can often mislead the user's perception. Kasapakis and Gavalas [30] presented 3 alternative geolocative raycasting techniques designed to help outdoor pervasive game developers solve the occlusion problem by integrating real-time building recognition to generate a realistic field of view for the player. The geographic raycasting approach has been implemented in the location-based pervasive game *Eliminate Order*, which uses publicly available free building data to calculate the player's field of view in real time. The proposed algorithm applies to many sensor-based AR applications and can be ported to any real-world environment. A few years earlier, Evans et al [42] examined the design of the *Malthusian Paradox* and highlighted how it redefines the framework of performance in sometimes disturbing ways by blurring the traditional roles of performer and audience. Players engage with the game through various interactive channels, including performative group performances and one-on-one interactions with game characters in public settings, using low-end and high-tech physical and web-based artifacts such as customization and third-party websites. Players and game characters communicate in planned and unplanned ways via phone and social media. We reflect on the production and choreography of the game, including the dynamic nature of strong episodic narratives driven by professionally produced short films that attempt to respond to the player's actions and the difficulties of designing for engagement across hybrid and time-dilated performance spaces.

Realistic 3D environments, such as existing city models, have the potential to serve as a bridge between the physical and the environments in pervasive games. Smooth attention shifts and transitions between these 2 realities are largely unexplored in the context of pervasive games. Alavesa et al [19] conducted 2 field experiments using a pervasive live-action role-playing game to investigate the effects of transitions between the web-based and physical environments on coexistence and memorability. Although there were few differences in copresence during play, they highlighted the subtleties in the social structure of the universal game. 3D environments are more memorable because of their spatial similarities to the physical world. We then identified 2 important factors to consider when integrating web-based environments into pervasive games: the structuring of social interactions and spatial realism. The emerging genre of pervasive games combines reality with computation. Bellotti et al [20] explored the concept of "reality-enhanced games" through a simple set of pervasive games. A reality-enhanced game is a model that links game mechanics to the outcomes or measurements of real-world activities. The prototype game was created as part of the TEAM Industrial Research Project, which aims to develop mobile apps for flexible and collaborative mobility. The proposed game is an example of various user interfaces that are believed to be useful for various important scenarios, goals, and user types, particularly for improving driving styles. This concept allows pervasive game developers to focus on their game logic while seamlessly leveraging a variety of in-field sensors, and it is generic.

AR is an emerging technology that superimposes objects onto the physical world. Recent computer and mobile technology advances have made AR increasingly accessible in education. Costa et al [21] described an educational mobile AR platform. The platform includes a mobile app consisting of a pervasive game designed to encourage learning about the universe. In addition, it includes a backend that enables teachers to present information about celestial bodies and create multiple-choice questions to assess students' knowledge of the participants they are studying. The mobile app provides users with real-world physical movement and social interaction while playing the game; therefore, it falls within the paradigm of pervasive games. In addition to engaging students to play games, they believe that this platform can be implemented in both informal and formal learning environments. Mobile AR applications are gaining prominence in education, but there is a need to design educational games that are both appropriate and enjoyable. Costa et al [16] described an interactive information system to facilitate the implementation of a pervasive game for game-based learning. *PlanetarySystemGO* includes a location-based mobile AR game that facilitates learning about cosmic objects and planetary systems and a web application that interacts with mobile device apps. This resource can be used for web-based and face-to-face classes, which are useful in socially isolated situations, such as those caused by the COVID-19 pandemic. In addition, adding web applications with a backend to the information system allows for the inclusion of curriculum content based on the student's grade level. Similarly, teachers are expected to use the information system to incorporate content that they feel is appropriate for their teaching grade level. Therefore, it is critical to provide them with the professional development they need to use this resource. Teachers found this resource helpful in motivating students to learn, recognizing that the web application facilitated the introduction of appropriate curriculum content and was useful in assessing student performance in games.

Users and Experience

Children's User Experience

There is a growing body of research on pervasive outdoor games, with most studies focusing on adult mobile phone players. Most published assessments of player experience in such games are based on anecdotal descriptions and postgame surveys. The latter approach is particularly difficult to implement when the game testers are children. Until now, observations of games have been ad hoc and based on unstructured observations, making it difficult to draw reliable conclusions from observations and compare games. The Outdoor Play Observation Scheme and GroupSorter are 2 methods developed specifically to assess the player experience of children's outdoor play [51]. They discussed their application in 3 case studies and concluded that Outdoor Play Observation Scheme is useful for quantifying various play behaviors in outdoor play. GroupSorter adds qualitative data about play experiences. Moreover, the application of GroupSorter is not limited to game development; it can be used to collect user input in other contexts. In the same year, Papagiannakis et al [50] described the design, development, and evaluation of AmI Playfield, a technical framework for learning applications designed to create challenging learning conditions through play. An AmI Playfield is a guided ambient intelligence. It emphasizes using kinesthetic and collaborative technologies in a natural, play-based learning environment. It also incorporates performance measurement techniques. The *Apple Hunt* application was created to test and evaluate AmI Playfield, engaging child learners in arithmetic thinking through kinesthetic and collaborative play. Simultaneously, AmI technology observes behind the scenes. *Apple Hunt* has been assessed using a combination of methods suitable for young testers, and the Children's Commission is presented as a promising assessment method for children. The results indicate the system's high capacity to stimulate thinking and enjoyment, thanks to the learners' whole-body kinesthetic play and teamwork.

Acquiring literacy skills requires developing phonological awareness, a metacognitive skill. This allows thinking about and manipulating language structures from an early age. Learning requires multisensory stimulation as well as curiosity and interest. Communication technologies play an important role in this, as learning-oriented use can stimulate interest and thinking in current digital natives. Oliva-Maza et al [17] described a pervasive game with tangible technology that can be used for interventions and diagnostic, formative, and summative assessments. Multiple case studies were conducted with 4 kindergarteners over 2 weeks to test the user experience. They were given a multimedia pervasive adventure game in which they had to use tangible technology to solve phonological awareness challenges to reach the final goal. Observations were recorded in an evaluation model for posttriangulation data analysis and subsequent qualitative analysis of pre- and postintervention data. The results showed improvements in phonological awareness and traces of gamified experiences. These encouraging results justify the application of these methodologies to a learner-centered education model.

Adults' User Experience

The emergence of pervasive technologies has sparked an interest in designing and developing pervasive games. There are numerous designs of pervasive games for adult users. Chamberlain et al [45] presented *Them and Us*, a pervasive indoor game that uses dramatic processes to encourage social interaction within the context of the game. The *Them and Us* gameplay brings a group of people together in a space to interact with each other. At the same time, location-based technology reveals *us* the locational nature of the social interactions occurring in the space (who, where, and when). It allows *us* to score based on these interactions. *Them and Us* took a narrative-based approach in which a script instructed participants on how to play the game and how their social behaviors were incorporated into the game mechanics. This new interactive game-based artwork blends the player's physical and web-based worlds to create a new and exciting experience for *them*. Designed specifically for adults, the pervasive game—*Them and Us*—emphasizes the use of audience and performer tracking as a means of encouraging interaction within the play space.

The pervasive game has also made a significant contribution to the education of adults. Providing pervasive game-based learning scenarios for at-risk students is effective and motivating. Schmitz et al [44] provided a detailed example of an educational environment in which a mobile game is combined with a PC browser game. They evaluated how this pairing helps the target group engage and learn. The study surveyed 19 people, ranging in age from 17 to 21 years, who participated in the game and explored it. The results of the 7-week game study suggest that pervasive games can increase learners' interest in a topic while also supporting learning activities. Other studies have been conducted in the context of intense debate about how pervasive games can be used to provide new constructivist learning opportunities for students. Jong [32] developed a theoretical foundation for the Virtual Interactive Student-Oriented Learning Environment (VISOLE). It was a pedagogical framework for implementing constructive web-based gamified learning in teaching formal curricula. In addition to highlighting the pedagogical features of VISOLE, Jong [32] discussed the Stages of Concern model, which investigates 118 teachers' concerns about this educational innovation in terms of 5 categorical concerns: evaluation, information, management, consequences, and refocusing. All participants had completed introductory VISOLE training before taking the Stages of Concern survey. He was also able to develop more precise interventions tailored to the actual needs of teachers to help him use this *diagnostic* knowledge to implement VISOLE in their schools. The findings also shed light on how to design, develop, or adapt pervasive games to aid learning and teaching in the classroom.

Older Adults' User Experience

Promoting active lifestyles among older adults can have a significant positive impact on their quality of life. Pervasive games aim to create more fun and engaging experience by incorporating real-world elements into the game. The innovative mechanics of pervasive games, combining real and web-based worlds, can further engage and motivate older adults to achieve this goal. They can be a powerful strategy to encourage physical activity among older adults as they are integrated into players' lives and naturally promote more casual play. Santos et al [26] designed and evaluated the feasibility of a pervasive game using social interaction as a case study to understand how game design elements can influence the physical activity levels of older adults. They created a mobile, location-based pervasive game and tested its feasibility as an experimental system among community-dwelling older volunteers in Kyoto, Japan. Participants found the theme and visual style of the game appropriate, and the rules and objectives of the game were easy to understand. The game was praised for its challenging and entertaining nature. Further research suggests that future iterations of the system will require special attention to the complexity of the controls and new ways to connect players when few people are playing or when they are too far apart.

In the same year, the goal of Santos et al [25] was to test the impact of changing a specific design element of a popular game for older adults, namely social interaction, on physical activity levels. Therefore, they experimented by comparing 2 variations of the same popular game over 4 weeks: the test group received social interaction, whereas the control group received no social interaction. In both versions, players had to walk to physical locations to collect cards, but the socially interactive version allowed people to cooperate in obtaining more cards. The impact on each group was assessed using the number of steps taken per week, and the number of places visited was used to measure game activity. A total of 32 people were recruited for the experiment (no social interaction=15; social interaction=17); 18 people persisted until the end (no social interaction=7; social interaction=11). The experiment found that the social interaction design element of the popularity game may have had some positive effects on promoting physical activity. Subsequently, in 2021, Santos et al [18] continued with the same study, comparing 2 variations of the same pervasive game over 4 weeks with the same purpose and type of experiment: the test group received social interaction whereas the control group did not. In this test, 20 participants were recruited for this experiment (no social interaction group, n=10; social interaction group, n=10), 18 of whom remained active until the end of the study (no social interaction group, n=9). After several tests of pervasive games with older adults, they concluded that the social interaction design element of pervasive games might positively affect physical activity. Although other factors may have influenced this effect, it has tremendous implications for the fitness and health of older adults.

Evaluation and Service

Evaluation in the Area of Health

Recently, games have gained attention as a medium for changing health behaviors. However, current projects on healthy games face a major obstacle: the evaluation methods used to assess and formally evaluate such games do not adequately measure the acceptability and integration of the games into participants' lives. These are important components of ensuring participants adhere to the games to induce behavior change. El-Nasr et al [40] described the data-driven retrospective interviewing method that we developed for formative evaluations. Used in a naturalistic setting, the data-driven retrospective interviewing examines how participants embrace the game and integrate it into their lives. The procedure consists of several steps. First, a game is designed to collect behavioral data, which are then analyzed to provide a basis for developing interview questions that retrospectively understand and reflect participants' behavior. The contribution of this paper lies in its assessment methodology and application to *SpaPlay*, a universal health game [52]. As a result of this investigation, designers could rethink and improve their game design as they discovered that users were not using the game as initially envisioned. Such results would not have been possible with traditional evaluation techniques.

Self-monitoring, goal setting and coaching, education, and social support are daily care strategies for patients with chronic diseases. Various tools, such as mobile digital coaching systems linked to wearable sensors, pervasive games, and patient portals for personal health records, have been developed to assist patients with chronic conditions and their caregivers in achieving the ideal of self-management. Klaassen et al [28] described a platform that integrates these tools to help young patients self-manage their diabetes through educational games, monitoring, and motivational feedback. The platform's design references health care, persuasive system design, and serious game design principles. A coach is a game guide that provides personalized feedback on the user's daily care-related activities and helps them progress in the game world. User evaluations with patients under pediatric supervision suggest that using mobile technology in conjunction with web-based elements is feasible. However, assumptions about how users connect to the platform are not met in practice, resulting in a suboptimal user experience. They discuss the challenges and provide recommendations for advancing the integration of coaching and gamification platforms prevalent in medical practices.

Evaluation in Other Areas

Some scholars have explored a new approach to conducting user evaluation trials for pervasive games. In a case study, Kasapakis et al [5] examined the evaluation process of the pervasive role-playing game *Barbaros* consisting of preliminary and main implementation phases. The former is freely accessible to anyone and can be played at any time or place without the investigator's team's organizational and coordination investment. The latter defines 3 interdependent player roles that must cooperate in the scavenger hunt to achieve a common game goal. Players' eligibility to participate in the main game phase is determined by their position in the previous phase. Using concepts from cultural theory, they designed the preparation phase as a dynamic environment from which potential evaluators would emerge. The main hypothesis being investigated is that implementing such a cost-effective preparation phase could recruit highly qualified participants for user trials of the pervasive game study prototype, thereby increasing the reliability and quality of evaluation results.

The requirement's engineering community has not yet given enough attention to games. It becomes even more critical as we move toward newer forms of games, such as pervasive games. Pervasiveness (the characteristic that distinguishes traditional digital games) can mean being everywhere, pervading something, or propagating something through physical space. Each time a game is played, the boundaries of the game expand from the fictional world to the real world, indicating pervasiveness. Pervasive games, also known as alternate reality games, transmedia games, and cross-media games, are a new type of digital entertainment that has developed in various forms. The rapid development of this new type of digital product can be attributed to sensor technologies, networking capabilities, AR systems, computer vision technologies, the internet, and, in particular, mobile devices. Valente et al [7] defined it as pervasive games played on mobile devices. Mobile devices are currently the main drivers for the promise of pervasive games. Using various information sources, they compiled a list of interrelated characteristics critical to the success of these games. They presented a 2-level conceptual map of nonfunctional requirements based on these fundamentals to help achieve pervasiveness in pervasive mobile games.

Furthermore, Valente et al [29] proposed a new method for evaluating the quality of pervasiveness in pervasive games that can be adapted and applied to other pervasive applications. This approach produces a quality report consisting of a quality spreadsheet (containing metric values and comments) and a quality vector (representing the game quality profile in the form of a histogram). In addition, they can compare quality vectors based on similarity criteria. They applied the proposed approach to commercial and academic prototype games to elucidate their universality characteristics and identify ways to improve the overall quality of these games. In this sense, what distinguishes them from traditional digital games is the universality.

Discussion

Principal Findings

The analysis and results of the systematic literature review broadly divided these articles into 4 directions. These 4 directions are the direction of design and development, the direction of interaction and technology, the direction of the user and experience, and the direction of evaluation and service. These 4 directions appear to be independent of each other, but they are interdependent, which is consistent with the idea of this study. At this point, these directions can be correlated to the research objectives of this study one by one. Therefore, after abstracting and simplifying the themes of these literature analysis results, it is possible to sublimate them into corresponding design fields. Namely, the direction of design and development corresponds to the field of game design; the direction of interaction and technology corresponds to the field of interaction design; the direction of user and experience corresponds to the field of experience design; and the direction of evaluation and service corresponds to the field of service design. Therefore, these 4 design fields are the 4 research objectives to be analyzed in this study: game design, interaction design, experience design, and service design. They are also important indicators for analyzing the pervasive game from the perspective of different design thinking.

The game design aspect of pervasive games presents polymorphic research, which can be roughly divided into 3 categories: the development mode of game design, the development tool of game design, and the development direction of game design. Because pervasive games are a class of games, they naturally have a game design and development properties. As early as 2015, Kasapakis and Gavalas [36] introduced the historical development lineage of pervasive games, player acceptance factors, game development principles, and future development trends by analyzing 2 generations of 18 successful pervasive games. Subsequently, scholars have proposed different toolkits for developing pervasive games, enriching the toolbox of pervasive game design [15,22,31]. Moreover, the development direction of pervasive game design has never stopped research from 2013 to 2021. Inside these ideas are those that let players create game content directly [49], those that let designers find inspiration in the field [48], and those that let the game itself incorporate smart homes [23]. Furthermore, some research studies pervasive games from a storytelling and narrative perspective. This approach guides designers and developers through the different stages of game development, providing tools to define narrative elements, locations, and interactions between users and the game [15,39]. It is evident from looking at various aspects of pervasive game design, a popular focus of scholars' research, showing a promising trend of multifaceted and multidimensional development.

The interaction design aspect of pervasive games has been the most studied by scholars, comprising 15 articles. It is only natural that this is the case, as pervasive games are a large category of games, and players must have a variety of interaction designs or interaction technologies in them when they play. First, pervasive games are location-based games, so there is a large body of scholarship on how they use interactive technology to interact outdoors [24,37,41,43,46]. Second, there were scholars in industrial applications to study how pervasive games can increase interactive communication of artworks and how to improve interactive communication of cultural heritage in museums [34,47]. Touchless interaction is then used in designing the interactive interface and physical user interface of pervasive games [33,38]. Finally, scholars have mostly studied pervasive games combined with AR [16,19-21,30,42]. Furthermore, it can be seen that the technological development factor in the interaction design of pervasive games is influenced. Owing to the limitations of mobile technology in the early years, the interaction design of pervasive games was most explored by SMS text messaging and Bluetooth [42]. By 2021, scholars were exploring ways to integrate AR into the interaction design of pervasive games [16]. Nevertheless, these studies continue to expand the boundaries of interaction design for pervasive games.

The design of the pervasive game experience involves gamers of all ages. Among these articles, pervasive games are designed for children mainly to exercise their reaction and thinking skills [50,51]. Subsequently, there are pervasive games designed for adults, teachers, and students to learn [32,44]. At the same time, there are pervasive games for older adults, indicating some positive effects on promoting physical activity [18]. From the literature, it can see some hints of the research tendencies of scholars: in the early days, they studied the pervasive game design experiences of children users, followed by the pervasive game design experiences of adult users, and in recent years, they focused on the pervasive game design experiences of older adult users. In particular, Santos, a Japanese scholar, and his research team have been studying the effects of social interaction mechanics in pervasive games on the physical activity levels of older adults in recent years [25]. They used multiple experimental measurements to thoroughly analyze older users' perceptions of a pervasive game designed specifically for them, ranging from the game theme and visual style to game complexity and sociality. The direction of Santos's research is very similar to the direction of this study, which is to investigate the effects of pervasive games on fitness among older adults, except that the players' countries are different, the methods used are different, and the details of the specific participants studied are different. However, the research topics are very similar in terms of the effects of pervasive games on fitness among older adults. Nevertheless, the research conducted by Santos et al [25] is of great reference value to this study.

There are also some studies on service design for pervasive games, mainly from the evaluation perspective. This is probably because the service design concept is relatively new and has gradually emerged in design thinking and academic research in recent years. Perhaps it is therefore that the academic research perspective on pervasive games is still limited to simply evaluating the game itself. However, while evaluating the pervasive game itself, scholars are also exploring ways to improve and upgrade the pervasive game under study, which can be seen as an important manifestation of the service design concept. For example, refining the details of game mechanics and upgrading the details of game experience can be considered as research manifestations of service design for pervasive games. As in the case of El-Nasr et al [40] and Klaassen et al [28], the pervasive game for health programs was evaluated and measured for acceptability and integration into the participants' lives, and at the same time, the pervasive game they studied was optimized and iterated. It is the best example of the service design philosophy running through the pervasive game. Of course, other studies also included such early concepts of service design.

Limitations

The first limitation of this study is the database. This study only targeted 3 mainstream literature databases and did not include other databases, such as gray literature or PubMed. This may foreshadow the fact that, although the results obtained in this study through a systematic literature review method are authoritative, they could be more extensive and comprehensive. Another limitation of the study was that the search was conducted up to April 2022, and no articles were found in 2022 at the time of conducting the search, leaving an impression that the search left out publications of 2022.

Future Studies

After a systematic analysis, it was found that none of the themes in this literature were related to branding design. However, the article by Kasapakis and Gavalas [36] on the pervasive game's status, trends, and design principles can be considered a review of the existing successful pervasive games as branding. Pløhn et al [39] studied a dynamic and popular narrative approach to creating stories that can reinforce a sense of game maintenance and the brand of pervasive games. Valente et al [7] emphasized the need for nonfunctionality and highlighted aspects, such as cultural awareness, which can be seen as designing a brand strategy for pervasive games. Therefore, this literature does not explicitly go into the brand design of pervasive games but only touches on it to a greater or lesser extent. These results and findings were not coincident with the research object of brand design in this study. Thus, we believe that this systematic literature review has identified a research gap for branding design research on pervasive games and that it could be a future study direction.

Conclusions

A new generation of applications that blend the real and digital worlds, such as pervasive games, presents daunting obstacles for software developers. This type of game has recently become a worldwide phenomenon, with thousands of people using their mobile phones to interact with the surrounding physical environment while walking down the street.

At the beginning of the *Introduction* section, an accurate description of the current situation of the game industry is provided, explaining the entertainment nature and economic value of the pervasive game. In the *Methods* section, this study adopted a rigorous systematic literature review research process with graphs and tables. This study identified 4 themes: design and development, interaction and technology, user and experience, and evaluation and service. Each of these 4 themes was subdivided into subsections and interpreted. Finally, in the *Discussion* section, the 4 themes are explained in terms of this study's objectives: game design, interaction design, experience design, and service design. It also provides ideas for future research directions in pervasive games based on brand design.

Conflicts of Interest

None declared.

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Abbreviations

AR: augmented reality
DPS: Dynamic Pervasive Storytelling
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SSR: smart substitute reality
VISOLE: Virtual Interactive Student-Oriented Learning Environment

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Review

The Success of Serious Games and Gamified Systems in HIV Prevention and Care: Scoping Review

Waritsara Jitmun[1], MSc; Patison Palee[1], PhD; Noppon Choosri[2], PhD; Tisinee Surapunt[1], MSc

[1]College of Arts, Media, and Technology, Chiang Mai University, Chiang Mai, Thailand

[2]Data Analytics and Knowledge Synthesis for Healthcare (DAKSH) Research Group, College of Arts, Media, and Technology, Chiang Mai University, Chiang Mai, Thailand

Corresponding Author:
Noppon Choosri, PhD
Data Analytics and Knowledge Synthesis for Healthcare (DAKSH) Research Group
College of Arts, Media, and Technology
Chiang Mai University
239 Huay Kaew Rd, Su Thep Road, Mueang
Chiang Mai, 50200
Thailand
Phone: 66 918592114
Email: noppon.c@cmu.ac.th

Abstract

Background: AIDS, which is caused by HIV, has long been one of the most significant global public health issues. Since the beginning of the HIV epidemic, various types of nonelectronic communication tools have been commonly used in HIV/AIDS prevention and care, but studies that apply the potential of electronic games are still limited.

Objective: We aimed to identify, compare, and describe serious games and gamified systems currently used in HIV/AIDS prevention and care that were studied over a specific period of time.

Methods: A scoping review was conducted into serious games and gamified systems used in HIV prevention and care in various well-known digital libraries from January 2010 to July 2021.

Results: After identifying research papers and completing the article selection process, 49 of the 496 publications met the inclusion criteria and were examined. A total of 32 articles described 22 different serious games, while 17 articles described 13 gamified systems for HIV prevention and care.

Conclusions: Most of the studies described in the publications were conducted in the United States, while only a few studies were performed in sub-Saharan African countries, which have the highest global HIV/AIDS infection rates. Regarding the development platform, the vast majority of HIV/AIDS gaming systems were typically deployed on mobile devices. This study demonstrates the effectiveness of using serious games and gamified systems. Both can improve the efficacy of HIV/AIDS prevention strategies, particularly those that encourage behavior change.

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KEYWORDS

HIV; serious game; gamification; public health; primary health care; patient care; behavioral health

Introduction

HIV can cause a chronic infection that leads to disease. Without appropriate medical care, many people with HIV develop immunodeficiency syndrome within 10 years of infection [1]. HIV has long been one of the major global public health issues. In 2018, the estimated numbers of people living with HIV in Africa, Southeast Asia, the Americas, and Europe were 25.7 million, 3.8 million, 3.5 million, and 2.5 million, respectively [2]. Because HIV is a communicable infection that can affect the health status of large groups of people, early detection and treatment for one person can prevent future HIV transmission to other individuals, providing benefits for the overall population [3]. Since the beginning of the HIV epidemic, various international organizations have used different types of communications, such as TV advertisements, billboards, school-based events [4], and technology-based health intervention and prevention tools to educate societies [5-7].

Serious games are digital games created with the purpose of entertaining and achieving at least one additional goal [8]. While digital video games are commonly used in the health care domain for purposes such as training health care professionals [9-14], studies that apply the potential of games as HIV/AIDS intervention and prevention tools are still limited. In contrast with serious games, the term *gamification* is described as "the use of game-design elements in non-game contexts" [15]. Additionally, a gamified system is not a game in itself, while a serious game has elements of a real game and looks and feels like a real game [16]. Gamification interventions can be described by their "game mechanics"—the mechanisms that define how the intervention works [17]. They are a powerful tool to engage employees, customers, and the public that can change behaviors, develop skills, and drive innovation [18]. This approach may be one of the most important social and commercial developments in the next 50 years [19]. The difference between a serious game and a gamified system can be seen in their output formats. If the tool has the clearly declared purpose of enhancing the game players' performance, it is a serious game. In contrast, if it is an application with embedded game elements, is a gamified system.

The benefits of this scoping review include presenting a compilation of HIV care techniques and best practices. Currently, the available reviews in the HIV literature only address detection, treatment, and prevention [20,21]. However, there is no research that identifies game applications as either serious games or gamified systems. The purpose of this review is to identify, compare, and report on the situation of serious games and gamification for HIV interventions from January 2010 to July 2021. It also provides informative sources for an organization or game developers who intend to use games as communication or education tools for social services for HIV/AIDS prevention and care.

Methods

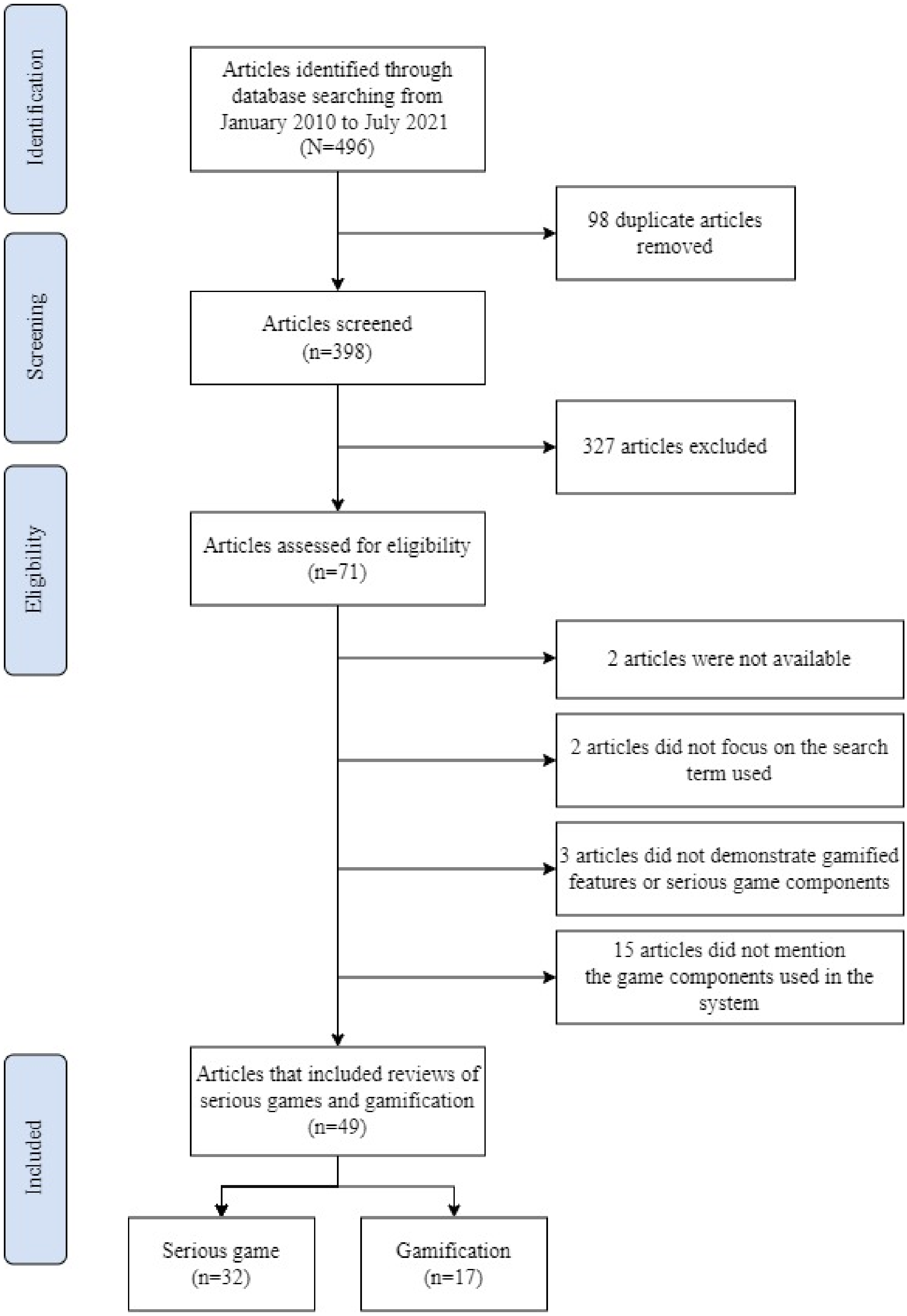
The review was conducted using the databases PubMed, Web of Science, and Scopus.

Although there are various definitions of the terms *serious game* and *gamification*, we decided to use the following search terms: (serious gam* OR videogame* OR video gam* OR gaming OR gamification) AND (HIV). The search results included only articles published in English between January 2010 and July 2021. The procedure is shown in Figure 1.

The criteria that we used to distinguish articles about serious games were as follows: (1) the article included the words (case-insensitive) *serious game* or *serious video game* in its title, keywords, abstract, or main text and (2) the article described a digital game, computer game, or video game created for a purpose related to HIV/AIDS care and prevention. Articles matching either criterion 1, 2, or both were included in this survey.

The criteria that we used to differentiate articles about gamification from those about serious games were as follows: (1) The article included the word (case-insensitive) *gamification* in its title, keywords, abstract, or main text and (2) the article described the use of a gaming approach and game-design components or game elements in a nongame context related to HIV/AIDS care and prevention. Articles matching either criterion 1, 2, or both were included in this survey.

Figure 1. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.



Results

After the article selection process was conducted, we found that 49 of the 496 publications were eligible for inclusion. Of these, 32 articles were on serious games and 17 articles were on gamified systems for HIV prevention and care. We identified the locations where the research was conducted, what platforms were used for serious games, gamification approaches, the purposes of implementing a serious game or gamification, and outcomes.

Study Sites

There were 32 serious games and 17 gamified systems described in the 49 articles. The majority of articles (36/49, 74%) mentioned that the study's scope was limited to the United States. Moreover, 2 of 49 (4%) studies took place in Uganda, 1 (2%) in Swaziland, 2 (4%) in Kenya, 1 (2%) in Tanzania, and

2 (4%) in other sub-Saharan African countries (these were studies that designed and developed digital gamified systems for evaluating students' perceptions about sexual education). Outside Africa, 1 of the 49 (2%) studies took place in the Philippines, 1 (2%) in Indonesia, 1 (2%) in Ireland, and 2 (4%) in Spain. These results indicate that researchers pay more attention to making use of games and gaming in HIV/AIDS prevention and care in the United States than in other countries.

Video and Nonvideo Game Systems in HIV Prevention and Care

There were a total of 35 electronic gaming systems developed for the 49 studies. Of these, 22 (63%) were serious games and 13 (37%) were gamified systems.

Platforms Used for Serious Games and Gamification

A platform is the hardware or electronic system used to run a game [22]. The most pervasive game platforms were the PC (desktop computers and laptops), mobile devices (tablets and smartphones), and game consoles (Nintendo Wii, Sony PlayStation, and Xbox). Mobile devices were the most common platform, with 13 studies using this platform for serious games and 11 for gamified systems. There were 8 serious games and 1 gamified system developed for the PC platform. One study on a serious game and one on a gamified system did not clearly indicate whether they used mobile devices or PCs.

Purposes of Serious Games and Gamified Systems

Table 1 demonstrates the objectives of serious games and gamified systems. The key objectives of eligible gaming systems were identified. We discovered that serious games for HIV/AIDS prevention and care emphasized education, while gamified systems were aimed at promoting HIV testing and screening. The objectives of each gaming system are elaborated in the "Serious Game and Gamified System Implementation" section of this paper.

Table 1. Purposes of serious games and gamified systems used in HIV/AIDS prevention and care.

	Serious games, n	Gamified systems, n
Education on prevention	6	2
Reducing risk behaviors	3	3
Building peer resistance skills	1	0
Promotion of HIV testing and screening	3	4
Encouragement of pre-exposure prophylaxis	2	2
Cognitive rehabilitation	3	0
Physical rehabilitation	1	0
Adherence to and engagement in HIV care	3	3

Serious Game and Gamified System Implementation

Because the implementation of serious games and gamified systems can differ, this section describes and discusses serious games and gamification separately.

Serious Games

The implementation of serious games includes 2 important factors: game genre and outcomes (results), as described in the following sections. Table 2 summarizes these factors, as well as the target populations.

Table 2. Summary of serious games used for HIV prevention and care.

Title	Genre	Target	Purpose	Results
PlayForward: Elm City Stories [23,24]	Role-playing	Young minority Spanish adolescents	To help players learn about risk behaviors, particularly sexual risk	Significant
Secret of Seven Stones [25]	Adventure	Young adolescents aged 11-14 years	To help prevent unintended pregnancy and sexually transmitted infections	Significant
Socially Optimized Learning in Virtual Environments [26]	Role-playing	Young MSM[a]	To reduce sexual shame among MSM and increase HIV testing rate	Significant
Untitled [27]	Role-playing	Adolescents and young adults	Improve HIV testing and pre-exposure prophylaxis access	Preliminary
BattleViro [28]	Action-oriented adventure	Youth living with HIV	To help increase adherence to antiretroviral treatment	Preliminary
Battle in the Blood [29]	Role-playing	Young populations in the Philippines	To influence behavior determinants of HIV	Preliminary
ViralCombat [30]	Action-oriented adventure	Young MSM	To transmit knowledge, behavior, and skills for increased pre-exposure prophylaxis adherence and HIV prevention	Preliminary
My Future Begins Today [31]	Not identified	Secondary school students in sub-Saharan Africa	Sexual health education	Preliminary
Tumaini [32,33]	Role-playing, simulation	Young Africans in high HIV prevalence settings	To help prevent HIV by delaying first sex and increasing condom use at first sex	Preliminary
Insight (including 5 different games and exercises) [34]	Not identified	Cognitively vulnerable adults with HIV	Improving cognitive and everyday functioning in the target population	Preliminary
Game-based training program [35]	Exergame	Older people living with HIV	To ameliorate some aspects of frailty in individuals with HIV	Preliminary
HealthMpowerment [36]	Not identified	Young MSM&T[b]	To promote HIV-related knowledge and behavior with acceptance of individuals with HIV to prevent the spread of infection	Preliminary
DRAMA-RAMA [37]	Role-playing	Adolescents	To build peer resistance skills to avoid being pressured into risky behaviors such as early sexual behavior	Significant
Brain Powered Games [38]	Not identified	At-risk African children	Cognitive training and rehabilitation	Significant
Captain's Log (BrainTrain Corporation) [39]	Not identified	Children with HIV	Cognitive training and rehabilitation	Significant

[a]MSM: men who have sex with men.

[b]MSM&T: men who have sex with men and transgender people.

Genres of Serious Games

We identified 15 serious games specifically designed for HIV prevention with 4 different genres, as presented in Table 2. There was 1 untitled game. Role-playing was the predominant category of serious games that focused on HIV prevention (n=6). Among role-playing games, there were 4 educational games, including Play Forward: Elm City, Tumaini, SwaziYolo, and Battle in the Blood [29], and 2 games aiming to reduce risk behaviors, including Socially Optimized Learning in Virtual Environments (SOLVE) and DRAMA-RAMA, the latter of which focused on strengthening peer resistance skills. The second most popular game genre was adventure (n=3), including an educational game called The Secret of Seven Stones (SSS) and an action-oriented adventure game called ViralCombat [30] designed to encourage the use of antiretroviral medications to reduce the risk of acquiring HIV infection. Another game was BattleViro, which encouraged adherence to prescribed antiretroviral treatment (ART). Other genres of serious games among these studies included (1) racing (Fast Car: Travelling Safely around the World, a game that sought to educate adolescents on HIV prevention), (2) a collection of party games (The Test [40], which promoted HIV testing), and (3) an untitled exergame that promoted physical rehabilitation. Another game, My Future Begins Today, which promoted sexual well-being in low-technology settings, had an unidentified genre. [31] Three serious games for cognitive rehabilitation and one collection of games specifically developed to increase adherence to ART also had unidentified genres.

Outcomes of Studies on Serious Games

To classify the outcomes of the studies using serious games for HIV intervention and care, we defined 2 types of outcome. The first type was "preliminary results"; these studies focused on proofs of concept for the intervention. Typically, these studies were conducted in a laboratory setting. The second type of outcome was “significant results”; these studies implemented and tested the solution in real-world environments.

Serious Games Studies With Preliminary Results

In a pilot study, a theory-based smartphone game titled Tumaini [32] was designed to delay the age of a couple having their first sex and to promote condom use in young Kenyans. The preliminary results indicated that participants who played Tumaini for an average of approximately 27 hours showed significant gains in sexual health–related knowledge and self-efficacy, behavioral intentions for risk-avoidance strategies, and sexual risk communication. This pilot study suggests the need for further research to assess the efficacy of game-based interventions. Another study examined the preliminary effects of Insight [34], a computer program that consists of 5 different games designed to improve cognitive and everyday functioning in older adults living with HIV. The study found that those who performed more poorly at baseline on a useful field of view (UFOV) test that measures visual speed of processing and a test of timed instrumental activities of daily living (TIADL) had more training gains in response to the intervention. In addition, the results revealed that a higher HIV viral load and insufficient medication adherence were predictive of greater TIADL training gains. These results illustrate that middle-aged and older adults with HIV who experience problems with speed of cognition and everyday functioning may benefit from this type of training. Another study evaluated the effectiveness and acceptability of a novel game-based training program (ie, an exergame) [35] aiming to improve various aspects of physical frailty in 10 older persons who were living with HIV. The initial results showed a significant reduction in center of mass sway, a significant increase in gait speed during a motor-cognitive assessment, and a remarkable reduction in reported pain. Other studies examined games aimed at enhancing HIV prevention behaviors and adherence to pre-exposure prophylaxis (PrEP). Viral Combat, a novel and entertaining game or app focused on increasing PrEP adherence and imparting HIV prevention knowledge and skills, was first evaluated through qualitative interviews with 20 young men who have sex with men (MSM). Then, a randomized trial with 60 participants preliminarily tested the game’s effectiveness by evaluating knowledge acquisition, behavior change, and skill improvement after the gaming intervention among young MSM.

Although the Viral Combat study is ongoing, it has returned significant data on changes in motivation to increase PrEP adherence and decrease HIV infection. A mobile game called Battle in the Blood was developed as a role-playing game to influence behavior related to the use of HIV services. During a 12-month study period, the game was installed on 3325 unique devices.

The game received a positive response among casual gamers during playtests. The game’s narrative is a key part of its strategy for delivering HIV knowledge. Another project launched a randomized controlled trial (RCT) to examine the initial effects of an action-oriented adventure game called BattleViro [28], which was developed as a tool to improve adherence to ART, decrease viral load, and increase relevant knowledge in 61 youth living with HIV. The study demonstrated promising results but no significant improvements in HIV knowledge, ART knowledge, or social support. However, those who recently started ART (in the past 3 months) and used BattleViro had a greater decrease in viral load, better ART adherence, and more HIV and ART knowledge than the control group.

One game we identified, in the study by Castel et al [27], never started testing as an intervention by the time that the paper was published, as it was still in a participant recruitment stage. Another game, called My Future Begins Today, was developed for sexual health education and was improved based on user responses in a low-technology setting. The 348 participants (193 boys and 155 girls) were students in secondary school aged 11 to 15 years. The results show that groups using a gamified learning approach outperformed those that used a conventional learning approach. Moreover, a game designed for low-technology settings could be more helpful in delivering sexual health education than formal educational approaches.

Other studies have examined mobile health apps and nonvideo serious games that serve as self-learning tools. These include an app called HealthMpowerment (HMP) [36] and an mHealth app [41] to increase users’ knowledge of HIV and social support pertaining to caring for HIV-positive people and living behaviors of HIV-positive people. The contents were evaluated by a group of young MSM and transgender women in the United States and Indonesia. After testing with the target group, the authors determined that the app-based intervention was easily accessible and could support people with HIV in the long term, resulting in a significant increase in comprehension and knowledge of HIV.

Serious Games Studies With Significant Results

We identified 6 serious games with significant results, including PlayForward: Elm City Stories, SOLVE, DRAMA-RAMA (an avatar-based virtual reality game for peer resistance skill building), SSS (a web-based adventure game), and games focusing on cognitive rehabilitation called Captain’s Log and Brain Powered Games.

In a study to evaluate PlayForward [24], a video game that was specifically developed as an HIV prevention tool targeted at HIV risk behaviors (ie, substance use and sex) in young adolescents, the authors showed that after 6 weeks of playing the game, the intervention group had higher knowledge scores than the control group at 6 weeks and at 3 months. Moreover, an analysis of 1,289,903 events in log files of the game revealed that the number of game levels completed was positively correlated with gains in knowledge measured at 6 weeks and at 3 months. These findings demonstrated that PlayForward increased HIV risk–related knowledge among adolescents and that exposure to the video game’s content was highly correlated with knowledge. Another study of the same game [23] analyzed log files from 166 participants in an RCT and showed that higher knowledge scores for substance use at 3- and 6-month follow-ups were related to successfully completing more of the game levels, rather than to total gameplay time.

Another study aimed to investigate the effects of SOLVE [26], a role-playing video game focused on sexual shame reduction among MSM. MSM in the SOLVE intervention reported more shame reduction than MSM in the control condition. Moreover, greater reductions in shame among participants in the SOLVE treatment condition in turn predicted reductions in risky sexual behavior at follow-up. Additionally, SOLVE was the first intervention to significantly reduce shame and risks for MSM from unprotected anal intercourse.

DRAMA-RAMA [37] is an avatar-based video game focusing on peer resistance skill building in teenagers. An RCT was conducted to assess how positively the game was perceived by 45 young Hispanic girls. Separate analyses of covariance showed a significant difference between pre- and posttest scores for peer resistance self-efficacy measured after the game play session, but these findings were not repeated at a 2-month follow-up. The results provided preliminary support for the hypotheses that playing an avatar-based virtual reality technology game would strengthen peer resistance skills and that early adolescent Hispanic girls would have a positive response to this game.

SSS [25] is a web-based adventure game for teenagers aged 11 to 14 years in the United States aimed at education to prevent unwanted pregnancy and sexually transmitted infections. SSS emphasizes educational training to acquire knowledge about sex-related topics and is based on an intervention mapping approach. It can be used at home and is an intergenerational communication channel with parents.

We found 2 studies that examined the efficacy of serious game interventions for cognitive rehabilitation in African children. In the first study, 33 African children with HIV who lived in rural Uganda and were aged between 6 and 12 years played 45-minute sessions of Brain Powered Games several times a week for 2 months. After the intervention, participants demonstrated clinically significant changes on specific Test of Variables of Attention and CogState measures, reflecting processing speed, attention, visual-motor coordination, maze learning, and problem solving. The second study evaluated the neuropsychological and behavioral benefits of Captain's Log [39], a computer program specially designed for cognitive training and rehabilitation in children living with HIV in Uganda. The 159 participants were randomized to 1 of 3 treatment groups over a 2-month period and were assessed at enrollment, immediately following a 2-month computerized cognitive rehabilitation training (CCRT) course, and 3 months after CCRT completion. The CCRT groups, which used Captain's Log, had significantly greater gains at the 3-month follow-up compared to a passive control group in an overall mental processing index measured with the Kaufman Assessment Battery for Children, Second Edition (KABC-II); they also showed gains in planning and knowledge. A group that received limited CCRT with the same games rotated randomly from simple to moderate levels of training performed better than a passive control group receiving no training. Moreover, both CCRT arms had significant improvements in CogState Groton maze learning.

Gamified Systems

Our examination of gamified systems aims to understand 4 important factors: types of gamification approaches, elements of gamification, rewards and incentives used, and effectiveness outcomes, as described in the following sections.

Types of Gamification Approaches

In contrast with serious games, gamification is an approach that applies game mechanics in nongame settings. It is used in a broader context and has more specific outcomes. There are typically 3 types of gamification [15]: internal, external, and behavior-change gamification. Internal gamification targets users within an organization, aiming to improve productivity and increase innovation. External gamification is generally driven by marketing objectives to improve relationships between businesses and customers and improves engagement by clients. Finally, the purpose of behavior-change gamification is healthy habit formation among a population. After removing duplicate and conceptual articles describing the initial development phase of gamification projects that lacked a system prototype, we identified 13 different electronic gamified systems in 17 publications. The majority (n=11, 85%) of the surveyed studies used a behavior-change gamification approach and a minority (n=2, 15%) used external gamification. Six mechanics can be distinguished among behavior-change gamification techniques as defined by Werbach and Hunter [15]: challenge, rewards, feedback, resource acquisition, cooperation, and competition. Challenge aims to motivate users to make an effort with content unlocking and requires users' effort to complete a list of objectives to be fulfilled; rewards are an indicator of players' achievements; feedback provides information to players about their progress and status during the game through leaderboards or other visual or informational displays; resource acquisition is intended to motivate users to collect and own useful tools; cooperation uses team-building and requires collaboration between players to achieve an objective that is not possible alone; and competition motivates in-game contention between users.

Elements of Gamification

We examined the game mechanics that underlie various game components; these directly affect gamification designs [42], as illustrated in Table 3.

The game components used in the surveyed studies comprised avatars, levels, content unlocking, leaderboards, virtual goods, achievements, badges, points, and teams.

Table 3. Game mechanics and behavior-change strategies used in behavior-change gamification.

System name	Game mechanics [42]						Behavior change strategies [43]
	Challenge	Rewards	Competition	Cooperation	Resource acquisition	Feedback	
Bijou [44]	No	Yes	No	No	No	Yes	Provide feedback on performance
Sexual health education programs on the Moodle platform [45]	No	Yes	Yes	No	Yes	Yes	Compare progress; provide feedback on performance
UBESAFE [46]	No	Yes	Yes	No	No	Yes	Capacity to overcome challenges; provide feedback on performance; reinforcement
A community-based HIV and sexually transmitted infection testing system [47]	No	No	No	No	No	No	None
Epic Allies [48,49]	Yes	Yes	Yes	Yes	Yes	Yes	Provide feedback on performance
AllyQuest [50]	Yes	Yes	No	No	Yes	Yes	Goal setting and social connectivity
P3 [51]	Yes	Yes	No	No	Yes	Yes	Goal setting; social connectivity; provide feedback on performance
HealthMpowerment [52,53]	No	Yes	No	No	No	No	Goal setting; social connectivity
Stick To It [54,55]	No	No	Yes	Yes	Yes	Yes	Compare progress; provide feedback on performance
Thrive with Me [56]	No	Yes	Yes	No	Yes	Yes	Social connectivity; provide feedback on performance
Game Plan [57,58]	No	Yes	No	No	No	No	Goal setting

Avatars are visual representations of players in the game. They are presented to learners as their visual representations and future selves. The avatar component of gamification is used to activate the reward mechanic. In the surveyed studies, we found avatar use in gamified systems including Epic Allies, AllyQuest, P3, HMP, Stick To It, Thrive with Me, Bijou [44], Dot [59], and Game Plan.

Levels show the player's position at any point during the game to serve as feedback. For example, Besoain et al [46] embedded an experience bar, visualized as medals, that was incremented when users had a significant interaction with the system. In Bijou [44], a completion bar was used to give feedback on the level of completion.

Content unlocking allows a player to access game content or narrative without meeting certain points or specific criteria. The component of content unlocking serves the mechanics of challenge, feedback, and reward.

A leaderboard is a list that shows a ranking of players according to their scores and collections after in-game assessment. The leaderboard allows players to monitor their own ranking and compare it with that of others. The leaderboard component is used to initiate competition and feedback mechanics.

Virtual goods are valuable items that players can purchase during the game in exchange for their points. A representative use of virtual goods was in the game Epic Allies, which used "virtual cards" that players can buy and upgrade using points earned by engaging in other parts of the app. This component is used for the resource acquisition mechanic.

Achievements are rights and rewards given to the player in return for accomplishing an objective; they serve the mechanic of rewards. An example is the gems that are used to signify achievements in Bijou [44].

Badges are commonly used for setting goals, providing explanations about learning activities, identifying players who have shared experiences, and providing users with status. For instance, a badge that shows the level of engagement is given to users in UBESAFE [46]

Points are used to measure success and quantify player progress. In the surveyed studies, users earn points if their responses and in-game actions support healthy behavior and are consistent with HIV prevention measures. Players also earn points in a form of in-app virtual currency in the games AllyQuest and P3. Points can also be earned in the form of scores, as in sexual health education programs with a gamification technique [45] and mobile apps. This component serves the mechanics of resource acquisition and feedback.

Teams represent cooperation to achieve common objectives in the game. Participants can recruit team members to achieve in-game challenges in the games Epic Allies and Stick To It. This component serves the mechanic of cooperation.

Additionally, we found that 6 of 7 gamification strategies for health behavior changes determined by behavioral science [43] were discussed in the surveyed articles. The 7 gamification strategies and validated behavior changes were (1) goal setting, (2) increasing capacity to overcome challenges, (3) providing feedback on performance, (4) providing reinforcement, (5) comparing progress, (6) providing social connectivity, and (7) providing fun and playfulness. Only the strategy of providing fun and playfulness was not found to be used in any games. Game mechanics and behavior change strategies that were used in behavior-change gamification in the studies examined here are shown in Table 3.

Moreover, among the surveyed studies, we found one that described a community-based HIV and sexually transmitted infection (STI) testing system [47] that mentioned using gamification techniques, but that article did not clearly explain the game components, game mechanics, or behavior change strategies, except to state that they automated text messages and graphical quizzes. The system appears only to have integrated quizzes into existing systems.

After examination, we found that gamified systems had both educational and advertising purposes using points or scores as the primary element to attract and engage nonpatients who shared similar goals. However, avatar and level elements were commonly used to improve ART adherence in HIV patients.

Rewards and Incentives

We found patterns of reward use based on in-game or virtual reward systems [48,50,51] and physical reward systems that allowed exchanging virtual points and in-game currencies into cash prizes or tangible gifts [52-54,56], as illustrated in Table 4.

In addition, there were 3 systems that were classified as using external gamification, that is, social marketing techniques related to a web page's visitors or use of particular online tools to improve the attitudes of a population toward an HIV testing service and encourage people to physically visit an HIV clinic [60,61] (Table 5).

Table 4. Behavior-change gamification, game mechanics, and reward use.

System name	Reward use
Sexual health education programs on Moodle platform [45]	None
Community-based HIV and sexually transmitted infection testing system [47]	None
Epic Allies [48,49]	Buy and upgrade virtual cards using points
Ally Quest [50]	Earn and redeem in-app currency to unlock new app features
P3 [51]	Earn and redeem in-app currency to unlock new narratives and new app features
HealthMpowerment [52,53]	Built-in rewards can be redeemed for physical prizes from the HealthMpowerment online store
Stick To It [54,55]	In-game points increase chance of winning prizes that cost US $5
Thrive with Me [56]	App use can be exchanged for a weekly prize of a US $25 online gift card
Game Plan [57,58]	None

Table 5. External gamification and reward use.

System name	Reward use	Game component	Behavior changes strategies
Testing is Healthy [60]	Points can be converted into real-world prizes (eg, food and drinks)	In-game points	Social connectivity (sharing on social media)
Untitled intervention activities [61]	Points can be redeemed for gifts or exchanged for raffle tickets	In-game points	Social connectivity (making use of social marketing principles and social networking sites)

Outcomes of Studies of Gamified Systems

Gamified Systems Studies With Preliminary Results

We identified examples of studies with preliminary outcomes related to the effectiveness of gamified systems that examined the following apps and systems: Stick To It, AllyQuest, Game Plan, a gamified website (HMP), and UBESAFE.

A pilot study assessing Stick To It determined whether an intervention using gamification was acceptable to young MSM in California and effectively increased repeat HIV screening. The preliminary outcome was that engagement in the intervention was moderate; however, the inclusion of game elements was motivating. Additionally, young MSM who enrolled in a clinic were more strongly engaged than young MSM who registered online. Moreover, the repeat HIV screening rate among the subset of participants who were recruited in the clinic was higher than a comparison group of similar young MSM attending the same clinic the previous year. Another pilot study assessed the feasibility and acceptability of AllyQuest [50], a novel smartphone app designed to improve engagement in HIV care and social support among young MSM living with HIV. A pilot trial conducted with 20 participants showed high levels of app use that were positively correlated to HIV self-management outcomes. There was also a statistically significant relationship between the number of days logged into the app and knowledge and confidence in taking HIV medications. These primary outcomes raised the possibility that AllyQuest could impact long-term HIV ART adherence among HIV-positive young MSM. Moreover, a 4-week pilot trial conducted with young Black MSM and transwomen tested HMP [53], a mobile-optimized intervention that included game-based elements to reduce sexual risk behavior by providing information. In this pilot trial, HMP showed promise for being able to deliver a sufficient intervention dose and maintain exposure and engagement over time sufficient to achieve behavioral change. In this qualitative assessment of 15 participants, the researchers found a correlation between the number of times the intervention site was used and stages of behavioral change. Another study explored the initial effectiveness of Game Plan [58], a tablet-based brief motivational intervention for alcohol use and HIV risk. Over 3 months of follow-up, the participants who used Game Plan reported fewer drinking days, fewer binge drinking days, fewer alcohol problems, and fewer new anal sex partners compared to those in the control group. These initial results suggest that web-based brief motivational interventions could be a promising tool to help MSM reduce HIV-related risk behavior. Additionally, a feasibility evaluation of UBESAFE [46] indicated that the gamified features encouraged users to interact more with the system, by up to 100%.

Gamified Systems Studies With Significant Results

There were 3 studies of gamified systems with significant results (Table 6), including a pedagogical framework called Motivation, Attitude, Knowledge, and Engagement (MAKE), a promotional campaign aimed at STI and HIV prevention called Testing is Healthy, and the gamified website HMP.

Table 6. Results of studies on gamified systems used in HIV prevention and care.

Title	Target	Game's purpose	Results
Motivation, Attitude, Knowledge, and Engagement framework [45]	Adolescent students aged 11-15 years	Provide pedagogy for sexual health education/improve sexual health education programs for adolescent students	Significant
AllyQuest [50]	Young MSM[a]; mean age of focus group participants was 23 years	Support engagement in care and medication adherence for HIV-positive young MSM	Preliminary
HealthMpowerment [52,53]	HIV-positive and negative young Black MSM and transwomen aged 18-30 years	Use behavior change and gaming theories to reduce risky sexual behaviors and build community with a mobile phone–optimized intervention	Significant
Stick To It [54,55]	College students (aged 18-24 years)	Increase HIV screening among young MSM	Preliminary
Game Plan [57,58]	MSM aged 18-53 years	Help MSM reduce their HIV risk and alcohol use	Significant
Testing is Healthy [60]	Young adults aged 20-29 years	Use digital gaming as a medium for preventing sexually transmitted infections and HIV	Significant

[a]MSM: men who have sex with men.

An RCT was conducted to investigate the extent to which game-based learning and the gamified MAKE framework [45] could improve sexual health education among 120 young students in Tanzania. The adolescents were divided into groups that received teaching with 1 of 3 methods: game-based learning, gamified MAKE, and the control group, which used a conventional teaching method. The results suggested that the first 2 teaching approaches delivered better learning outcomes than the conventional teaching method and could be used as tools to improve sexual health behavior and increase HIV/AIDS knowledge in young students.

The evaluation of Testing is Healthy [60] used a technology-based platform called Cineplex TimePlay that included gaming elements to engage people who often go to the cinema to answer STI/HIV-related questions. The system also provided a clinic finder service on a website. Although this was the first time this platform was used for sexual health promotion, the campaign received a great response, with 548,410 views and 77,149 plays. Additionally, server-side rendering web analytics showed a significant increase in the clinic finder page's unique page views between the first and second campaigns. The results demonstrate that this technique could be used to reach a large population at a low cost.

The last study [52] was an RCT that compared the efficacy of the HMP intervention to an information-only control website. The results indicated that the rate of self-reported condomless anal intercourse at 3 months was 32%, suggesting that exposure to an online intervention can reduce the rate of condomless anal intercourse among young Black MSM, at least in the short term.

Discussion

In order to provide a comprehensive map of the available evidence on HIV prevention and care, we used a scoping review methodology to conduct this review. The literature included in this study adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) standard, which facilitated the inclusion of extensive information on serious games and gamified systems. Nevertheless, this scoping review was restricted to providing answers to particular issues. Therefore, a future systematic review would enhance and enrich our knowledge.

The results of this scoping review show that 74% (36/49) of study sites, as reported in 16 articles that examined serious games and 10 that examined gamification, were in the United States. A small minority of reviewed studies were performed in sub-Saharan African countries, which have the highest global HIV/AIDS infection rates. Because of the unavailability of electricity and communication facilities, the level of technological solutions in rural areas of Africa is very low [62]. Therefore, researchers need to make the most of their resources by applying other communication tools and methods that focus on users' behaviors and lifestyles instead of depending on digital technology and gaming.

Moreover, the majority of the serious game and gamified systems used mobile platforms. This confirms that improvements in mobile computing hardware and wireless networking improve outcomes and not only make interventions accessible for users but are also beneficial for game developers, as they allow them to create dynamic and realistic worlds and characters [63].

The major purpose of serious games and gamified systems applied in HIV/AIDS studies is to enhance the effectiveness of HIV/AIDS prevention strategies by reducing sexual risk behaviors and increasing the HIV/AIDS screening rate. The surveyed results are consistent with findings from previous studies [64,65] that indicate that early diagnosis and prevention of HIV infection is more cost-efficient than lifetime HIV treatment. Moreover, 6 of the 16 serious games we identified were in the role-playing genre, of which half were designed for educational prevention and reducing risky behaviors.

For our analysis of game elements in gamified systems, we followed the categories proposed by Werbach and Hunter [15] because there is no universal standard to classify game elements in gamified systems. Their taxonomy of game elements is one of the most widely used taxonomies in research on gamified systems [66-69]. The taxonomy includes 15 game components that can represent specific mechanical forms or can be dynamic, including achievements, avatars, badges, boss fights, collection, combat, content unlocking, giving, leaderboards, levels, points, quests, social graphs, teams, and virtual goods. We then attempted to match the selected studies to this taxonomy to determine the characteristics of gamified system components in the HIV domain. The common patterns we observed in the development of gamified systems for HIV are consequently a guide for future studies.

The majority (11/13, 85%) of the surveyed approaches were classified as using behavior-change gamification, which is a technique that seeks to encourage healthy sexual habits in a given population. Some fundamental game components are embedded in the kinds of systems we reviewed here, such as points, badges, leveling, and rewards. However, some systems claimed to incorporate gamification despite the fact that they only used graphical quizzes and had no other defined game elements or strategies. This reflects the complexity of the gamification concept, as well as its application; both the concept and its application are in the introductory stages in the domain of HIV/AIDS prevention and care. Our findings also show patterns of reward use, including in-game rewards and physical prizes, that have the same behavioral change objectives for HIV/AIDS care and prevention.

The in-depth analysis of the effects of game mechanics and behavioral change strategies used in behavior-change gamification shown in Table 3 reveals that the first-ranked, most frequently used game mechanic was rewards. Kocadere and Çağlar [42] indicate that rewards serve as a gauge of a player's performance; the components of the reward mechanic are badges, achievements, avatars, and content unlocking. Moreover, rewards can be used for players to progress and to create player emotions, including apprehension, excitement, grief, and happiness with dynamic use of constraints, emotions, progression, and relationships [15].

Feedback was the second-ranked mechanic. Feedback is data presented to the player regarding their performance in the game. The feedback mechanic serves the dynamics of progression and emotions. Feedback can be both formative (badges, levels, leaderboards, content unlocking) and summative (points, badges, leaderboards, levels) [42]. The reason that rewards and feedback are used in behavior-change gamification is that player progress and emotions are largely influenced by the rewards and feedback they receive. Therefore, if the goal of the gamified system is to improve the behavior of users, a mechanism for providing rewards and feedback should be considered when developing a behavior-change gamification system.

Conclusion

As the reach of the internet and cell phones improves, their use as health intervention and prevention tools has increasingly been researched to strengthen their impact on behavior and social change in HIV/AIDS prevention and care. However, the study sites of research on serious games and gamified systems mentioned in articles from 2010 to 2021 were mostly in the United States. This contrasts with the small number of studies undertaken in sub-Saharan Africa, which has the highest global HIV/AIDS infection rate. We also discovered that the majority of serious games use mobile platforms. This finding demonstrates that improvement in mobile computing hardware and wireless networking has made them more accessible for users.

The majority (11/13, 85%) of the surveyed studies were classified as using a behavior-change gamification approach. This is a technique that seeks to form healthy habits among the population. Additionally, the results highlight the intricacy of gamification and its applications, which are still in their infancy in the field of HIV/AIDS prevention and care. Furthermore, the survey results show that the most important goal of serious games and gamification is to improve the effectiveness of HIV/AIDS prevention efforts. This is consistent with findings from previous studies that indicate that early prevention and early ART of HIV/AIDS infection are more cost-efficient than lifetime HIV/AIDS treatment. This study identifies, compares, and describes serious games and gamified systems currently used in HIV/AIDS prevention and care. The study results reveal the situation in the studied period pertaining to common popular study sites, game platforms, and gamification approaches among serious games and gamified systems used in HIVAIDS prevention and care. The contributions of this review should provide a resource of information for organizations, game developers, and other parties who intend to use games as communication or education tools for HIV/AIDS.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.
[PDF File (Adobe PDF File), 88 KB - games_v11i1e39915_app1.pdf]

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Abbreviations

ART: antiretroviral treatment
CCRT: computerized cognitive rehabilitation training
HMP: HealthMpowerment
MAKE: Motivation, Attitude, Knowledge, and Engagement
MSM: men who have sex with men
PrEP: pre-exposure prophylaxis
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
SOLVE: Socially Optimized Learning in Virtual Environments
SSS: Secret of Seven Stones
STI: sexually transmitted infection
TIADL: timed instrumental activities of daily living
UFOV: useful field of view

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Review

Short- to Long-Term Effects of Virtual Reality on Motor Skill Learning in Children With Cerebral Palsy: Systematic Review and Meta-Analysis

Seyma Kilcioglu[1], MSc; Benoît Schiltz[1], MSc; Rodrigo Araneda[1,2], PhD; Yannick Bleyenheuft[1], PhD

[1]Institute of Neuroscience, Université Catholique de Louvain (UCLouvain), Brussels, Belgium

[2]Exercise and Rehabilitation Science Institute, School of Physical Therapy, Faculty of Rehabilitation Science, Universidad Andrés Bello, Santiago, Chile

Corresponding Author:
Rodrigo Araneda, PhD
Institute of Neuroscience
Université Catholique de Louvain (UCLouvain)
Avenue E. Mounier 53, 1200
Brussels
Belgium
Phone: 32 27645446
Email: rodrigo.araneda@uclouvain.be

Abstract

Background: Many studies have started integrating virtual reality (VR) into neurorehabilitation for children with cerebral palsy (CP). The results of the effects of VR on motor skill learning, including the short- to long-term results of relevant studies, must be pooled in a generic framework.

Objective: This systematic review and meta-analysis aimed to investigate the short- to long-term effects of therapies including VR on motor skill learning in children with CP.

Methods: Two examiners followed the inclusion and exclusion criteria of the "Participant, Intervention, Control, and Outcome" framework. Randomized controlled trials (RCTs) and non-RCTs were considered if they compared VR-included interventions with control groups on motor functions and daily life activities in children with CP. PubMed, ScienceDirect, Embase, and IEEE Xplore databases were searched. The modified Downs and Black assessment was used to assess the methodological quality of the included studies. Meta-analyses and subgroup analyses for RCTs were conducted whenever possible.

Results: A total of 7 RCTs, 2 non-RCTs, and 258 children with CP were included. The priority focus of 78% (7/9) of the studies was upper limb functions. There was a significant short-term effect of adding VR to conventional therapies on upper limb functions when compared with conventional therapies (*P*=.04; standardized mean difference [SMD]=0.39, 95% CI 0.01-0.76). The overall medium- to long-term effects showed a trend toward favoring the VR group, although the difference was not statistically significant (*P*=.06; SMD=0.37, 95% CI −0.02 to 0.77). For balance (*P*=.06; SMD=1.04, 95% CI −0.04 to 2.12), gross motor functions (*P*=.30; SMD=2.85, 95% CI −2.57 to 8.28), and daily life activities outcomes (*P*=.21; SMD=0.29, 95% CI −0.16 to 0.74), the overall effect in the short term also showed a trend toward favoring the VR group, but these results were not statistically significant.

Conclusions: VR seems to have additional benefits for motor skill learning in children with CP. Studies with follow-up outcomes of VR training focusing on balance and gross motor functions in patients with CP were quite limited. Future research on balance and gross motor function outcomes should target particularly long-term results of therapies including VR on motor skill learning.

Trial Registration: PROSPERO International Prospective Register of Systematic Reviews CRD42021227734; https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021227734

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KEYWORDS

cerebral palsy; virtual reality; motor skill learning; long-term effect; daily life activities; motor functions

Introduction

Background

Cerebral palsy (CP), the leading motor disability in childhood with a worldwide prevalence of 2 per 1000 live births, is a group of permanent movement and posture disorders caused by an early brain lesion during pregnancy, childbirth, or shortly after birth [1,2]. In addition to the motor consequences, sensory and cognitive functions affecting daily life activities may also be impaired [2]. From the rehabilitation perspective, motor skill learning–based approaches have shown encouraging efficacy in improving motor functions in children with CP in recent years [3]. Interventions based on motor skill learning principles (more intensity, performance of daily living activities, repeating functional tasks, individually tailored, progressively challenging, and motivating feedback) have been shown to promote persistent motor skill acquisition and neuroplasticity (practice-induced brain changes) [4,5]. In addition, it is now well established that sustaining children's attention, interest, and enjoyment for a long time is one of the critical factors, but it is also challenging for optimizing rehabilitation outcomes and neuroplastic changes [6]. Consequently, researchers have focused on how to foster neuroplastic changes and functional improvements with more intensity and diversity of practice without a trade-off in terms of entertainment.

Thus, with the results of recent studies and the increase in access to computer-assisted technologies, the use of virtual reality (VR) as a means of neurorehabilitation for children with CP has been encouraged. VR refers to a computer-generated simulation that may vary in complexity and reality owing to the rapidly evolving nature of technology [7,8]. The VR environment can be experienced through a variety of display hardware, including standard monitors, flat screens, projection screens, and head-mounted displays. The method of interacting with the VR system may also vary from simple activation of computer keyboard keys, mouse, or joystick to more advanced motion camera interfaces [9,10]. Consequently, VR devices used in rehabilitation can be classified as immersive, semi-immersive, and nonimmersive depending on the level of immersion [11,12]. Furthermore, certain devices are specifically designed for rehabilitation purposes, whereas commercially available devices and games are also used in the rehabilitation of various disorders. A systematic review on the clinical utility of VR in neurorehabilitation reported that CP is the second most studied neurological disorder in VR rehabilitation [13]. In addition, You et al [14] and Golomb et al [15] showed cortical reorganization after VR therapy in children with CP and the association of the cortical changes with functional abilities. The advantage of using VR in rehabilitation is not only to increase entertainment with playful interactive games but also to have games with individually tailored, progressively adjustable difficulty levels and to provide active repetition in an enriched environment [9]. Thus, with these advantages, VR may well correspond to the challenges in rehabilitation such as the use of motor skill learning principles to develop long-lasting motor skill acquisition in children.

Objectives

Several systematic reviews investigated the effectiveness of VR on upper and lower limb functions, gross motor functions, and postural control in children with CP in the short term, that is, immediately after treatment [16-18]. They showed a promising potential of adding VR into CP interventions for improving motor functions. However, the long-term effects of VR interventions on motor skill learning remain unclear, although durable retention of acquired skills is one of the crucial factors for rehabilitation objectives. Consequently, this systematic review and meta-analysis was conducted to examine the effect of VR on motor functions and daily life activities of children with CP from the short term (immediately after the intervention) to the medium term (≥1 week to <12 weeks after the end of the intervention) or long term (≥12 weeks after the end of the intervention).

Methods

Protocol and Registration

We followed the guidelines of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 statement to conduct this systematic review and meta-analysis and reported our results according to PRISMA 2020 checklist [19]. The protocol of this review was registered in the PROSPERO database (CRD42021227734).

Eligibility Criteria

Inclusion criteria of the studies were defined after discussion among all authors according to the PICO (Population, Intervention, Comparison, and Outcome) framework [20]. As a result, studies (1) with a population of children with CP aged <18 years; (2) using VR for main intervention; (3) comparing the experimental group (therapy involving VR) with any control group (another intervention except VR, nonintervention, placebo effect, or different cohorts); and (4) including baseline, postintervention, and follow-up assessments by using outcome measures on motor functions and daily life activities were included. We excluded studies if they (1) involved populations other than children with CP aged <18 years; (2) used VR only for assessment or focused on the development of VR devices; (3) used different outcome measures than on motor functions and daily life activities; (4) were not published in English; (5) were reviews, meta-analyses, commentaries, protocols, and conference abstracts; and (6) did not have follow-up assessment (ie, had only baseline and postintervention assessments). In this review, we decided to include studies involving commercially available VR devices or those specifically developed for therapy, regardless of the degree of immersive experience, type of display hardware, or the method of interaction with the VR system.

Information Sources and Search Strategy

Two authors systematically and independently searched PubMed, ScienceDirect, Embase, and IEEE Xplore databases in September 2021 using predetermined keyword combinations, which were "virtual reality," "virtual environment," "videogaming," "computer game," "Kinect," "Wii," "PlayStation," "cerebral palsy," "CP," "rehabilitation," "therapy" and "motor skill learning." The results of the search in the 4 databases were transferred to the EndNote (version 9; Clarivate), and duplicates were removed by 1 author. The search strategy used for each database is detailed in Multimedia Appendix 1. We did not apply any restriction regarding the date of publication for our search strategy.

Study Selection Process

After detecting and eliminating duplicated studies obtained from the searches, 2 authors first screened titles and abstracts according to the inclusion and exclusion criteria. After several discussions and resolving the conflicts between authors, full texts of studies that have the potential to be included were obtained. Then, the eligibility of the studies was assessed using full-text screening. All screening and study selection processes were performed by the same 2 authors who were blinded to each other using Rayyan web-based software (Qatar Computing Research Institute) [21].

Data Collection Process and Data Items

The following information was extracted by 2 authors independently to a predesigned Microsoft Excel (Microsoft Corp) sheet: characteristics of the study (first author, year of publication, and study design), characteristics of the participants (number of participants, CP type, age, Manual Ability Classification System [MACS], and Gross Motor Function Classification System [GMFCS] level), characteristics of the VR interventions and comparison interventions (name, duration, frequency, length, total hour, priority focus, and motor skill learning principles involved in experimental interventions), characteristics of outcomes measures (timing and measures), and main outcomes. In addition, to collect the data from the included studies, another predesigned Microsoft Excel sheet was used, with the following content: mean and SD of experimental (VR) and control groups at postintervention and follow-up points and sample sizes of both groups. When there was no information about the means and SDs of results, they were calculated from SE, CI, *t* test, or *P* value as recommended by the Cochrane handbook [22]. Disagreements between the data collectors were resolved by a discussion.

Methodological Quality Assessment

Two authors independently assessed the methodological quality of the included studies using the modified Downs and Black checklist. This is a valid and reliable tool to assess the quality of both randomized controlled trials (RCTs) and non-RCTs [23]. Conflicts were resolved by discussion. This checklist comprises 27 items on the quality of reporting (10 items), external validity (3 items), internal validity (bias and confounding; 13 items), and statistical power (1 item).

The highest possible score for the original checklist was 32. However, as item 27 was complicated to score (from 0 to 5), a modified version of the scoring method was proposed, as observed in previous studies [17,24,25]. Thus, each item was scored as 0 (no) or 1 (yes), except for the fifth item that was scored as 0 (no), 1 (partially), or 2 (yes). Consequently, scores on the modified Downs and Black checklist corresponding to quality levels ranged between "excellent" (scores of 24-28), "good" (scores of 19-23), "fair" (scores of 14-18), and "poor" (scores of ≤13) [26,27].

Effect Measures and Synthesis Methods

We conducted a meta-analysis for the RCTs that met the criteria for eligible design and outcomes. The results from the studies on motor functions and activities of daily living were extracted into a Microsoft Excel sheet. For continuous data, standardized mean difference (SMD) with a 95% CI, which refers to the effect size, was measured using a random effects model because of the different clinical tests used in the included studies. For the interpretation of effect sizes, we followed Cohen rule in which 0.2, 0.5, and 0.8 represent small, medium, and large effect sizes, respectively [28]. Statistical significance was set at .05, and statistical heterogeneity was examined using the I^2 statistic. Heterogeneity was rated as low (I^2≤25%), moderate (25%<I^2<75%), or high (I^2≥75%).

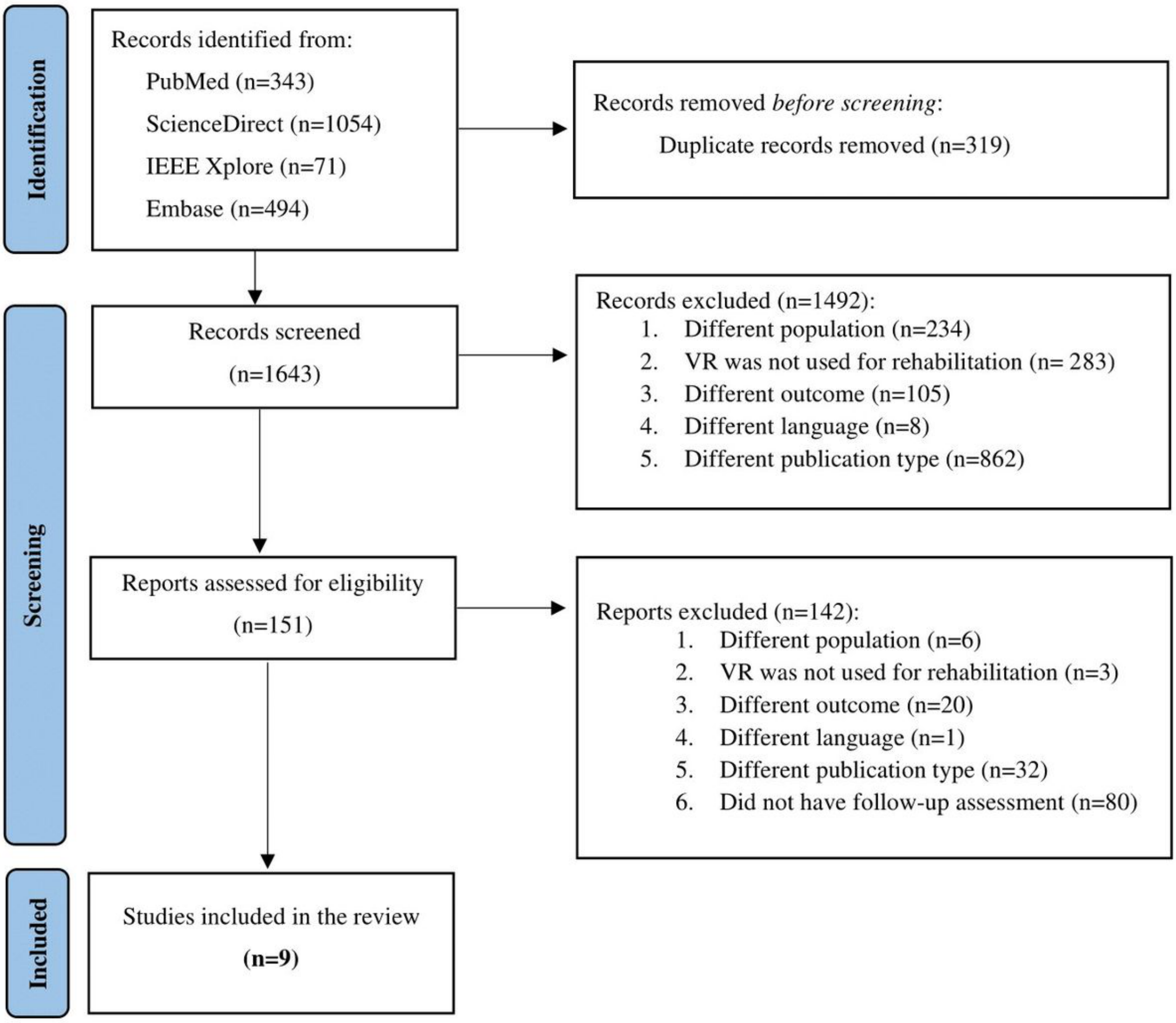
To explore whether the duration and intensity of VR training (more intensive: more therapy time per week, which is obtained by the higher frequency of sessions or longer duration of each therapy session) as well as the type of VR had some influence on the results, subgroup analyses were performed (when possible) according to the following criteria: duration (<30 min per session, ≥30 to <60 min per session, or ≥60 min per session), intensity (≤120 min per week or >120 min per week) and VR type (specifically developed for therapy or commercially available). The software Review Manager (version 5.4.1; Cochrane) for Windows was used to conduct the analyses of the included studies.

Results

Study Selection

Our database search resulted in 1643 studies after removing 319 duplicate records. After title and abstract screening, we excluded 1492 records for the reasons specified in Figure 1. Full texts of the remaining 151 studies were assessed for eligibility, and finally, 9 studies met the inclusion criteria, 7 (78%) of which were RCTs.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the study selection process. VR: virtual reality.



Study Characteristics

Overview

The 9 included studies involved 258 children, 163 with unilateral CP and 95 with bilateral CP (BCP), aged between 3 and 18 years. Four studies reported the gross motor functions of children, classifying them from levels I to V according to the GMFCS [29-32]. Five studies classified children from level I to V regarding the use of their hands when handling objects in daily activities using the MACS [29,32-35]. The characteristics of the included studies are presented in Tables 1-3.

Table 1. List of study characteristics.

Study	Participants	Experimental group			Control group			Outcomes measures: timing and measures	Main outcomes
		Intervention	Duration, frequency, length, and total time of VR[a]	Priority focus	Intervention	Duration, frequency, length, and total time	Priority focus		
Choi et al [33], 2021	34 children with unilateral CP[b] and 44 children with bilateral CP, age: 3-18 years	VR (RAPAEL Smart Kids) + conventional occupational therapy (stretching, strengthening, and task-oriented training)	30 min, 5 sessions, 4 weeks, and 10 h	Upper limb	Conventional occupational therapy	60 min, 5 sessions, 4 weeks, and 20 h	Upper limb	Baseline, postintervention, follow-up (8 +1 or −1 weeks after completion of intervention); MA-2[c], ULPRS[d], and PEDI-CAT[e]	More improvement in VR group in MA-2 and performance of activities of daily living domain of PEDI-CAT. Improvements were retained at follow-up.
Preston et al [34], 2016	14 children with unilateral CP and 1 child with bilateral CP, age: 5-12 years	VR (computer-assisted arm rehabilitation gaming technology) + conventional therapy + botulinum toxin	7 min per session, 6 weeks, and 1 h 39 min	Upper limb	Conventional therapy + botulinum toxin	6 weeks	Upper limb	Baseline, postintervention, follow-up (6 weeks after completion of intervention); ABILHAND-Kids questionnaire, and COPM[f]	No improvement in both groups in ABILHAND-Kids, and no difference between groups at any time point. Improvement in all participants in COPM.
Peper et al [35], 2013	6 children with unilateral CP, age: 7-12 years	VR (computer games with Lissajous feedback) + conventional therapy (if any)	30 min, 3 sessions, 6 weeks, and 9 h	Upper limb	Conventional therapy	6 weeks	—[g]	Baseline, postintervention, follow-up (6 weeks after completion of intervention); AHA[h]	No improvement at group level in AHA.
Rostami et al [36], 2012	32 children with unilateral CP, age: 6-12 years	VR group: VR (E-Link Evaluation and Exercise System) + conventional therapy, VR + mCIMT[i] group	90 min, 3 sessions, 4 weeks, and 18 h	Upper limb	Conventional therapy	30 min, 2 sessions, 4 weeks, and 4 h	Upper limb	Baseline, postintervention, follow-up (12 weeks after completion of intervention); PMAL[j], and speed and dexterity subtest of BOTMP[k]	More improvement in VR + mCIMT group in PMAL and BOTMP. Improvements were retained at follow-up.
Kassee et al [29], 2017	6 children with unilateral CP, age: 7-12 years	VR (Nintendo Wii)	40 min, 5 sessions, 6 weeks, and 20 h	Upper limb	Resistance training	36-48 min, 5 sessions, 6 weeks, and 18-24 h	Upper limb	Baseline, postintervention, follow-up (4 weeks after completion of intervention); MA-2, ABILHAND-Kids questionnaire, and grip strength	No statistical analysis to determine group differences.

Study	Participants	Experimental group			Control group			Outcomes measures: timing and measures	Main outcomes
		Intervention	Duration, frequency, length, and total time of VR[a]	Priority focus	Intervention	Duration, frequency, length, and total time	Priority focus		
Psychouli and Kennedy [37], 2016	9 children with unilateral CP, age: 5-11 years	VR (computer game with a joystick) + mCIMT	20 min, 7 sessions, 4 weeks, and 9 h	Upper limb	mCIMT	4 weeks	Upper limb	Baseline, postintervention, follow-up (4 weeks after completion of intervention); MA, and QUEST[l]	More improvement in VR + mCIMT group in MA, QUEST. Improvement in MA was retained at follow-up.
Decavele et al [30], 2020	32 children with bilateral CP, age: 6-15 years	VR (Open-Feasyo games with Wii Balance Board) + conventional therapy	At least 15-20 min, 2 sessions, 12 weeks, and approximately 5 h	Upper and lower limb, trunk control	Conventional therapy	32.6 min, 20.6 sessions (total),12 weeks, and approximately 11 h	—	Baseline, postintervention, after washout period (12 weeks after), after control period; GAS[m], TCMS[n], PBS[o], and GMFM[p]-88	More improvement after intervention period (VR + conventional therapy) compared with control period (conventional therapy) in GAS, TCMS, PBS, GMFM-88. Improvements were not retained at follow-up.
Pin and Butler, 2019 [31]	18 children with bilateral CP, age: 6-14 years	VR (TYROMOTION force plate) + conventional therapy	20 min, 4 sessions, 6 weeks, and 8 h	Postural control	Conventional therapy	6 weeks	—	Baseline, midpoint of intervention (week 3), postintervention (week 6), follow-up (6 weeks after completion of intervention); PRT[q], GMFM-66, and 2-min walk test	No significant difference between the groups at any time and in any of the assessments. Improvements in both groups in GMFM-66 after 6 weeks of the intervention.

Study	Participants	Experimental group			Control group			Outcomes measures: timing and measures	Main outcomes
		Intervention	Duration, frequency, length, and total time of VR[a]	Priority focus	Intervention	Duration, frequency, length, and total time	Priority focus		
Chiu et al [32], 2014	62 children with unilateral CP, age: 6-13 years	VR (Wii Sports Resort) + conventional therapy	40 min, 3 sessions, 6 weeks, and 12 h	Upper limb	Conventional therapy	6 weeks	—	Baseline, postintervention, follow-up (6 weeks after completion of the intervention); coordination (elbow and finger), grip strength, Nine-Hole Peg Test, JTTHF[r], and FUS[s]	No significant difference between the groups in coordination, Nine-Hole Peg Test, and Jebsen-Taylor Test. Trend for the experimental group to have more grip strength and FUS quantity.

[a]VR: virtual reality.

[b]CP: cerebral palsy.

[c]MA-2: Melbourne Assessment 2.

[d]ULPRS: Upper Limb Physician's Rating Scale.

[e]PEDI-CAT: Pediatric Evaluation of Disability Inventory Computer Adaptive Test.

[f]COPM: Canadian Occupational Performance Measure.

[g]Not available.

[h]AHA: Assisting Hand Assessment.

[i]mCIMT: modified constraint-induced movement therapy.

[j]PMAL: Pediatric Motor Activity Log.

[k]BOTMP: Bruininks-Oseretsky Test of Motor Proficiency.

[l]QUEST: Quality of Upper Extremity Skills Test.

[m]GAS: Goal Attainment Scale.

[n]TCMS: Trunk Control Measurement Scale.

[o]PBS: Pediatric Balance Scale.

[p]GMFM: Gross Motor Function Measure.

[q]PRT: Pediatric Reach Test.

[r]JTHFT: Jebsen-Taylor Hand Function Test.

[s]FUS: Functional Use Survey.

Table 2. Motor skill learning principles of experimental interventions and results in upper limb functions and daily life activities.

Study	Experimental intervention	Motor skill learning principles involved in the experimental intervention	Changes in upper limb functions and daily life activities
Choi et al [33], 2021	Conventional occupational therapy + VR[a] (specifically developed for therapy)	More intensity, performance of daily life activities, repeating specific functional tasks, individually tailored, progressively challenging training, and simultaneous feedback (auditory and visual)	↑↑[b]
Preston et al [34], 2016	Conventional therapy + botulinum toxin + VR (specifically developed for therapy)	—[c]	→[d]
Peper et al [35], 2013	Conventional therapy (if any) + VR (specifically developed for therapy)	Many repetitions of the movements, progressively challenging, and Lissajous feedback	→
Rostami et al [36], 2012	mCIMT[e] + VR (specifically developed for therapy)	More intensity, performance of daily life activities, repetitive motor practice, individually tailored, progressively challenging training, and simultaneous feedback (auditory and visual)	↑↑
Kassee et al [29], 2017	VR (commercially available)	More intensity	No statistical analysis
Psychouli and Kennedy [37], 2016	mCIMT + VR (commercially available)	More intensity, performance of daily life activities, repeating specific functional tasks, individually tailored, and augmented motivating feedback	↑↑
Chiu et al [32], 2014	Conventional therapy + VR (commercially available)	Simultaneous feedback	→

[a]VR: virtual reality.

[b]More improvement (retained at follow-up) in the experimental group compared with the control group.

[c]Not available.

[d]No improvement in the experimental group or no significant difference between the groups (experimental and control groups).

[e]mCIMT: modified constraint-induced movement therapy.

Table 3. Motor skill learning principles of experimental interventions and results in balance, trunk control, gross motor functions, and daily life activities.

Study	Experimental intervention	Motor skill learning principles involved in the experimental intervention	Changes in balance, trunk control, and gross motor functions and daily life activities
Decavele et al [30], 2020	Conventional therapy + VR[a] (specifically developed for therapy)	Individually tailored, and progressively challenging	↑→ [b]
Pin and Butler [31], 2019	Conventional therapy + VR (specifically developed for therapy)	Progressively challenging	→ [c]

[a]VR: virtual reality.

[b]More improvement (not retained at follow-up) in the experimental group compared with the control group.

[c]No improvement in the experimental group or no significant difference between the groups (experimental and control groups).

The types of VR devices used for the experimental groups in the studies varied considerably. Two studies used Wii training [29,32], and 1 study used the OpenFeasyo software platform (rehabilitation-specific gaming software) using the Kinect sensor and the Nintendo Wii Balance Board [30]. One study used the TYROMOTION force plate, which was specifically designed to assess and treat postural control [31], whereas another study used the RAPAEL Smart Kids [33], which was developed for rehabilitation purposes. Computer games with Lissajous feedback, targeting particularly bimanual coordination [35]; E-Link Evaluation and Exercise System [36]; and a computer game with a joystick [37] were used in the other studies. In one of the studies, the VR device was reported as a computer-assisted arm rehabilitation gaming technology [34].

Overall, most of the devices used in the studies (6/9, 67%) were specifically developed for therapy, whereas one-third (3/9, 33%) of the studies used commercially available VR devices. No safety issues or adverse events associated with VR training were reported.

The primary focus of VR interventions for most studies (7/9, 78%) was on the upper limb. Only 2 studies included trunk control training [30,31]. Similarly, the outcome measures in the studies included in this review were mainly related to upper limb functions and performance.

The duration of each VR session varied from 15 to 90 minutes, and the participants performed the VR intervention 2 to 7 times a week. In 1 study, participants' compliance with the duration of VR interventions could not be fixed, and the mean daily duration of VR sessions was only 7 minutes [34]. As a result, the total amount of VR intervention of the included studies in this review was a minimum of 1 hour 39 minutes and a maximum of 20 hours.

In general (7/9, 78%), VR as the experimental group was mostly combined with conventional therapy and compared with a control group receiving only conventional therapy [30-36]. In one of these studies, there was >1 experimental group, with one group undergoing VR with conventional therapy (VR group) and the other following VR with modified constraint-induced movement therapy (mCIMT; VR + mCIMT group) [36]. One study applied VR therapy alone in the experimental group [29], whereas in another study, the experimental group participated in functional activities and the computer game while wearing the constraint (VR + mCIMT) [37].

The included studies had various outcome measures on motor functions and daily life activities at baseline (before intervention), after intervention, and at follow-up, which ranged from 4 to 12 weeks after completion of the interventions.

Upper Limb Functions

Overall, 78% (7/9) of the studies included in this review used a variety of outcome measures related to upper limb functions and performance. Furthermore, 3 studies used the Melbourne Assessment of Unilateral Upper Limb Function [29,33,37] and 2 studies used the ABILHAND-Kids questionnaire [29,34]. The Upper Limb Physician's Rating Scale [33], Pediatrics Motor Activity Log, Speed and Dexterity subtest (subtest 8) of the Bruininks-Oseretsky test of Motor Proficiency [36], Nine-Hole Peg Test, Jebsen-Taylor Hand Function Test, Functional Use Survey [32], Assisting Hand Assessment [35], and Quality of Upper Extremity Skills Test [37] were also used in the studies.

Regarding the results of upper limb functions and performance, Kassee et al [29] did not conduct statistical analysis to determine group differences for the Melbourne Assessment and the ABILHAND-Kids questionnaire owing to the small sample size (n=3 for each group). Choi et al [33] and Psychouli and Kennedy [37] found a significant improvement in both experimental (VR with conventional therapy and VR with mCIMT, respectively) and control groups (conventional therapy and mCIMT, respectively) in the Melbourne Assessment after the intervention, but the VR groups showed more improvement in both studies. These improvements were retained at follow-up, after 4 or 8 weeks [33,37]. Moreover, Psychouli and Kennedy [37] found further improvement in the VR group in the Quality of Upper Extremity Skills Test after the intervention [37]. Rostamia et al [36] also demonstrated significant improvements in the experimental groups (VR and VR + mCIMT) in the Pediatrics Motor Activity Log and the Bruininks-Oseretsky test of Motor Proficiency but not in the control group (conventional therapy) [36]. The combined group (VR + mCIMT) showed the most significant improvements, which were maintained at the 3-month follow-up assessment [36].

Neither group improvements nor group differences in the ABILHAND-Kids questionnaire were found by Preston et al [34]. Chiu et al [32] did not find a difference between the experimental and the control group after the intervention or 6 weeks after the interventions in the Nine-Hole Peg Test and the Jebsen-Taylor Hand Function Test [32]. They also assessed elbow and finger coordination, and grip strength. As a result, there was a trend of mean difference for the experimental group to have more grip strength and Functional Use Survey (quantity) score [32]. In Assisting Hand Assessment scores at a group level, no significant improvements were observed by Peper et al [35].

Balance, Trunk Control, and Gross Motor Functions

Only 2 studies evaluated balance and trunk control using the Trunk Control Measurement Scale, Pediatric Balance Scale, or Pediatric Reach Test, and they also reported gross motor function results with Gross Motor Function Measure (GMFM; GMFM-66 or GMFM-88) [30,31]. Decavele et al [30] observed more improvement in Trunk Control Measurement Scale, Pediatric Balance Scale, and GMFM-88 after the intervention period (conventional therapy including rehabilitation-specific gaming) compared with the control period (conventional therapy), but the results did not persist after the 12-week follow-up [30]. Pin and Butler [31] found no significant difference in changes in the Pediatric Reach Test and the GMFM-66 between the 2 groups [31].

Daily Life Activities

Overall, 3 studies reported outcomes on daily life activities using the Goal Attainment Scale (GAS) [30], Pediatric Evaluation of Disability Inventory Computer Adaptive Test (PEDI-CAT) [33], or Canadian Occupational Performance Measure [34]. Decavele et al [30], in the GAS, and Choi et al [33], in the daily activities domain of the PEDI-CAT, found significant improvements in the VR group compared with the control group after intervention. The improvement in the PEDI-CAT was maintained at the 8-week follow-up [33] but not in the GAS at the 12-week follow-up [30]. Preston et al [34] found no significant differences in the changes on the Canadian Occupational Performance Measure between the 2 groups.

Methodological Quality

All studies in this review (7 RCTs and 2 non-RCTs) were included in the methodological quality assessment. The total score of these studies ranged from fair to excellent. Of these 9 studies, 3 (33%) studies were classified as excellent-quality studies [32,34,36], 4 (44%) as good-quality studies [30,31,33,37], and 2 (22%) as fair-quality studies [29,35]. Table 4 presents the 4 main subscales and the total scores of the modified Downs and Black checklist. Scoring of all 27 items for the included studies is provided in Multimedia Appendix 2.

Table 4. Results of the quality assessment of included studies based on the modified Downs and Black checklist.

Study	Study type	Quality of reporting score (out of 11)	External validity score (out of 3)	Internal validity score (out of 13)	Statistical power score (out of 1)	Total score (out of 28)
Choi et al [33], 2021	RCT[a]	11	0	11	1	23
Preston et al [34], 2016	RCT	11	2	11	0	24
Peper et al [35], 2013	non-RCT	6	0	8	0	14
Rostami et al [36], 2012	RCT	10	2	12	0	24
Kassee et al [29], 2017	RCT	6	0	8	0	14
Psychouli and Kennedy [37], 2016	non-RCT	10	0	10	0	20
Decavele et al [30], 2020	RCT	10	0	10	1	21
Pin and Butler [31], 2019	RCT	9	2	11	0	22
Chiu et al [32], 2014	RCT	10	2	12	1	25

[a]RCT: randomized controlled trial.

Results of Meta-Analysis

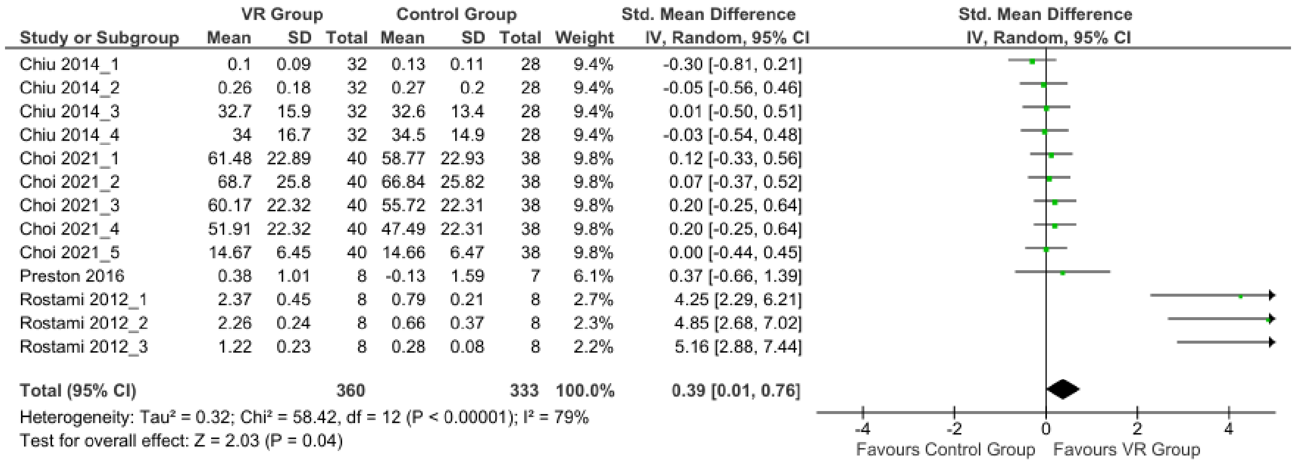
Overview

We performed meta-analyses with 6 RCTs supplying the essential data and classified them as good- to excellent-quality studies [30-34,36]. The upper limb function results of 4 studies were included in the meta-analysis [32-34,36], whereas results on balance, trunk control, and gross motor functions of only 2 studies were included [30,31]. Similarly, changes in daily life activities were documented in only 3 studies. However, as 1 study did not report the group mean scores separately [34], the results of 2 studies were used in the analysis [30,33]. In general, in all studies included in the meta-analysis, the results used for analyses were the postintervention and follow-up outcomes of the VR group (conventional therapy with VR training) and the control group (conventional therapy). Meta-analyses on follow-up results and subgroup analyses were conducted only for the studies with the outcomes of upper limb functions because there were enough studies (n=4) and results. We did not use any test to assess funnel plot asymmetry (reporting biases) because at least 10 studies included in the meta-analysis were required for meaningful results [38].

Effects of VR and Intervention of Control Group on the Upper Limb Functions of Children With CP From Short Term to Long Term

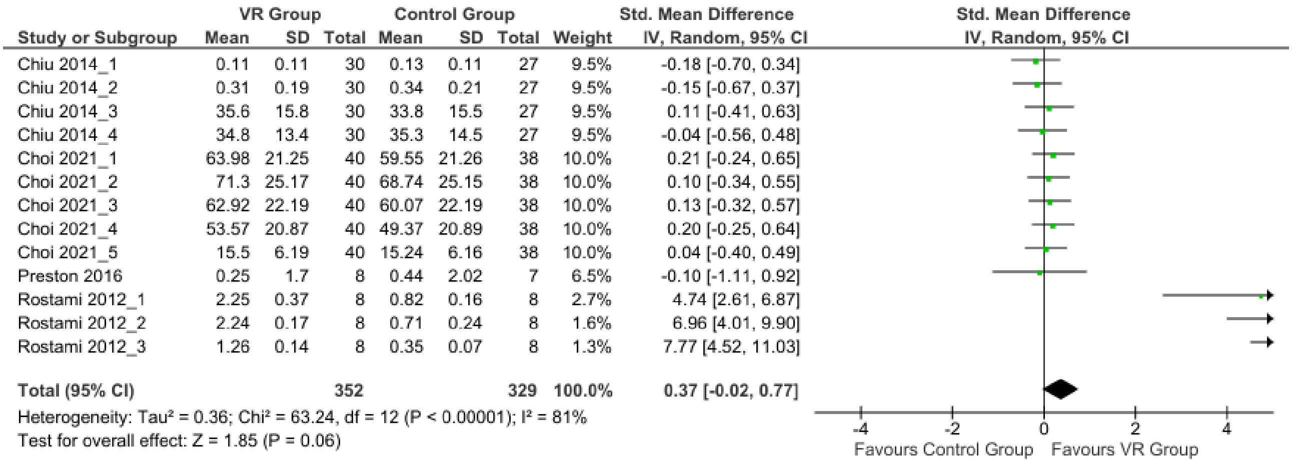
The overall effect size was 0.39 (small effect; 95% CI 0.01-0.76; random effects model) with high heterogeneity (I^2=79%). The results showed that after the intervention, overall effect on upper limb functions and performance in children with CP was in favor of the VR group when compared with the control group (*P*=.04; Figure 2 [32-34,36]).

Figure 2. Forest plot of the postintervention upper limb functions outcomes [32-34,36]. Control group: conventional therapy; IV: inverse variance; VR group: virtual reality with conventional therapy.



Concerning the medium- to long-term effects of interventions, the overall effect size was 0.37 (small effect; 95% CI −0.02 to 0.77; random effects model) with high heterogeneity (I^2=81%). The overall effect showed a trend toward favoring the VR group 6 to 12 weeks after the completion of the interventions (*P*=.06; Figure 3 [32-34,36]), but the result was not statistically significant.

Figure 3. Forest plot of the follow-up upper limb functions outcomes (from 6 to 12 weeks after completion of the intervention) [32-34,36]. Control group: conventional therapy; IV: inverse variance; VR group: virtual reality with conventional therapy.

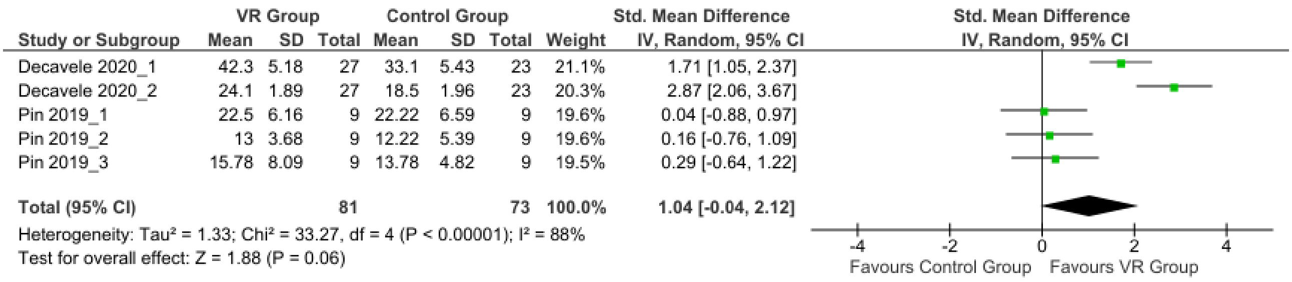


The subgroup analyses of both postintervention and follow-up results of upper limb functions showed that the duration and intensity of VR intervention and VR type were significant factors (*P*<.01). Studies that included more intensive and higher duration (≥60 min) of VR interventions had larger effects. Moreover, a larger effect was found when VR devices specifically developed for therapy were used compared with commercially available apparatuses. The figures are provided in Multimedia Appendix 3 [32-34,36].

Effects of VR and Intervention of Control Group on the Balance and Trunk Control of Children With BCP

The overall effect size was 1.04 (large effect; 95% CI −0.04 to 2.12; random effects model) with high heterogeneity (I^2=88%). The postintervention overall effect on balance and trunk control in children with BCP showed a trend toward favoring the VR group compared with the control group (*P*=.06; Figure 4 [30,31]), but the result was not statistically significant.

Figure 4. Forest plot of the postintervention balance and trunk control outcomes [30,31]. Control group: conventional therapy; IV: inverse variance; VR group: virtual reality with conventional therapy.

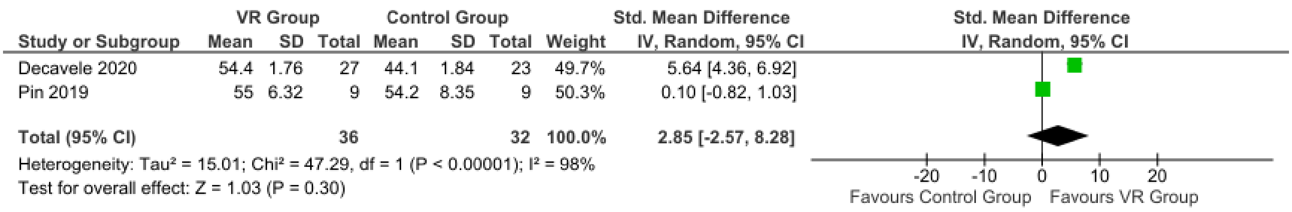


Effects of VR and Intervention of Control Group on the Gross Motor Functions of Children With BCP

The overall effect size was 2.85 (large effect; 95% CI −2.57 to 8.28; random effects model) with high heterogeneity (I^2=98%).

The postintervention overall effect on gross motor functions in children with BCP showed a trend toward favoring the VR group compared with the control group (*P*=.30; Figure 5 [30,31]), but the result was not statistically significant.

Figure 5. Forest plot of the postintervention gross motor functions outcomes [30,31]. Control group: conventional therapy; IV: inverse variance; VR group: virtual reality with conventional therapy.

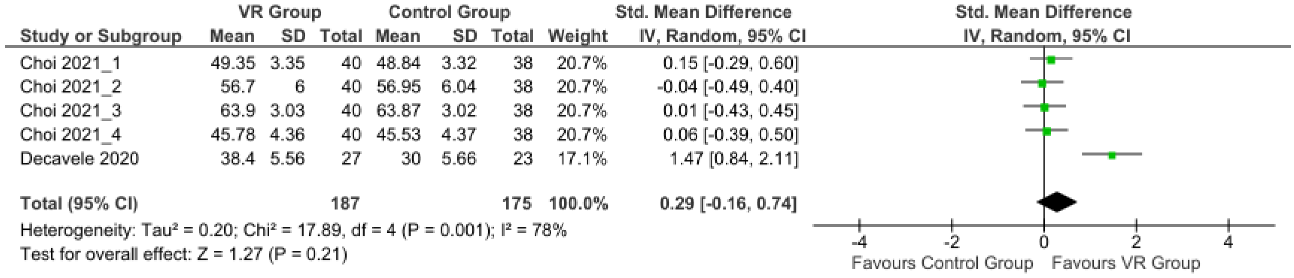


Effects of VR and Intervention of Control Group on the Activities of Daily Life of Children With CP

The overall effect size was 0.29 (small effect; 95% CI −0.16 to 0.74; random effects model) with high heterogeneity (I^2=78%).

The postintervention overall effect on daily functions of children with CP showed a trend toward favoring the VR group compared with the control group. (*P*=.21; Figure 6 [30,33]), but the result was not statistically significant.

Figure 6. Forest plot of the postintervention activities of daily life outcomes [30,33]. Control group: conventional therapy; IV: inverse variance; VR group: virtual reality with conventional therapy.



Discussion

Principal Findings

This systematic review and meta-analysis aimed to investigate whether VR-included therapies are effective on motor skill learning in children with CP compared with a control group, with special attention to the middle- and long-term effects. Overall, the results on upper limb function and performance showed the benefits of adding VR to CP rehabilitation in terms of postintervention improvements and supported that these acquisitions were mostly retained at follow-up. The meta-analysis results on upper limb functions and performance confirmed these benefits. In particular, Rostami et al [36] and Psychouli and Kennedy [37] used VR with mCIMT for 4 weeks, and greater improvements have been shown in the upper limb functions after VR with mCIMT compared with conventional therapy or mCIMT alone. Choi et al [33] matched VR with conventional occupational therapy for 4 weeks, and similarly, greater improvements have been shown in the upper limb functions following the intervention including VR compared with conventional occupational therapy alone [33]. In addition, these improvements were maintained at follow-up. It should also be noted that the contents of experimental interventions were shaped with motor skill learning principles (more intensity, the performance of daily living activities, repeating functional tasks, individually tailored, progressively challenging, and motivating feedback) in these 3 studies, which showed greater and long-lasting improvements in the VR groups (Table 2) [33,36,37]). Choi et al [33] and Rostami et al [36] applied these motor skill learning principles in VR game sessions, whereas Psychouli and Kennedy [37] used them mostly in mCIMT sessions and added a computer game as motivating feedback at the end of the intervention. Therefore, we concluded that incorporating motor skill learning principles into interventions including VR, through VR or therapy, induces greater benefits in motor function improvements in the long term. In addition, in the motor skill learning–based, VR-included interventions, VR has a substantially effect on maintaining motivation and eventually ensuring more intensity and repetition of child-initiated active movements during the interventions.

Furthermore, in line with our results from the subgroup analysis, applying more intensive VR training (involving more total hours in a shorter time, 4 weeks vs 6 weeks) had a significant influence on these larger improvements in the VR group both after the intervention and at follow-up compared with the other studies reporting no significant benefit of adding VR [32,34]. Thus, a higher intensity of VR training with either a longer duration or a higher frequency of training appears to be another essential factor for enhancing motor skill learning through VR. These findings were similar to the results of previous systematic reviews and meta-analyses [16,39-42]. They highlighted some principles of VR use in the neurorehabilitation of children with CP [13]. Rathinam et al [16] and Chen et al [39] also noticed in their reviews that more intensive VR training has more potential to result in improvements of functions in children with CP immediately after the intervention.

Furthermore, a study included in our review stated that parents were asked to encourage their children to use VR for 30 minutes daily. However, they played the games only for 7 minutes as a mean daily amount because of children's low interest and motivation for the games in VR games [34]. This may explain why they did not find any improvement after VR-included therapy. In other words, maintaining interest and motivation also helps active participation in gaming in VR therapy and provides the expected therapy duration.

We also performed a subgroup analysis to determine whether VR types affected the upper limb function improvements. The results demonstrated that VR devices specifically developed for therapy have more potential benefits on the training of upper limb functions in children with CP when compared with the commercially available VR device (Nintendo Wii). In addition, VR devices specifically developed for therapy had a greater potential to make acquisitions persistent in the medium or long term. As explained by Chen et al [39], it seems more feasible to provide individually tailored interventions with active repetition in various contexts by integrating motor skill learning principles into VR devices when they are specifically developed for therapy purposes.

Concerning the outcomes of balance, trunk control, gross motor functions, and daily life functions induced by therapies combined with VR, we found only 2 studies that met the eligibility criteria of this systematic review and meta-analysis [30,31]. In addition, these 2 studies had different results. Decavele et al [30] found more improvement (though impermanent) after the VR combined period, whereas Pin and Butler [31] observed no significant difference between the groups. Even so, with the postintervention meta-analysis results of 2 good-quality studies, we showed that adding VR into therapy may offer additional benefits on balance and trunk control (SMD=1.04; P=.06) and likely in gross motor functions (SMD=2.85; P=.30) in children with BCP. Our findings were consistent with those of other reviews on balance and gross motor functions after VR interventions [18,43,44]. However, the very limited number of studies and small number of participants (<50) made it difficult to conclude the follow-up effects. Thus, it remains unclear whether there is more potential in VR-included therapy to facilitate long-lasting acquisitions in balance and gross motor functions in children with CP. The fact that both studies [30,31] only included children with BCP with GMFCS III-IV levels may also have affected the results. Further studies are needed to address the long-term effects of VR intervention on balance and gross motor functions in children with different severity of CP. The number of studies with long-term results that included daily functions was also very low (n=3) [30,33,34]. In fact, 2 out of 3 studies noted that changes in daily living activities after therapies with VR were significantly different between groups, with a tendency toward the VR group [30,33]. Similarly, the meta-analysis results were in favor of the VR group (SMD=0.29; *P*=.21). Considering that there are insufficient results on whether the acquisitions are long lasting, more studies on the daily function outcomes are also needed.

Limitations

First, we found a limited number of studies and participants that met our inclusion criteria, especially for medium- and long-term outcomes. Only 7 RCTs and 2 non-RTCs were included in our systematic review, and most of them (7/9, 78%) had a relatively small sample size (<50). In addition, many studies did not report the MACS and GMFCS levels of the included children. The studies that reported the levels also included children with a relatively wide range of functional abilities. For instance, 1 study included children with GMFCS I-II level [29], whereas another study included children with GMFCS III-IV level [30]. As a result, this heterogeneity may have affected the results, but we could not perform a subgroup analysis because of the limited number of studies. Regarding the outcome measures, wide variations were used in the studies, and this heterogeneity of the outcome measures made it difficult to combine and interpret the results. Another limitation of this study is that if a study included in our review used different clinical tests to determine similar outcomes (upper limb functions, balance and trunk control, gross motor functions, and activities of daily living), all results were included in the analysis. Although the outcome measures were different, the intervention process of VR was identical in the same study. In addition, as one of the studies [30] had a crossover design, at the end of the study period, a control group (the group that did not receive VR) did not exist to allow comparison with the follow-up results of the VR group. Therefore, we were unable to conduct a meta-analysis of follow-up outcomes for balance, gross motor functions, and daily life activities, as there was only one study providing follow-up results on these outcomes.

Conclusions

This review shows that adding VR into upper limb rehabilitation of children with CP offers additional benefits in motor skill learning and enhances the maintenance of obtained improvements when the VR included training that cooperates with motor skill learning principles, with the inclusion of functional tasks as well as repetitive practice, more intensity, individual adjustment, progressive challenge, and motivation. For these reasons, it appears more appropriate to make use of VR devices specifically developed for therapy. In terms of balance, trunk control, gross motor functions, and daily life activity outcomes, combining VR with therapies can help induce more improvements in children with CP. However, the priority focus of most of the interventions with VR (7/9, 78%) in the included studies, and their outcomes, was upper limb functions. The effect size on motor skill learning of adding balance-focused VR devices into different therapies in children with CP is still not entirely clear; therefore, studies with long-term outcomes are needed.

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Authors' Contributions

All the authors contributed to deciding the protocol and PICO (Population, Intervention, Comparison, and Outcome) framework of this study. SK and BS performed the search, study selection, data extraction, and methodological quality assessment. SK performed the meta-analysis and drafted the initial manuscript. BS, RA, and YB critically reviewed and edited the manuscript. All the authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 13 KB - games_v11i1e42067_app1.docx]

Multimedia Appendix 2
Scoring of all 27 items of the modified Downs and Black checklist for the included studies.
[XLSX File (Microsoft Excel File), 30 KB - games_v11i1e42067_app2.xlsx]

Multimedia Appendix 3
Subgroup analyses.
[DOCX File , 1003 KB - games_v11i1e42067_app3.docx]

Multimedia Appendix 4
PRISMA 2020 checklist.
[PDF File (Adobe PDF File), 55 KB - games_v11i1e42067_app4.pdf]

Multimedia Appendix 5
PRISMA 2020 abstract checklist.
[PDF File (Adobe PDF File), 26 KB - games_v11i1e42067_app5.pdf]

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Abbreviations

BCP: bilateral cerebral palsy
CP: cerebral palsy
GAS: Goal Attainment Scale
GMFCS: Gross Motor Function Classification System
GMFM: Gross Motor Function Measure
MACS: Manual Ability Classification System
mCIMT: modified constraint-induced movement therapy
PEDI-CAT: Pediatric Evaluation of Disability Inventory Computer Adaptive Test
PICO: Population, Intervention, Comparison, and Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
SMD: standardized mean difference
VR: virtual reality

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Review

Using Augmented Reality Toward Improving Social Skills: Scoping Review

Gloria Mittmann[1,2], Dr; Vanessa Zehetner[1], MSc; Stefanie Hoehl[3], Prof Dr; Beate Schrank[2,4], Dr med, PhD; Adam Barnard[1], MA; Kate Woodcock[5], PhD

[1]Die offene Tür Research Group for Mental Health of Children and Adolescents, Ludwig Boltzmann Society at Karl Landsteiner University of Health Sciences, Krems, Austria

[2]Research Centre Transitional Psychiatry, Karl Landsteiner University of Health Sciences, Krems, Austria

[3]Department of Developmental and Educational Psychology, University of Vienna, Vienna, Austria

[4]Department of Psychiatry and Psychotherapeutic Medicine, University Hospital Tulln, Tulln, Austria

[5]School of Psychology, University of Birmingham, Birmingham, United Kingdom

Corresponding Author:
Kate Woodcock, PhD
School of Psychology
University of Birmingham
52 Pritchatts Road
Birmingham, B15 2SA
United Kingdom
Phone: 44 121 414 6036
Email: papers@katewoodcock.com

Abstract

Background: Augmented reality (AR) has emerged as a promising technology in educational settings owing to its engaging nature. However, apart from applications aimed at the autism spectrum disorder population, the potential of AR in social-emotional learning has received less attention.

Objective: This scoping review aims to map the range of AR applications that improve social skills and map the characteristics of such applications.

Methods: In total, 2 independent researchers screened 2748 records derived from 3 databases in December 2021—PubMed, IEEE Xplore, and ACM Guide to Computing Literature. In addition, the reference lists of all the included records and existing reviews were screened. Records that had developed a prototype with the main outcome of improving social skills were included in the scoping review. Included records were narratively described for their content regarding AR and social skills, their target populations, and their outcomes. Evaluation studies were assessed for methodological quality.

Results: A total of 17 records met the inclusion criteria for this study. Overall, 10 records describe applications for children with autism, primarily teaching about reading emotions in facial expressions; 7 records describe applications for a general population, targeting both children and adults, with a diverse range of outcome goals. The methodological quality of evaluation studies was found to be weak.

Conclusions: Most applications are designed to be used alone, although AR is well suited to facilitating real-world interactions during a digital experience, including interactions with other people. Therefore, future AR applications could endorse social skills in a general population in more complex group settings.

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KEYWORDS

virtual reality; serious games; autism spectrum disorder; social learning; communication; cooperation; mobile phone

Introduction

Background

Digital technology has begun to move beyond the constraints of static, screen-based media toward more dynamic, immersive environments such as virtual reality (VR). One specific technology that is embedded in the concept of VR and is being increasingly used in various sectors is augmented reality (AR). AR creates visual situations where virtual components overlap with the real world, inviting the user's complicity in the illusion that these virtual components exist in the real world. As such, AR does not create a virtual environment per se but acts as a digital supplement to the real environment [1], clearly distinguishing it from VR. Its accessibility makes it easier to use than, for example, VR while still immersing the user in a partly virtual world. A wide range of technology supports AR. Although in the early stages, AR was a form of VR with a head-mounted display [2], current advanced hardware and software deliver AR through handheld devices, including tablets and mobile phones [3]. AR can be either marker based (activated through a specific physical image pattern, such as a QR code) or markerless. Markerless AR uses location-based AR (eg, via GPS), projection-based AR (tied to a specific physical space), or superimposition AR (replacing an object with an augmented view, eg, a real face with a cartoon face).

These advances have made AR a successful technology for commercial gaming (the most popular being the 2016 Pokémon Go by Niantic) and for informal learning sites, such as exhibits or museums to increase interaction with showcased topics [4]. In addition, the use of AR in formal educational settings such as classrooms has increased because of the cost-effective, interactive, and innovative features of AR (for literature reviews, refer to studies by Koutromanos et al [5] and Laine [6]). In their review of AR and education, Garzón et al [7] found that most AR technology is used in the field of natural sciences, highlighting the focus of current educational AR applications.

Social Skills

Social skills are crucial throughout life for social functioning [8] and for forming and maintaining relationships and reacting appropriately in social interactions through successful communication and socioemotional functions [9]. Furthermore, social skills relate to other important concepts: during childhood, they influence learning motivation and academic achievements and competences [10,11], whereas a lack of social skills can lead to mental health difficulties [12] such as depression [13]. Moreover, social competence in childhood is significantly related to adult well-being [14].

There is no commonly shared definition for social skills. Various terms are often used synonymously to refer to the concept of social skills, including *social competence*, *soft skills*, *emotional learning*, or *social behavior* [15], although some authors argue that these terms cannot be used interchangeably [16]. Most definitions of social skills include successful communication and adaptive interactions with others, and researchers agree that social skills are acquired through specific learned behaviors that are also socially reinforced [17]. For example, Bedell and Lennox [18] described social skills as "the ability to (a) accurately select relevant and useful information from an interpersonal context, (b) use that information to determine appropriate goal directed behavior, and (c) execute verbal and nonverbal behaviors that maximize the likelihood of goal attainment and the maintenance of good relations with others." Grover et al [19] synthesized existing definitions into 4 core social skill areas for a general population: communication skills, emotion regulation, cognitive skills, and social problem solving. In the literature search for this review, we concentrated on the 2 terms *social* and *communication* as the vital parts of social skills [9,17].

Social Skills and AR

Analog social and emotional skills training interventions have been successfully implemented, for example, in preschool children. The results of a meta-analysis showed small to medium effects of these interventions on social skills development and problem behavior reduction [20], demonstrating the potential of using interventions to improve social skills. Furthermore, serious games without an AR focus also cover so-called *21st-century skills* [21], such as media and technology skills or learning and innovation skills (eg, critical thinking and collaboration). Although social-emotional learning trainings are often developed for a nondigital classroom setting, AR could also be particularly interesting in the field of social-emotional learning. First, using a digital approach with AR allows a controlled setting while still only partly immersing the user in a digital environment, thus making the setting more realistic. Second, it harnesses people's increasing interest in digital tools while still being able to engage them in real-world complex social interactions. A look at the positive effects of existing commercial AR games on sociability offers promising results; for example, Ewell et al [22] found in a 7-day diary study on the commercial AR game *Pokémon Go* that the time spent with the game was connected to more social interactions, and Ruiz-Ariza et al [23] found that *Pokémon Go* significantly increased sociability levels and good social relationships.

In the field of psychology, AR is primarily used as a successful form of exposure therapy for phobias such as fear of small animals, for example, cockroaches and spiders [24], or as an additional tool to treat posttraumatic stress disorder [25]. Little focus has been put on improving social or emotional skills. In terms of social-emotional learning, most existing literature related to AR focuses on improving social skills in populations diagnosed with autism spectrum disorder (ASD). In a systematic review of AR applications for children and adolescents with autism by Khowaja et al [26], 20 of 30 included studies reported outcomes related to social skills and competences. Considering the existing deficits in social skills in people with autism [27], it makes sense to develop and implement interventions specifically for this population. Yet, social skills are generally essential for all populations. Consequently, the question arises if and what AR applications that improve social skills are being developed without a specific focus on an autistic population.

This Study

The challenges of identifying relevant literature due to the interdisciplinarity of the topic, the different denominations of social skills, and the existing focus on ASD in existing reviews highlight the need to map out the existing literature on AR and social skills. Thus, the aim of this scoping review was to systematically identify the range and characteristics of records that report the use of AR to improve social skills. Specifically, within this literature, our objective was to answer the following questions: what are the characteristics? What are the target groups? What types of AR are being used? What social skills are being targeted? What social settings are being targeted? What are the methodological characteristics of the studies evaluating the applications? We followed the guidelines for conducting systematic scoping reviews by Peters et al [28]. The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist can be found in Multimedia Appendix 1.

Methods

Data Sources and Search Strategy

Initial Limited Search

The first step was to identify the strings and terms that identify most of the relevant literature to answer the research question. We used a nonsystematic literature search to come up with our search strings for social skills, “social” and “communication.” We further started manually with a few articles that we found through existing reviews and an initial search that would fit our inclusion criteria; looked at their keywords, references, and the terms they used; and collected the most used and most relevant terms.

Included Databases

We used 2 main databases for our search: one was intervention focused, that is, PubMed, and the other leaned toward computer science, that is, IEEE Xplore. After double-checking and realizing that some of our initial articles could not be found in either of these databases, we decided to also include a third database: the ACM Guide to Computing Literature. We selected these databases to comprehensively cover all relevant disciplines.

Primary Search

Our final search terms included “augmented reality” plus “social” or “communication” (derived from definitions of social skills) or “collaboration” or “cooperation” (derived from keywords related to AR). The decision to not use the word “skill” in the search was intentional to capture a wider range of relevant terms, such as “social competence.” We limited our search to the period from 2010 to December 2021. Owing to advancements in technology, AR has only become available for use on everyday smartphones during the last decades, and nowadays, applications are hardly comparable with the first versions of AR in the 1990s and 2000s. Specific search strings for each database are listed in Table 1. The search strategy was supervised by an experienced researcher (KW).

Table 1. Search strings used in the different databases.

Database	Search string	Filters
PubMed	(“augmented reality”) AND ((soci*) OR (collaborat*) OR (communicat*) OR (cooperat*))	≥2010
IEEE Xplore	(“Abstract”: “augmented reality”) AND ((“Abstract”:soci*) OR (“Abstract”:collaborat*) OR (“Abstract”:communicat*) OR (“Abstract”:cooperat*))	≥2010
ACM Guide to Computing Literature	[Abstract: “augmented reality”] AND [[Abstract: soci*] OR [Abstract: collaborat*] OR [Abstract: communicat*] OR [Abstract: cooperat*]] AND [Publication Date: (01/01/2010 TO *)]	—[a]

[a]Not available.

Additional Search

In addition to the primary search, we screened existing recent reviews on AR [7,26,29-41] as well as reference lists of all included papers for additional references and searched for follow-up papers of records that were excluded because they did not reach the development phase of the application.

Citation Management

All references were imported and processed using EndNote20 (Clarivate) [42]. Duplicates were removed using the program’s function to find duplicates and by manually going through all references. In the first step of screening, 2 independent reviewers (GM and VZ) screened all references on a title, and in a second step, 3 independent reviewers (GM, VZ, and a group of 3 research group members) screened all references on an abstract level. In the third step, the reviewers screened the remaining references on a full-text level. Discrepancies between reviewers were resolved through discussions after each step.

Eligibility Criteria

The eligibility criteria were developed before the screening process and applied to all stages of the review. Some modifications were made to the eligibility criteria during the screening process, as described in the *Results* section. This review included all records that met the inclusion criteria, as described in Textbox 1.

Textbox 1. Eligibility criteria.

Inclusion criteria

- Studies related to the research questions, that is, described the use of augmented reality (AR) to improve social skills, defined as successful communication and adaptive interpersonal interactions
- The application has at least reached the end of prototype development
- Social skills were the goal of the application and the main outcome of the study (added after the first round of abstract screening)
- Records were in English, German, Portuguese, or Spanish

Exclusion criterion (added after the first round of abstract screening)

- The AR applications scaffold aspect of social functioning without actually improving a social skill in a transferable manner

Data Characterization

For all included articles, the following study characteristics were retrieved: general characteristics (authors, title, year, country of origin, sector, and paper length); application information (type, name, description of application, description of AR part, development software, duration, description of social skill, description of social setting, description of other outcomes if any, and co-design if any); study information (population, setting, design, methods, analysis, results, and effect sizes if any); and challenges and limitations. The data were summarized in an Excel (Microsoft Corporation) spreadsheet. Statistical analysis was performed using SPSS Statistics 27 (IBM Corp).

Results

Search and Selection of Articles

The primary search was conducted on December 2, 2021, and yielded 2748 potential records. The main reason for exclusion at the abstract level was that the AR system did not address social skills as an outcome. For example, although many articles had keywords in their abstracts, "collaboration" was only used as a means to teach other outcomes, "cooperation" tackled human-machine interactions, or "communication" related to a technical term (eg, network communication). The low reviewer agreement after the first round of abstract screening (500 vs 69 included records after abstract screening) resulted in refining the eligibility criteria and repeating the abstract screening process. Specifically, the initial inclusion criteria included all records that had social skills as one outcome instead of the main outcome. This change was made because many included references had little to do with social skills (>900). Furthermore, an exclusion criterion was added to exclude AR applications that only supported existing communication by adding AR elements (such as adding an AR avatar to a web-based communication tool or including information about the current conversation partner, such as their hobbies), as we argue that these applications only support communication in that specific situation instead of improving social skills in a transferable manner.

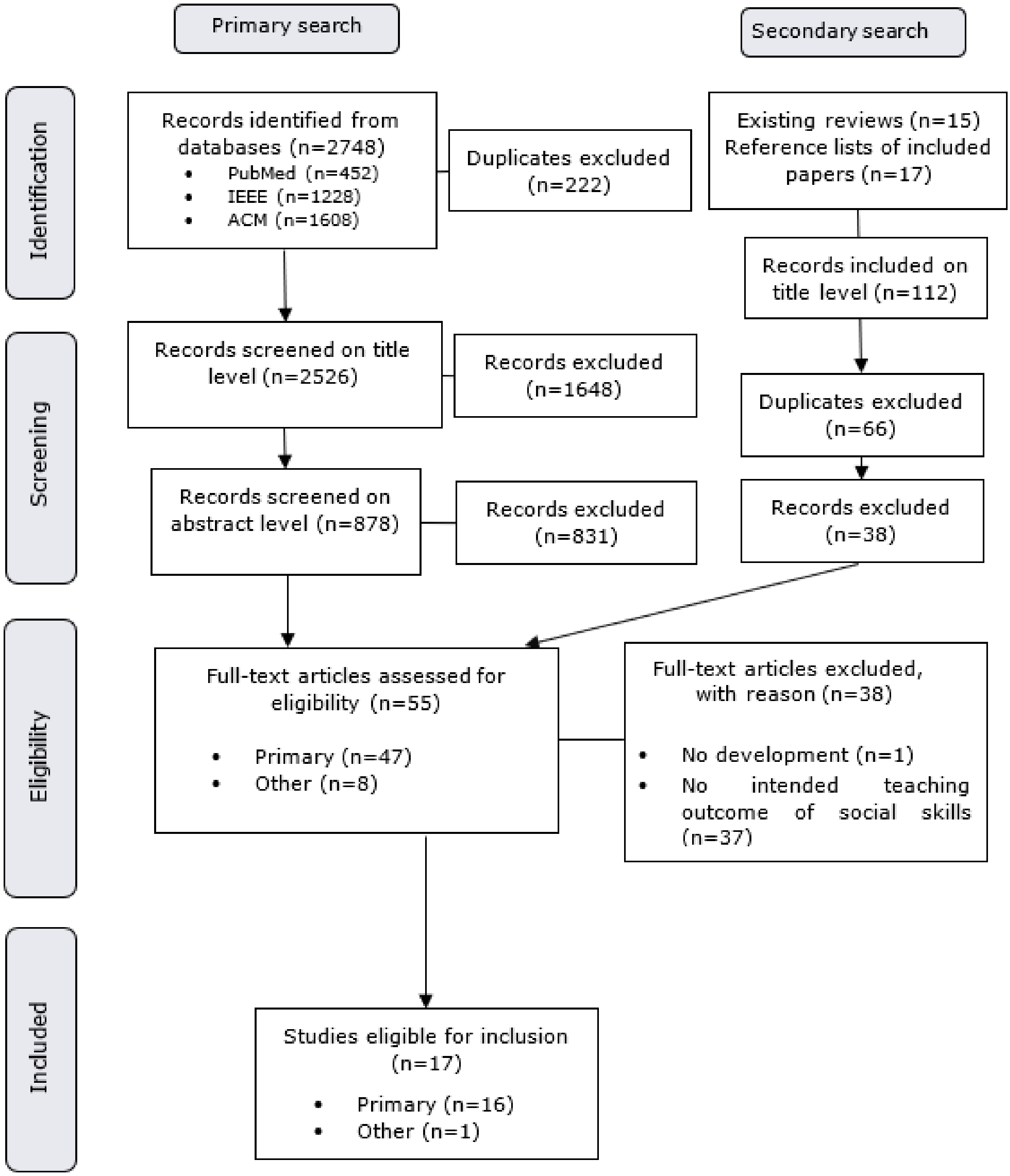
After refinement of the eligibility criteria, in addition to the 2 main reviewers GM and VZ, a group of 3 research members collectively screened all abstracts and full texts to ensure the sufficiency of the new criteria. This was done to include naive reviewers, as the new eligibility criteria were developed by the first 2 reviewers who may have been more likely to agree. Decisions during the screening process were categorized as "yes (include)," "maybe," or "no (exclude)." Cohen weighted κ was used to evaluate the reviewer agreement, and linear- and quadratic-weighted κ coefficients were reported to specify the shape of the disagreement distribution for the 3-ordinal scale ("yes," "maybe," and "no") [43]. Table 2 presents the agreement between the 3 reviewers at the abstract and full-text levels. The agreements ranged from moderate (Cohen weighted κ=0.594) to almost perfect (Cohen weighted κ=0.861) [44]. After full-text screening, a total of 17 records were included in this review (for the selection process, see Figure 1).

Table 2. Reviewer agreement on the abstract (second round) and full-text levels.

	Abstract level (linear-weighted κ/quadratic-weighted κ)	Full-text level (linear-weighted κ/quadratic-weighted κ)
Reviewer 1 (GM)–Reviewer 2 (VZ)	0.594/0.689	0.766/0.842
Reviewer 1 (GM)–Reviewer 3 (RG[a])	0.628/0.817	0.794/0.861
Reviewer 2 (VZ)–Reviewer 3 (RG)	0.775/0.640	0.792/0.820

[a]RG: research group members.

Figure 1. A flowchart of the record selection process.



General Characteristics of Included Records

The general characteristics of all included records are presented in Table 3. All included records were published between 2012 and 2021, although notably, only 2 included records were published before 2015, emphasizing the recent increase in the interest in AR. Most records have their origins in Asia and North America, and the majority have been published via conference proceedings (with journals primarily publishing with a focus on an autistic population), although they were relatively evenly spread between the social sciences, computer science, and interdisciplinary sectors.

Table 3. General characteristics of included records (N=17).

	Values, n (%)	Reference
Year of publication		
2010-2014	2 (12)	[45,46]
2015-2017	8 (47)	[47-54]
2018-2021	7 (41)	[55-61]
Origin of reference		
Asia	8 (47)	[45,48,52,53,55,57,60,61]
Europe (including the United Kingdom)	3 (18)	[47,49,51]
North America	5 (29)	[46,54,56,58,59]
South America	1 (6)	[50]
Type of publication		
Journal article	7 (41)	[48,50,52,54,59-61]
Conference proceedings	9 (53)	[45-47,49,51,53,55,56,58]
Other	1 (6)	Book chapter [57]
Sector		
Social science	4 (24)	[48,54,59,61]
Computer science	5 (29)	[50,51,53,55,56]
Interdisciplinary	8 (47)	[45-47,49,52,57,58,60]

Characteristics of AR Applications to Improve Social Skills in Autistic Populations

Of the 17 included records, 10 targeted autistic populations. As AR applications for this population have already been the subject of different reviews (although not specifically focused on social skills) and because of the unique social challenges faced by individuals with autism, we examined their characteristics separately to provide an overview of applications designed for autistic populations (Table 4). All records included in the autistic populations describe applications developed for children. Most of the applications (n=4) aimed to teach facial or emotional expressions as a social skill, often focusing on the basic emotions (happiness, sadness, fear, disgust, surprise, and anger). For instance, in *FaceMe* [55], children play minigames in which players must remember virtual expressions, identify expressions, choose the right expression, and imitate expressions. Similarly, in *Brain Power System (BPS)* [54], children learn to identify facial expressions in a gamified environment by selecting the right emotional expression for a virtualized human, and in *GameBook* [51], the emotional expressions are picked for a fictional character. In *augmented reality-based self-facial modeling* [48], the participants see their own virtual faces that can be overlaid with AR facial expressions in fictional scenarios, and in *augmented reality-based video modeling storybook* [52], social cues are taught by using a storybook that can be augmented with additional AR video clips.

Table 4. Characteristics of augmented reality application for an autistic population (n=10).

Study, year	Name	Type	Targeted social skill	Description of application	Target group (all individuals with autism)
Chen et al [48], 2015	ARSFM[a]	Mask or self-facial modeling	Facial or emotional expressions	Users choose facial masks that fit to emotions of a short story and see their faces overlaid with the emotion	Age 10-13 y
Chen et al [52], 2016	ARVMS[b]	Virtual book	Facial or emotional expressions	Users train to recognize significant social cues in a digital storybook and short video stories	Age 11-13 y
Cunha et al [51], 2016	GameBook	Virtual book	Facial or emotional expressions	The user learns to identify and choose emotions of a fictional character in different parts of the story	Children
Escobedo et al [46], 2012	MOSOCO[c]	Smartphones	Communication skills, gaze or eye contact	Phones detect cues in real-life social situations, give feedback for social missteps, and offer advice	Age 8-11 y
Lee [60], 2020	Kinect training system	Video	Social greeting behavior	Trainer "plays" virtual characters in different social interactions with the user to teach appropriate social greeting responses	Age 7-9 y
Lee et al [57], 2018	AR-RPG[d]	Tabletop	Social greeting behavior	Users role-play different social events and different greeting scenarios	Age 7-9 y
Lee et al [61], 2018	ARCM[e] training system	Tabletop and screen	Social greeting behavior	The user plays roles of different avatars in social situations and needs to choose correct greeting behaviors	Age 8-9 y
Li et al [55], 2021	FaceMe	Touchscreen	Facial or emotional expressions	Minigames, where the user has to remember, choose, and make facial expressions	—[f]
Liu, Salisbury [54], 2017	BPS[g]; FaceGame and Emotion Game	Smart glasses	Facial or emotional expressions, gaze or eye contact	Users learn to gaze at another person and identify emotions of another person's detected face	Age 8-9 y
Vahabzadeh et al [59], 2018	Empowered Brain or Face2Face module	Smart glasses	Communication skills, gaze or eye contact	Users get prosocial cues through smart glasses during interactions with a trainer, social performance can be seen in digital web portal	Age 6-8 y

[a]ARSFM: augmented reality-based self-facial modeling.

[b]ARVMS: augmented reality-based video modeling storybook.

[c]MOSOCO: mobile social compass.

[d]AR-RPG: augmented reality-tabletop role-playing game.

[e]ARCM: augmented reality concept mapping.

[f]Not available.

[g]BPS: Brain Power System.

Other applications aim to teach gaze direction, such as engaging in mutual eye contact during interactions and being attentive. In *Empowered Brain* [59], the user wears smart glasses while interacting with a facilitator who provides feedback on their head positioning relative to the facilitator and rewards attentive gaze. Similarly, in *BPS* [54], the user is rewarded with points to look at their virtual interaction partners and even receives higher rewards for looking at the socially salient central region of the face. In total, 3 records describe applications for teaching social greeting behavior [57,60,61], in which children learn to identify and use 6 different greeting behaviors (such as nodding their head, shaking hands, or hugging) in role-play scenarios or with virtual characters. Finally, *mobile social compass (MOSOCO)* [46] is the most versatile of the found applications: in this mobile app, 6 basic social skills are trained in a real-world environment by pairing children with autism with interaction partners (without a diagnosis of ASD). The system then detects, for example, eye contact to provide feedback and hints on how to behave in this situation. Other targeted skills include spatial boundaries, conversation initiators, shared interests, appropriate disengagement, and identifying potential communication partners.

Characteristics of AR Applications to Improve Social Skills in General Populations

We found 7 records describing AR applications in the general population (Table 5). Applications for the general populations are more diverse in terms of outcome goals and target a wider age range than applications for autistic populations. In total, 3 applications were designed for primary school children, whereas 4 targeted an adult population.

Table 5. Characteristics of augmented reality application for a general population (n=7).

Study, year	Name	Type	Targeted social skill	Description of application	Target group
Bai et al [47], 2015	FingAR Puppet System	Tabletop	Theory of mind, emotion expression, and understanding	Users use puppets (markers) and a magic wand to see or change the puppets' emotional expressions on a screen in social pretense play scenarios	Age 4-6 y
Kyungwon et al [45], 2014	AR Petite Theater	Virtual book or smart glasses	Empathy and perspective taking	Users read a story and author the story via changing emotional expressions and dialog, which can also be watched in an animated version	Age 7 y
Lin et al [58], 2020	Empathics System	Smart glasses	Emotion recognition	Smart glasses detect and feed back emotions of conversation partner in real time and visualize emotions for postsessions	Adults
Lorusso et al [49], 2016	Giok	Mobile game	Positive social interactions	Users steer the behaviors and social strategies of Giok the alien to achieve positive outcomes in various social situations	Age 4-5 y
Silva et al [50], 2017	Schizophrenia Simulator	Smart glasses	Stigma reduction and perspective taking	Users experience typical psychotic symptoms of schizophrenia	Students
Swearingen et al [56], 2021	The Woods	Mobile game	Positive social interactions	Collaborative game teaching about social isolation and the importance of social connectedness	Age 8-78 y
Metsiritrakul et al [53], 2016	UP2U	Screen	Gaze and phubbing awareness	Generated avatars show gaze direction of present persons and system teaches about phubbing behavior if people look down instead of to each other	Age 18-58 y

Applications for children target preschool and first-year graders (age 4-7 y). In *AR Petite Theater* [45], children read a story and can then choose suitable emotions for the characters and role-play these emotions, which makes them train their empathic behavior. Similarly, in *FingAR Puppet System* [47], children use a wand to change puppets' expression while they see themselves and the puppets in a magic mirror. Finally, in *Giok* [49], children followed a fictional character and decided their behavior through multiple-choice questions to lead it through social situations.

UP2U [53] describes an application that teaches people about phubbing behavior (ie, focusing on a mobile phone instead of people in a social situation) in public places. The system recognizes the present people and creates an avatar on a screen. Through head tracking, people receive feedback when their heads are not turned toward each other (screen goes red), and a video is played that educates them about phubbing behavior. Lin et al [58] described *Empathics System*, smart glasses that can be used during physician-patient communication (by both physicians and patients). The glasses collect real-time facial emotion information regarding the conversation partner and provide feedback to the user. Although this application mainly supports the current communication situation (ie, supporting performance rather than training), we included this paper because of the described postsessions in which the emotions are visualized so that the user can analyze them after the conversation. Participants also mentioned that the tool has the potential to serve as an educational tool for emerging physicians to learn about emotional cues and their effects. In their *Schizophrenia Simulator*, Silva et al [50] used smart glasses and an immersive AR environment to give users without schizophrenic symptoms an impression of what schizophrenia feels and looks like, with the intention of reducing the stigma around schizophrenia. Finally, *The Woods* [56] is a mobile smartphone game played by 2 players. Unlike other applications, it has a more holistic approach to teaching the importance of positive human connections. Players need to choreograph their movements to interact with virtual objects while engaging in a story about social isolation and reconciliation.

AR Applications to Improve Social Skills in Both Autistic and General Populations

Of the included records 2 describe applications involving both the autistic and general populations. First, *Empathic Systems* could be used by both patients diagnosed with ASD and physicians. The authors described that participants with autism had many concerns with smart glasses and concluded that their system needs to undergo some adaptations for an autistic population but shows potential in supporting real-life interactions by exemplifying emotions. Second, in *MOSOCO*, children with autism are paired with potential interaction partners without an ASD diagnosis. Although the general population was not the main target group of the study, the authors found that the application supported children without a diagnosis of ASD by destigmatizing missteps of children with autism and reacting in adaptive ways, which led to less teasing.

Types of AR Used in the Included Applications

The main development software used for the development of the applications was Unity or Vuforia. The included applications used a variety of AR types. Although *FaceMe* and *Giok* use marker-based AR to control virtual expressions and activate gameplay, respectively, and *The Woods* uses projection-based AR to guide players in the room, most of the included applications rely on superimposition AR. They overlay physical objects, other people interacting with the user, or the users themselves with an augmented view.

In the case of physical objects, AR overlays real-world physical scenes, such as books (*AR Petite Theater* and *augmented reality-based video modeling storybook*) or board games (*AR-RPG* and *ARCM*), with virtual scenes that either highlight specific parts or are used to manipulate the real scene. In *augmented reality-based self-facial modeling* and *FingARPuppet System*, users see themselves in a virtual scene to change their facial expressions and see themselves in an AR environment. *UP2U* uses computer vision to create avatars of a group of people that are then displayed on a screen. Finally, some applications use AR in their environment and interaction partners. In *Kinect training system*, the environment is augmented with the required visual background, and in *Schizophrenia Simulator*, psychotic symptoms are reproduced with AR. In *BPS*, human faces are overlaid with an AR cartoon face to engage the user, and *Empowered Brain* uses AR to keep the user attentive to the conversation partner. In *MOSOCO*, AR detects partners and provides support during real-life social situations, and in *Empathics System*, smart glasses detect the partner's emotions.

Social Setting of Included AR Applications

Considering the topic of social skills, we also examined the social settings of the applications. Of the 17 included applications, 10 were used as a single-player experience. In addition, 6 applications are performed in dyads, including both interactions with a human facilitator, therapist, or teacher who knows the system and experiences for pairs of naive users (eg, 2 children use the application together [*FingAR Puppet System*] or cooperative gameplay [*The Woods*]). Finally, 1 application (*UP2U*) uses a group setting by analyzing and teaching people to be more attentive to each other.

Methodological Characteristics of Evaluations of the AR Applications

A summary of the methodological characteristics of the evaluated studies is presented in Table 6. All the included applications have finished prototype development, and only 1 record [51] did not report any kind of evaluation. Most records report some form of co-design for their applications. Applications for autistic populations often include interviews with parents or teachers of the included children. In general, the quality of the evaluation studies was rather low. The paper length varied considerably (between 3 pages and 20 pages, mean 9.5, SD 5.5). Often, authors described the study as "prestudy," "pilot tests," or "preliminary tests." Only 2 studies had a sample size larger than 20 (with 21 and 25 participants). The level of detail reported for how the applications were evaluated varied considerably, including references that stated that it has been tested with users [56] to fully describe the methodology.

Table 6. Methodological characteristics of included augmented reality applications (N=17).

Development and study characteristics	Values, n (%)	Reference
Development and study characteristics		
Co-design	6 (35)	[50,52,55,57,58,60]
Only development	2 (12)	[51,56]
Usability	12 (71)	[45-47,49,50,53-56,58-60]
Intended learning outcome	13 (76)	[45-48,50,53-55,57-61]
Study design		
Observation, qualitative, or postquestionnaire	7 (41)	[47,49,53-56,58]
Pre-post	7 (41)	[46,48,50,57,59-61]
Pre-post with control group	1 (6)	[45]
Study sample size		
<5	7 (41)	[46,48,54,57,59-61]
5-10	3 (18)	[52,55,58]
11-30	5 (29)	[45,47,49,50,53]
Not specified	1 (6)	[56]
Study population age (years)		
0-6 (early childhood)	3 (18)	[47,49,55]
7-10 (primary school)	7 (41)	[45,46,54,57,59-61]
11-14 (early adolescence)	2 (12)	[48,52]
15-18 (late adolescence)	—[a]	—
>18 (adult)	2[b] (12)	[53,58]
Other	1 (6)	[56][c]
Not specified	1 (6)	[50]

[a]Not available.

[b]Students and physicians.

[c]Age 8-78 years.

Both usability and intended outcomes were generally positive in all the studies that tested the applications. A total of 12 records reported usability outcomes. We describe usability as a term that includes usability, feasibility, and acceptability. Moreover, 2 records report that there were no adverse effects and no conflicts; 4 records report that the users were able to understand and complete the intervention (especially in autistic populations), and 8 of the records report that participants found the application interesting and engaging or that users rated the application highly ("excellent" or "brilliant"). Only 1 record (*UP2U*) described the feasibility of the technical side of the application.

A total of 13 records described some form of testing for the intended outcomes. All of them reported positive results concerning their expected outcomes, for example, an increase in social behavior, a decrease in (ASD) symptoms (related to social skills), or verbal affirmation by participants that the application promotes and helps with the intended outcome.

Additional Findings

Although one of our eligibility criteria was that the application had to have an intended and transferable effect on social skills, during our review process, we found a variety of records that show how AR can be used as support in situations that require social skills or skills related to social skills. As our aim with this scoping review was to give an overview of existing literature, in this section, we want to give some examples of applications supporting users in social situations.

For instance, AR has been found to improve narrative skills during storytelling compared with non-AR story creation, possibly because of the engaging nature of AR [62]. In addition, AR can be used to track the emotions of an audience during a public speaking scenario to reduce fear of speaking by providing direct feedback to the speaker [63]. Furthermore, there is a thin line between improving social skills and just playing a collaborative game. One could argue that just by collaborating, social skills are endorsed and relationships are supported. Some games, for example, *BloxAR* [64], a social game in which teams compete to build AR block structures, use this concept. As we had to balance resources and breadth of inclusion, for this review, we focused on applications that focused on improving social skills in a transferable manner. Further reviews should adopt broader eligibility criteria.

Discussion

Overview

In this systematic scoping review, we mapped existing literature on AR applications that improve social skills. We found 17 records that fit our inclusion criteria, that is, reporting AR applications intended to improve social skills as the main goal. As expected due to existing reviews, most AR applications that teach social skills were developed for an autistic population (10/17, 59%). These applications aim to improve emotional expression recognition, social greeting behavior, or gaze direction in children. Applications for the general populations are more diverse and include emotional expression recognition, perspective taking, and empathy, as well as more specific topics such as destigmatization or antiphubbing behavior for both children and adults.

Principal Findings and Comparison With Prior Work

Most of the records we reviewed focused on developing applications for children with autism, which is reasonable, given that social skills deficits are 1 of the 2 defining characteristics of autism [65]. Our findings are consistent with those of previous reviews, indicating that numerous approaches are being developed for this population. However, we did not find any applications that target adults, suggesting a potential area for future research. When comparing AR applications for autistic populations and general populations, this review showed that facial expressions or emotion recognition and gaze behavior can be found as an outcome goal for both autistic and general populations. Although the application targeting phubbing behavior phrases the outcomes differently, it teaches gaze behavior similar to applications for populations with autism. Applications targeting children are similar for autistic and general populations in terms of intended learning goals and ways to teach these goals. For example, emotional expressions are the main topic addressed in applications for all populations, and allowing children to choose between different emotions is a popular way to teach these expressions.

The Use of AR in Social Skills Interventions

AR is considered a promising tool for teaching because of its potential for interaction between the virtual and real worlds and its ability to facilitate visualization [66]. The results from our scoping review show that AR for social skills applications is used in 2 different ways: first, as an indispensable part of the application that is crucial for its effects, such as smart glasses that scan the environment and other's faces, and second, as an additional tool to emphasize important information, animate the scenarios, and generally make the experience more exciting for the user. In these cases, the application does not necessarily rely on AR. Both approaches are valuable, and the positive results concerning usability and intended learning outcomes indicate that AR has a potentially positive effect on learning. However, because most of our included records did not evaluate their applications with a control group, it is not certain whether AR is essential for the intended outcomes. One of our included records [45] compared the AR condition with a non-AR condition for their application and found a significant difference in perspective taking, with children in the AR condition showing higher scores in perspective taking, as well as more engagement. Their sample consisted of 12 children, which shows the need for replications with larger samples.

Strengths and Limitations of the Included Records

Strengths lie in the inclusion of the target group in the design and development process, the iterative process that many records describe, and the creative detail and hard work that often goes into the development of a serious game or intervention. Limitations are mostly found in the methodology of evaluation of the applications, especially in the small sample size of studies targeting an autistic population, where fewer than 5 children were tested. Evaluations rarely follow rigorous methodology (such as randomized controlled trials). Although iterative development for technical applications is necessary and reporting of preliminary results and evaluations is desirable, our results suggest that systematic and methodologically rigorous evaluations of AR applications for promoting social skills are still lacking.

Strengths and Limitations of This Scoping Review

This review was conducted in a structured and transparent manner, and the authors tried to eliminate mistakes by repeating screening at the abstract level. The main limitation of this scoping review is that due to the broad field of social skills, our search criteria might have missed some AR applications related to social skills. For example, emotion regulation and empathy are vital skills for adaptive interpersonal relations and should thus be included in the field of social skills. However, owing to the large number of additional records, we did not include these strings as separate search strings. Although being a limitation, some facts show that our search strategy yielded results that appropriately reflect the social skills training field. First, our final data set contains studies related to empathy, which shows that our search had the potential to also find records with this specific skill. In addition, all but one of the records identified through our additional search of existing reviews, reference lists, and follow-up studies were duplicates or had to be excluded, indicating that our search terms were adequate. Further reviews could broaden the search and include specific terms such as "emotional learning" or "empathy." Second, the interdisciplinarity of the topic and consequent limitations in the databases and search terms used might have resulted in the overlooking of certain records. Finally, the heterogeneity of the included records posed challenges in the synthesizing of the findings. However, different aspects revealed the focus of the current literature, for example, the emphasis on children with autism, which can be valuable for guiding future research.

Future Directions

Our findings suggest that AR applications have the potential to enhance social skills, as indicated by the evaluations of player experience and usability. Although the intended outcomes were only preliminarily tested in most of the included studies, AR applications can be highly engaging tools for social-emotional learning in psychological, digital, and educational settings.

The search strings "cooperation" and "collaboration" were included because of their common appearance as keywords in

AR contexts. The results showed that these 2 strings were not very relevant for our final included records. Social skills are mostly taught in a single-user setting or with a human facilitator. Considering the advantage of AR in easily enabling cooperative or collaborative situations, future research could explore ways to improve social skills in pairs or even groups. The times have passed when the digital world was not social. Nowadays, most digital tools, such as apps and online gaming, include or are exclusively for connecting with other people. However, many of these web-based interactions happen while both or all people are at different locations. AR not only has the advantage of interacting with digital components in the real world but also has the potential for the user to interact with other people while using a digital tool in real life. AR offers the exciting possibility of playing a digital game or interacting with a digital tool while being in the same room with other people who the player interacts with, as such, aiming to improve skills in complex and real-time social situations. As an example, one of our included records, *MOSOCO*, uses AR to teach social interaction skills to children with autism during real-time conversations with other children. Their results show that the app helps both children with autism and neurotypical children during their social interactions with each other. Although the sample size in their study was small, this shows the great potential of such applications to reduce stigma and lead to better social connections in real-world and real-time complex social settings in autistic, general, and mixed populations.

Conclusions

This scoping review describes the range and characteristics of applications using AR to improve social skills. Applications have been developed for autistic and general populations. Most often, they target emotion recognition, although this varies. The evaluations show promising results in terms of both the usability and intended outcomes of these applications. In future work, more focus should be placed on high-quality evaluations to further substantiate these results, and more complex social interactions in real-world settings should be explored.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

GM contributed to conceptualization, investigation, formal analysis, writing the original draft, and review and editing. VZ contributed to investigation and formal analysis. SH contributed to supervision and writing—review and editing. BS and AB contributed to funding acquisition, supervision, and writing—review and editing. KW contributed to conceptualization, investigation, funding acquisition, supervision, and writing—review and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.

[PDF File (Adobe PDF File), 251 KB - games_v11i1e42117_app1.pdf]

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Abbreviations

AR: augmented reality
ASD: autism spectrum disorder
BPS: Brain Power System
MOSOCO: mobile social compass
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
VR: virtual reality

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Review

Effects of Serious Games for Patients With Chronic Obstructive Pulmonary Disease: Systematic Literature Review

Houqiang Huang[1*], MD; Min Huang[2*], MD; Qi Chen[3], PhD; Mark Hayter[4], PhD; Roger Watson[5], PhD

[1]Nursing Department, The Affiliated Hospital of Southwest Medical University, Luzhou, China
[2]Department of Respiratory and Critical Care Medicine, The Affiliated Hospital of Southwest Medical University, Luzhou, China
[3]Department of Endocrinology and Metabolism, The Affiliated Hospital of Southwest Medical University, Luzhou, China
[4]School of Nursing & Public Health, Manchester Metropolitan University, Manchester, United Kingdom
[5]Nursing Faculty, Southwest Medical University, Luzhou, China
[*]these authors contributed equally

Corresponding Author:
Houqiang Huang, MD
Nursing Department
The Affiliated Hospital of Southwest Medical University
Taiping No.25, Jiangyang District
Luzhou, 646000
China
Phone: 86 18715799162
Email: 878620130@qq.com

Abstract

Background: The use of serious games for rehabilitation has been an emerging intervention in health care fields, referred to as an entertaining and positive activity. Although related studies have been conducted on patients with chronic obstructive pulmonary disease (COPD), a more comprehensive study that summarizes and evaluates its effects in this area is needed.

Objective: This review aimed to systematically evaluate the effects of serious games in promoting rehabilitation and related outcome measures of serious game–based engagement in patients with COPD.

Methods: This review adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement. Searches were performed in the following databases: PubMed, Scopus, Embase (via Ovid), CINAHL, Science Direct, and China Biology Medicine disc. Only quantitative studies were included in this review, and the methodological quality and bias of the included studies were evaluated using related tools. Several outcomes, including clinical outcomes and serious game–based engagement outcomes, were ultimately collected in this review. The results were summarized and evaluated using descriptive methods due to significant heterogeneity.

Results: In total, 11 studies were included. Serious games played a potentially positive effect on pulmonary function and exercise capacity. However, no consistent findings were reported on dyspnea and psychological status. Additionally, serious game engagement showed favorable findings on adherence, enjoyment, and acceptability. Furthermore, no serious adverse effects were identified in all included studies.

Conclusions: This review preliminarily indicated the potential benefits of serious games in promoting rehabilitation for patients with COPD, despite the limited quality of the included studies. More studies with high methodological quality are needed to further explore the effects of serious games in this field.

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KEYWORDS

chronic obstructive pulmonary disease; COPD; serious game; rehabilitation; review; mobile phone

Introduction

Background

Chronic obstructive pulmonary disease (COPD) is a serious health condition that affects millions of people worldwide. It is characterized by progressive and irreversible obstruction of the airways, which leads to difficulties in breathing, reduced lung function, and increased risk of exacerbations [1]. COPD is currently the most common chronic respiratory disease worldwide [2] accounting for approximately 7% of deaths worldwide [3]. Pulmonary rehabilitation (PR) is an important tailored intervention involving several components that include but are not limited to exercise training, education, and breathing exercise in COPD management, as it can help patients improve their physical function, quality of life, and overall health outcomes [4]. Currently, PR has been widely recommended as an effective treatment but relies on continuous adherence for patients with COPD. However, despite the anticipated benefits of PR, the attendance, adherence, and completion rates of PR in patients with COPD are as low as 70%, 50%, and 40%, respectively [5-7], particularly for those who live in remote or underserved areas [8]. There are several potential barriers stopping patients from performing PR, such as low motivation, a lack of social support, transportation difficulties, and interest [7,9,10]. Hence, it appears essential and crucial to overcome these barriers and provide support for patients with COPD to engage in PR. Serious games, also known as therapeutic games, have emerged as a promising alternative therapy. Serious games encompass a broad concept that entails using distinct game elements to educate or induce changes in experiences or behaviors consisting of diverse forms such as video games and exergames [11]. These games, which may either be designed specifically for health purposes or be designed commercially for leisure exercise, use digital and engaging gameplay to deliver therapeutic interventions and promote healthy behaviors. Serious games have been used to address a wide range of health conditions, including mental health, chronic pain, and stroke rehabilitation [12,13]. In recent years, with the further widespread use of serious games, there has been a growing interest in the use of serious games for assisting patients with COPD in performing PR interventions. One of the potential reasons for the increasing popularity is that serious games may attract patients' attention away from briefly boring repetition of rehabilitation intervention and enhance their enjoyment [14,15]. Additionally, extra advantages of serious games over traditional PR have also been identified, such as objective data on performance and progress, low cost, enhanced motivation, and adherence [16]. However, the relationship between serious games and effectiveness in patients with COPD still remains poorly understood.

To date, there is only one systematic review that specifically examines the effects of active video games in patients with COPD [17]. However, this review, proving a potentially positive role of video games in terms of adherence, enjoyment, and various clinical outcomes, has limitations. First, it overlooks several relevant studies [18-22] that were published after the review was conducted. Second, the review only focuses on video games and lacks the inclusion of diverse types of serious games. As mentioned before, video games are a narrower category within the broader scope of serious games [23]. Third, the review lacks attention to certain outcome measures, such as pulmonary function and acceptability.

Additionally, 2 other reviews with a broader scope in respiratory conditions (asthma, COPD, emphysema, bronchiectasis, etc) separately reported consistent results in adherence and enjoyment [24] as well as exercise capacity and quality of life [25]. However, another review focused on respiratory diseases claimed no improvement in dyspnea or exercise capability [26].

Based on current evidence, the effects of serious games on patients with COPD remain unclear due to several limitations, including a limited number of enrolled original studies, a restricted scope of serious games, and inadequate and inconsistent reporting of results. A more comprehensive review is needed to further systematically evaluate the available evidence on the effects of health-related serious games for patients with COPD. Therefore, this review aims to include more eligible studies, a wider range of serious game types, and diverse outcomes to offer a comprehensive and unbiased overview of the current state of the evidence and identify areas for future research by using systematic methods.

Objectives

The overall aim of this review was to evaluate the effects of serious games for two categories of outcomes: (1) clinical outcomes, including pulmonary function, exercise capacity, daily steps, dyspnea, patient-reported outcome measures, and psychological condition, as well as adverse effects, and (2) related outcome measures of serious game–based engagement, including adherence, enjoyment, and acceptability.

Methods

Data Sources and Search Strategies

PICO, which stands for Participant, Intervention, Control, Outcome, was the most commonly used framework to guide review questions and facilitate searches [27]. In this review, the modified framework of "PICOs," which stands for patient problem, intervention, comparison, study of design, was used to explicitly state and derive the search terms that included subject headings and keywords in each part. However, it should be noted that due to differences in the expression forms of subject headings in diverse databases, the subject headings were adapted to fit each database accordingly. Additionally, the search strategy only used "P," "I," and "S" to broaden the search scope. The search strategies were separately searched in 6 electronic databases, which were PubMed, Scopus, Embase (via Ovid), CINAHL, Science Direct database, and China Biology Medicine disc, from inception to December 20, 2022. The search was initially undertaken in PubMed and then tailored and applied to the other 6 databases. Furthermore, the reference lists of eligible studies were also screened to identify studies. Multimedia Appendix 1 summarizes the search strategies that were used in all included databases.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) quantitative studies, including randomized controlled trials (RCTs) and pre-post studies; (2) studies, in which participants had been clinically diagnosed with COPD without limitations of age, gender, and ethnicity; (3) intervention involving serious games for therapeutic purposes using any electronic platform (tablets, computers, consoles, smartphones, televisions, or any other digital devices); (4) no control groups or the control group used usual care or nonserious games; (5) results included health-related outcomes such as exercise capacity, pulmonary function, dyspnea, or adverse effects, as well as serious game–based engagement outcomes such as adherence, enjoyment, or acceptability; and (6) studies must be peer-reviewed and be in English or Chinese.

The exclusion criteria were (1) duplicate records; (2) studies focused on measurement, diagnostic methods, serious game theory, or game development; (3) nondigital games and serious games used for other purposes, such as screening, or nonhealth educational purposes; or (4) conference abstracts or studies for which full texts could not be derived.

Study Selection and Data Extraction

Two authors (HH and QC) independently screened the titles and abstracts of relevant studies using EndNote software (version X9; Clarivate Analytics). The full texts of eligible studies were then independently identified by the same authors according to predefined selection criteria. Any conflicts that arose between the 2 authors were resolved through discussion. If a consensus could not be reached, a third author (M Huang) was consulted to make a final decision. A data collection form was created to extract various characteristics of the studies, including the authors, study design, setting, participant demographics, intervention, comparators, frequency of the course, outcome measures, and instruments used. Additionally, a serious game intervention protocol form was developed to summarize the details of the interventions, including the serious game modalities, source of the serious games, procedure of the serious game modality, duration, length, and frequency of the intervention. The data extraction procedure was as follows: 2 authors (HH and QC) independently extracted data using predefined forms. Any discrepancies were addressed through discussion, and a third author (M Huang) was consulted to reach a final decision. Two electronic documents of the extracted data were created and managed by HH and QC.

Quality Assessment of Included Studies

The Cochrane Library's RCT assessment tool [28] was used to evaluate the methodological quality and risk of bias in RCTs. This tool consists of 7 domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome reporting, incomplete outcome data, selective outcome reporting, and other biases. The JBI quasi-RCT assessment tool [29] was used to assess pre-post studies. The assessment of methodological quality and risk of bias was carried out by 2 authors (HH and M Huang), and a third author (QC) was consulted to make a final decision if any discrepancy occurred.

Data Synthesis

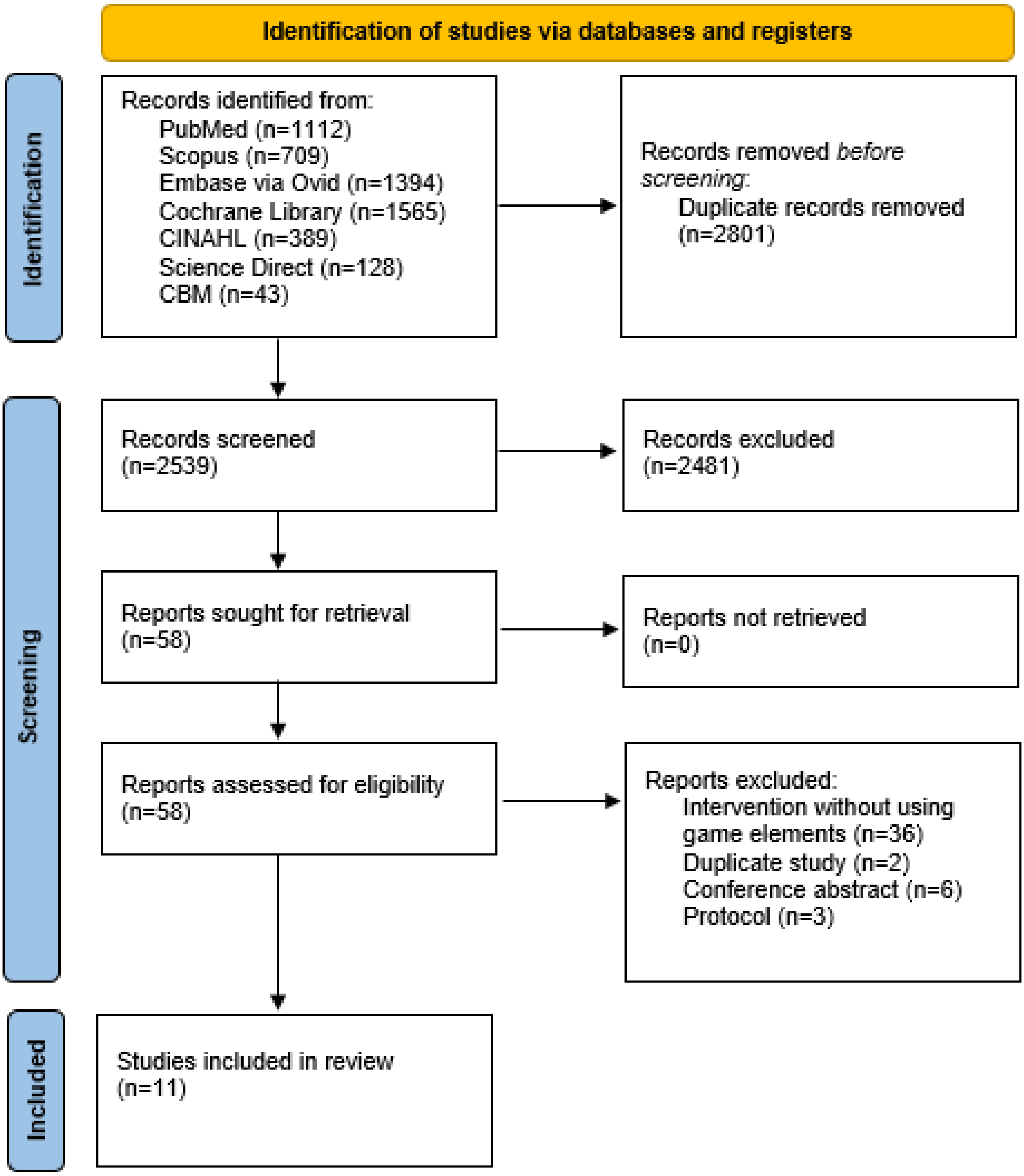
A meta-analysis was initially expected to calculate pooled effects. However, the significant clinical heterogeneity identified in the types of studies, comparisons, intervention protocols, and varied outcomes deemed it an inappropriate method for undertaking quantitative synthesis. Therefore, descriptive analysis was used to summarize the effects of serious games on rehabilitation in patients with COPD. The process of conducting descriptive analysis to present the research results involved tabulating various characteristics, such as participants, intervention details, comparison groups, outcomes, sample size, and study designs, from the original studies. This information was independently extracted in a predefined Excel (Microsoft Corp) form by HH and M Huang. Subsequently, the collected data were thoroughly reviewed and verified by the 2 authors to ensure accuracy and reliability. In case of any disagreements, consensus was reached through discussion. Finally, the data were compared against the planned studies for each specific outcome, facilitating a comprehensive evaluation of the findings. Specifically, the theme of identifying the relationships between serious game interventions and patient outcomes (eg, pulmonary function, exercise capacity, daily steps, dyspnea, psychological status, adverse effects, and measures of game-based engagement) was summarized.

Results

Search Results

The database search yielded 5340 publications in total. A total of 2801 duplicate items were excluded using EndNote (version X9), and another 2481 items were further removed after reading through titles and abstracts. The full texts of the remaining studies were retrieved for a more detailed assessment, of which 47 were removed for the following reasons: (1) intervention without using game elements (n=36), (2) duplicate study (n=2), (3) conference abstract (n=6), and (4) study protocol (n=3). As a result, a total of 11 studies were finally included in this review. Figure 1 illustrates a flowchart of the study screening process.

Figure 1. Flowchart of studies screening. CBM: China Biology Medicine.



General Characteristics of Included Studies

The key characteristics of the enrolled studies are shown in Multimedia Appendix 2. This review eventually consisted of 11 studies published between 2011 and 2021 with 8 RCT studies [18-22,30-32] and 3 pre-post studies [33-35]. Of the 11 studies, 3 were published in Chinese [21,22,32], and the remaining were reported in English [18-20,30,31,33-35]. The countries undertaking the interventions varied greatly, including mainland China in 3 studies [21,22,32], Canada in 2 studies [30,35], the United States in 2 studies [33,34], Australia in 1 study [18], Italy in 1 study [31], Poland in 1 study [19], and Indonesia in 1 study [20]. The studies' sample sizes ranged from 10 to 130 with most studies having fewer than 50 participants, and only 2 studies having sample sizes greater than 100 [19,21]. The mean age of participants was beyond 60 years in all included studies. Regarding the intervention protocols, 10 experimental studies [19-22,30-35] separately used commercial software containing game elements as intervention tools, and the most commonly used software was the Wii Fit system (Nintendo). Only 1 study [18] developed serious game software. The duration of the interventions ranged from 2 to 18 weeks in all experimental studies reporting intervention duration [18-21,31-34]. Meanwhile, the frequencies of using the interventions varied significantly across the studies.

Methodological Quality and Risk of Bias of the Included Studies

The results of the methodological quality of all studies except the descriptive one are presented in Tables 1 and 2. For RCT studies, randomization allocation was mentioned in all 8 studies, and 6 studies [19-22,30,32] reported the details on random sequence generation using random number tables or computer-generated number sequences or web-based number sequences. Allocation concealment was mentioned in only 1 study via sealed opaque envelopes [19]. Four studies [18-20,31] described blinding of participants and personnel as not applicable, and the remaining studies did not describe that blinding. Only 1 study stated blinding of outcome assessment [19]. All 8 studies stated participants' dropout rates, and all participants who completed the intervention were incorporated into the data analysis. In addition, all RCT studies were considered low risk of selective outcome reporting. For "other bias," 3 studies reported a sample size calculation. All studies conducted baseline assessment reporting without significant differences. Inclusion criteria, exclusion criteria, end points, and method of data analysis were clearly reported in all 8 studies. Only 2 studies described adverse events during the period of intervention [21,31]. For pre-post studies [33-35], 3 studies met all criteria except for a comparison group.

Table 1. Methodological assessment of the randomized controlled trial studies.

Criteria	Simmich et al [18]	Sutanto et al [20]	Hu et al [32]	LeGear et al [30]	Rutkowski et al [19]	Mazzoleni et al [31]	Zhou et al [21]	Jin et al [22]
Random sequence generation	?[a]	✓[b]	✓	✓	✓	?	✓	✓
Allocation concealment	?	?	?	?	✓	?	?	?
Blinding of participants and personnel	×[c]	×	?	?	×	×	?	?
Blinding of outcome assessment	×	×	?	?	✓	×	?	?
Incomplete outcome data	✓	✓	✓	✓	✓	✓	✓	✓
Selective outcome reporting	✓	✓	✓	✓	✓	✓	✓	✓
Other bias	×	✓	×	×	?	✓	×	×
Sample size calculation	×	✓	×	×	✓	✓	×	×
Baseline assessment	✓	✓	✓	✓	✓	✓	✓	✓
Inclusion criteria	✓	✓	✓	✓	✓	✓	✓	✓
Exclusion criteria	✓	✓	✓	✓	✓	✓	✓	✓
Evaluation of therapeutic effect	✓	✓	✓	✓	✓	✓	✓	✓
Report of adverse events	?	✓	?	?	?	✓	?	?
Method of data analysis	✓	✓	✓	✓	✓	✓	✓	✓

[a]Unclear.

[b]Low risk.

[c]High risk.

Table 2. Methodological assessment of the pre-post studies.

Criteria	Albores et al [33]	Wardini et al [34]	Parent et al [35]
Is it clear in the study what is the “cause” and what is the “effect” (ie, there is no confusion about which variable comes first)?	✓[a]	✓	✓
Were the participants included in any comparisons similar?	N/A[b]	N/A	N/A
Were the participants included in any comparisons receiving similar treatment or care other than the exposure or intervention of interest?	N/A	N/A	N/A
Was there a control group?	×[c]	×	×
Were there multiple measurements of the outcome both pre and post the intervention or exposure?	✓	✓	✓
Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analyzed?	✓	✓	✓
Were the outcomes of participants included in any comparisons measured in the same way?	✓	✓	✓
Were outcomes measured in a reliable way?	✓	✓	✓
Was appropriate statistical analysis used?	✓	✓	✓

[a]Yes.

[b]N/A: not applicable.

[c]No.

Current Serious Game Intervention Protocols of PR

The serious game intervention protocols used in the included studies are summarized in Table 3, including serious game modalities, source of serious game, the procedure of the serious game modality, duration, length, and frequency of the intervention. Of them, only 1 study [18] developed a serious game modality for the purposes of the study.

Table 3. Details of SG[a] intervention protocol.

Study	SG modalities	Source of SG	Procedure of the SG modality	Duration	Length and frequency
Simmich et al [18]	• HW[b]: Fitbit • SW[c]: grow stronger AVG app	Purpose-built	• Fitbit paired to SW on smartphones and tracked steps, physical activity, and heart rate • Game modes on SW • (1) Complete and report upper and lower body physical activity, (2) grow a garden, and (3) a cooperative multiplayer game visiting multiple well-known Australian destinations	3 weeks	Each day
Sutanto et al [20]	• HW: a balance board accessory • SW: game activities of Wii Fit system	Off-the-shelf	• Yoga: deep breathing and half moon • Strength training • Aerobic exercise	6 weeks	30 min per session, 3 times per week
Hu et al [32]	• HW: not reported • SW: game activities of BioMaster virtual reality digital rehabilitation training system	Off-the-shelf	• Upper body physical activities: housework activities, kitchen cooking, etc • Lower body physical activity: cycling	12 weeks	5-15 min per day
LeGear et al [30]	• HW: a balance board accessory • SW: game activities of Wii Fit system	Off-the-shelf	• Marching, dancing, and 2 air punching exercises in sequence	N/A[d]	15 min per session
Rutkowski et al [19]	• HW: the console, a Kinect motion sensor, and a projector with speakers • SW: game activities of Kinect somatosensory digital games	Off-the-shelf	• Rafting, cross-country running, hitting a ball in the direction of a player on the screen, and a mountain wagon ride	2 weeks	20 min per day, 5 days per week
Mazzoleni et al [31]	• HW: haptic sensor–based controllers and a balance board • SW: game activities of Wii Fit Plus	Off-the-shelf	• Two 5-min sessions of "yoga" activity consisting of deep breathing • Jogging Plus consisting of feedback aided 10-min running • Twisting and squat: 10-min trunk twisting and arm and leg squatting	1 week	60 min per day
Zhou et al [21]	• HW: console, Kinect motion sensor, and projector with speakers • SW: game activities of Kinect somatosensory digital games	Off-the-shelf	• Trail running, rafting, hitting, and mountain riding in sequence	18 weeks	30 min per day, 5 days per week
Jin et al [22]	• HW: remote controls • SW: game activities of somatosensory digital games developed by Chinese company	Off-the-shelf	• Kitchen knife, ping pong exercise, and swimming in sequence	Admission within 48 h to discharge from hospital	20 min per day
Albores et al [33]	• HW: haptic sensor–based controllers and a balance board • SW: game activities of Wii Fit unit	Off-the-shelf	• Basic run: warm-up exercise • Bird's eye • Bull's eye: mostly upper arm exercise • Free step: mostly lower extremity exercise • Obstacle course: upper and lower extremity exercise • Basic run: cool-down exercise	12 weeks	5 or more days per week

Study	SG modalities	Source of SG	Procedure of the SG modality	Duration	Length and frequency
Wardini et al [34]	• HW: a balance board accessory • SW: game activities of Wii Fit system	Off-the-shelf	• Basic run, basic step, obstacle course, and island cycling for lower body training • Boxing and canoeing for upper body training	3 to 4 weeks	3 times per week
Parent et al [35]	• HW: a console and a controller • SW: game activities of Kinect	Off-the-shelf	• A running game (Stunt Run), a boxing game (Arctic Punch), a core twist game (To the Core), and a squat game (Squat Me to the Moon) in sequence	N/A	30 min per session

[a]SG: serious game.
[b]HW: hardware.
[c]SW: software.
[d]N/A: not applicable.

Commercial Game Software Combined With Hardware

In total, 10 studies [19-22,30-35] used commercial serious game systems, of which 5 [20,30,31,33,34] used Wii game systems (Nintendo), 3 studies [19,22,35] used Kinect game systems (PrimeSense), 1 study [22] used a Chinese brand game system, and the remaining [32] used the BioMaster virtual reality digital rehabilitation training system. Serious game modalities in each study comprised 2 key components, hardware and software except one study [32] that did not report the details of hardware. Specifically, software provided game contexts and images, whereas hardware was responsible for capturing and conducting movements in the games. The procedure of the serious game modality greatly varied from different studies, but all included multiple sessions of games in regard to training the upper body, lower body, or breathing exercises. In total, 7 studies reported that the duration of the interventions varied from 2 to 18 weeks [19-21,31-34]. However, 2 studies [30,35] did not report the duration of the intervention, and 1 study [22] only reported the duration from admission within 48 hours to discharge, which made it impossible to confirm the duration. Regarding the length and frequencies of undertaking serious games across the studies, a consensus was not reached in the trials that reported this parameter, ranging between 5 and 60 minutes per day in length and between 3 days per week and each day in frequency.

Purpose-Built Game Software Combined With Hardware

Only 1 study [18] specifically developed its serious game modality combined with a Fitbit and games that was produced by a combination of researchers, patients with COPD, and clinicians with experience in PR. Fitbit was used to track steps, physical activity, and heart rate in participants with COPD, whereas a game with 2 game modes was developed to guide physical training. The duration of intervention was reported to be 3 weeks, and the frequency was just briefly stated as every day.

Relationships Between Serious Game Interventions and Patient Outcomes

The results of serious game interventions were presented using descriptive analysis for this review.

Pulmonary Function

In total, 2 of the 12 studies separately examined the outcomes of the index of pulmonary function using FEV (forced expiratory volume) 1%predicted and FEV1/FVC (forced vital capacity) at different time points. FEV1%predicted, indicating the severity of diseases, refers to FEV in 1 second predicted, and FEV1/FVC is the ratio of the amount of air that a person can forcefully exhale in 1 second (FEV1) to the total amount of air that can be exhaled (FVC) over the course of a full exhalation, revealing that the airways are obstructed or narrowed for respiratory diseases [36]. One study [32] comparing the BioMaster virtual system with the conventional PR program showed no significant difference in FEV1%predicted and FEV1/FVC at 4 weeks but presented significant improvements at 8 weeks and 12 weeks after the intervention, respectively ($P<.05$). Similarly, another study [21] reported consistent results in which the somatosensory game digital training group had a significant improvement compared with the traditional exercise training group after 18 weeks of the intervention.

Exercise Capacity

In total, 7 studies [19-22,31-33] examined physical exercise capacity with varied measurements, of which 5 [19-21,31,32] used a 6-minute walk test, 1 [22] used a brief balance evaluation system test, 1 [33] adopted the endurance shuttle walk test and arm-lift and sit-to-stand repetitions, and 1 [19] applied senior fitness test. Additionally, the protocols between groups highly varied, which were BioMaster virtual system versus the conventional PR program [32], Wii versus exercise training on a cycle ergometer [20], Wii versus the conventional PR program [31], somatosensory game digital training versus traditional exercise training [21], somatosensory game digital training versus usual care [22], endurance exercise training versus virtual reality training [19], and Wii only [33]. Four studies separately showed significant improvements in the 6-minute walk test at 1 [31], 2 [19], 12 [32], and 18 weeks [22], whereas 1 study [20] showed a reverse result at 6 weeks of the intervention between groups. In addition, the results in 2 studies showed a significant improvement between groups in the senior fitness test at 2 weeks [19], the endurance shuttle walk test and arm-lift and sit-to-stand repetitions at 12 weeks [33]. Furthermore, 1 study [22] found a significant improvement in the brief balance evaluation system test of somatosensory digital games from admission within 48 hours to discharge from the hospital of the intervention compared with the usual care group.

Daily Steps

Only 1 study [18] collected continuous data on daily steps using Fitbit devices. The protocol involved purpose-built serious games combined with Fitbit in the experimental group and Fitbit alone in the control group [18]. The result stated that participants in both groups had high adherence to wearing Fitbit, recording steps on >80% of days, and showed opposite trends between the 2 groups in daily steps across 3 weeks, which indicated a significant improvement in the experimental group and a decrease in the control group [18].

Dyspnea

In total, 6 studies [20,21,30,31,34,35] evaluated dyspnea using 2 different tools, of which 4 studies [21,30,34,35] used the Borg dyspnea scale, and the remaining 2 studies [20,31] used the Medical Research Council score. Currently, there are conflicting results. Specifically, 2 RCTs [21,30] in the Borg dyspnea scale and 2 RCTs [20,31] in the Medical Research Council reported no significant improvements between groups, and 1 pre-post study [35] also obtained a similar result in the Borg dyspnea scale. However, another pre-post study [34] presented an opposite result that showed a significant improvement after intervention in the Borg dyspnea scale.

Patient-Reported Outcome Measures and Psychological Evaluation

In total, 3 studies [20,31,33] evaluated psychological status, including quality of life with the Saint George's Respiratory Questionnaire in 2 studies [20,31] and the Chronic Respiratory Questionnaire in 1 study [33], and depression with the Beck Depression Inventory in 1 study [31]. Two studies [20,31] showed no significant improvements in Saint George's Respiratory Questionnaire between groups, whereas 1 study had the opposite result in which there was a significant increase in Chronic Respiratory Questionnaire after the intervention. In terms of depression, no statistically significant improvement in Beck Depression Inventory was identified between groups [31].

Adverse Effects

Most studies did not report adverse effects, but only 2 studies [33,34] revealed chest pain and decreased oxygen saturation in the process of intervention. No serious adverse effects were identified in any of the studies.

Related Outcome Measures of Serious Game–Based Engagement

Adherence and Use of Serious Games

Two studies [21,34] reported adherence, which was highly varied. The adherence rate was 64% in a pre-post study [34] to test Wii serious games with an intervention duration of 3-4 weeks, whereas it accounted for 83.61% in an RCT study [21] to evaluate somatosensory game digital training after 18 weeks. One study reported game use frequency as participants who were involved in the study automatically recorded activities on 58.6% (82/141) of the days during the 3-week intervention [18]. Additionally, another study obtained adherence data from self-reported patient diaries, reporting that patients used serious games for a total of 36 hours and 5.7 days per week with a mean number of hours per week ranging from 2.6 to 3.4 [33].

Enjoyment

Four studies reported outcome measures of enjoyment of serious games with different instruments [18,30,34,35]. One study [30] used a 5-question Likert scale to evaluate enjoyment and found that 90% of participants enjoyed using the Wii exercise program. Similarly, another study [35] assessed the enjoyment of Kinect game activities using a 5-question Likert scale and reported consistent results that participants were more likely to enjoy the games. Moreover, a 10-cm visual analog scale was used to measure overall enjoyment based on the Wii Fit system [34]. The results demonstrated that participants had a mean score of 8 out of 10. Participants also reported a mean score of 8 out of 10 when asked about their willingness to recommend serious games to another patient with COPD. Additionally, a subscale on the Intrinsic Motivation Inventory was used to test enjoyment with a mean score of 5.4 out of 7 [18]. In summary, participants in these studies found serious games enjoyable.

Acceptability

Only 1 study [31] reported using a Likert scale to test the acceptability of serious games. This study found a higher score of 42.4 out of 49 in the group that participated in digital video game–aided exercises, which was similar to the score of the standard PR group. However, no significant difference was identified between the 2 groups.

Discussion

Principal Findings

To the best of our knowledge, this review is not the first to systematically investigate the effects in this field. However, it provides a broader insight, contributing to the understanding of the effects of serious games by rigorously examining a greater number of original studies, various types of serious games, and outcomes. This review indicated a promising role of serious games in the rehabilitation of patients with COPD. Nevertheless, the findings should be interpreted carefully considering that relevant evidence on serious games in this area was deemed not fully conclusive due to the wide variation in the design of studies, serious game modality, characteristics and duration, study comparisons, outcomes, and high risks of bias identified in some included studies.

The findings showed that serious games could be beneficial to pulmonary function, indicating that serious games may be a potentially effective alternative or complement to traditional rehabilitation in improving pulmonary function for individuals with COPD. It is commonly believed that serious games can be tailored to the individual needs of the patient, allowing for more personalized and effective treatment [37]. Additionally, the use of serious games can provide a more engaging and digital experience for patients, which may lead to increased adherence and motivation to exercise [38]. Therefore, increased physical exercise in intervention groups may contribute to better pulmonary function compared to control groups. However, it is important to note that more research is needed to examine the long-term effects of serious games on pulmonary function.

The findings in this review indicated a potentially beneficial role of serious games on exercise capacity. Most studies reported consistent results in favor of significant improvement when using serious games compared to the control group, which was in line with the findings of a previous review [17]. Furthermore, continuous monitoring data on daily steps also supported the effectiveness of serious games [18]. It is likely that participation in serious games provides a more engaging and digital form of exercise, which motivates patients and facilitates engagement [38]. This has been identified as a key factor in increasing adherence to interventions [39-42]. Additionally, compared to traditional forms of exercise as walking on a treadmill or cycling on a stationary bike, serious games are less boring and more appealing to patients, providing explicit instructions for patients to perform physical exercises as well [43].

It appeared that current findings have not found evidence that serious games have a positive impact on dyspnea in patients with COPD. Most studies [20,21,30,31,34,35] included in the review focused on physical exercises combined with serious games rather than using breathing techniques or exercises. In addition, the findings may be limited by varied measurement tools and the quality of studies. Therefore, it remains unclear whether serious games alone have any impact on dyspnea in patients with COPD. Additional research that specifically examines the use of breathing techniques or exercises in serious games may provide more insights into potential benefits for patients with COPD in the future.

Findings regarding the impact of serious games on quality of life and depression in patients with COPD were inconclusive, which indicates there was no consistent improvement observed in these areas and serious games may not have a significant impact on psychological status when compared to other interventions [20,31,33]. It should be highlighted that improvements in human well-being and depression are probably influenced by multiple factors [44,45], and the studies included in this review primarily focused on physical levels rather than other components, such as health education, and self-management. This may result in the lack of observed improvements. Additionally, it is unclear whether significant improvements would be found with long-term intervention.

Safety outcomes associated with serious games were not reported in the majority of studies included in this review. Only 2 studies [33,34] described adverse effects, including chest pain and decreased oxygen saturation. This suggests that potential adverse reactions have not yet been fully identified, highlighting the need for future research to focus on evaluating the safety outcomes of serious games and identifying any potential adverse effects that may occur.

Current findings on serious games' impact on adherence, enjoyment, and acceptability highlighted positive outcomes. It is recognized that PR entails numerous benefits; however, adhering to the program is currently one of the most significant challenges [4,44,45]. Insights into patients' continuous attendance are essentially significant, and both patients' acceptability and enjoyment are valuable indicators of this [46,47]. The current studies [18,30,34,35] have reported a high level of enjoyment, whereas only one study [31] has mentioned acceptability, which was found to be higher in the serious games group. These findings may be attributed to the concept that serious games provide a fun virtual environment for the patients, combining physical exercises with games to make the patients have fun, thus improving patient enjoyment and acceptability [17]. Then, the high level of acceptability and enjoyment contributes to good patient adherence, as reported in this review. Additionally, the findings in this review also show that the somatosensory game digital system, which uses body movements and gestures as input, had a higher adherence rate than the Wii serious games system, which relies solely on hand-held controllers for interaction [21]. This suggests that the use of a more immersive and physically engaging system may lead to increased participation and engagement from users, resulting in a higher adherence rate. This highlights the importance of considering the type of digital system used in serious game interventions, as it may have a significant impact on the effectiveness of the intervention [11]. Additionally, the adherence rate may vary depending on the population and specific intervention being used [48], and further research is needed to fully understand the impact of digital systems on adherence rates in serious game interventions.

Significant variation involving intervention modality, the procedure of the intervention modality, duration, length, and frequency was observed in all studies. Commercial serious game systems were the most frequently used modalities compared to purpose-built game systems among all studies. In addition, Wii game systems involving economic cost were the most popular in all included studies. Additionally, the intervention modalities varied greatly among studies. Furthermore, significant variation in duration, length, and frequency was also identified. The considerable variation in serious game protocols among the included studies indicated that an optimal evidence-based serious game protocol in this area is lacking, and further study is therefore warranted to recognize the best available evidence to develop a research-based serious game protocol to promote rehabilitation.

Comparison to Prior Work

In comparison with the previous review [17], this study effectively addresses the limitation of omitting relevant studies published after its completion [18-22] by incorporating them into the analysis. Moreover, unlike the previous review, which exclusively concentrated on video games, this study embraces a more comprehensive range of serious games, acknowledging that video games represent only a subset of the broader category [23]. Furthermore, this review systematically considers supplementary outcome measures, such as pulmonary function and acceptability, which were inadequately addressed in the earlier review.

Strengths and Limitations

Strengths

This review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guideline (Multimedia Appendix 3) [49]; thus, it can be viewed as a transparent and reproducible review. The findings in this review are more likely to be comprehensive and provide implications for further understanding the effects of serious games in this area. There is a low risk of publication bias in this review, as the search was conducted to identify as many eligible studies as possible by searching relevant databases using a broad search strategy. Additionally, the risk of selection bias in this review is minimal, as the research process, including study selection, data extraction, and assessment of study quality, was carried out independently by 2 reviewers.

Limitations

Although this review identified that serious games are encouraging interventions for promoting rehabilitation in patients with COPD, research evidence of the effects remains inconclusive due to the following limitations in this review and the included studies. First, meta-analysis was not conducted in this review given the significant clinical heterogeneity of the included studies in terms of study design, serious game characteristics, comparisons, and duration, which was one of the main reasons for the inconclusive research evidence found in this review. Second, it is likely that language bias may exist due to the enrollment of only English and Chinese studies in this review. Third, methodological limitations were also found in the included studies. For example, most studies in RCT designs with a small sample size lacked sample size calculations, random allocation of participants, and the use of blinding methods. For pre-post studies, the present studies were limited by the sample size and the absence of an intervention and control group with traditional intervention. Fourth, the effects of serious games involving other vital rehabilitation components in patients with COPD, such as breathing exercises and disease-related health education, are lacking.

However, these limitations mentioned earlier, which could not be addressed in this review, provide significant implications for further studies to enhance the evidence on serious games in this field.

Implications for Future Research and Practices

An evidence-based serious game protocol should be developed to improve the health of patients with COPD, including an appropriate serious game modality tailored to personalized demands, optimal duration, and frequency, based on the research evidence. Additionally, rigorously designed, large-scale RCTs should be developed to determine the effects of serious games on rehabilitation in patients with COPD, such as random distribution, allocation concealment, and the use of blinding. Moreover, future research should also focus on exploring the effects of serious games on other components of COPD PR, such as breathing exercises or health education in patients with COPD, as knowledge in this area is still insufficient. Furthermore, a more robust systematic review, which includes higher quality studies, addresses language bias, and uses a meta-analysis method, is warranted in the future.

Conclusions

This review comprehensively summarized and indicated the potentially beneficial role of serious games in enhancing outcomes in patients with COPD. However, these findings should be interpreted with caution due to the unsatisfactory quality of the included studies. It is recommended that more research with rigorous methodological quality is necessary to further determine the role of serious games in promoting rehabilitation.

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Authors' Contributions

HH independently conceived and developed the idea while also formulating data collection methods based on the included studies in collaboration with M Huang to devise statistical analysis plans and prepare the original paper. RW and M Hayter meticulously conducted a comprehensive review and editing of the paper, ensuring intellectual clarity, coherence, and content accuracy. Furthermore, HH, M Huang, and QC adeptly generated graphical representations and figures to effectively illustrate the data. Throughout the review process, RW and M Hayter provided invaluable oversight, guidance, and mentorship. It is crucial to highlight that each author extensively examined and endorsed the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategies in databases.
[DOCX File , 25 KB - games_v11i1e46358_app1.docx]

Multimedia Appendix 2

General characteristics of included studies.
[DOCX File , 24 KB - games_v11i1e46358_app2.docx]

Multimedia Appendix 3
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[PDF File (Adobe PDF File), 101 KB - games_v11i1e46358_app3.pdf]

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Abbreviations

COPD: chronic obstructive pulmonary disease
FEV: forced expiratory volume
FVC: forced vital capacity
PR: pulmonary rehabilitation
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial

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Review

Playfulness and New Technologies in Hand Therapy for Children With Cerebral Palsy: Scoping Review

Tamara Veronica Pinos Cisneros[1,2], MSc; Annette Brons[1], MSc; Ben Kröse[1], Prof Dr; Ben Schouten[3], Prof Dr; Geke Ludden[2], Prof Dr

[1]Digital Life Centre, Amsterdam University of Applied Sciences, Amsterdam, Netherlands

[2]Interaction Design, University of Twente, Enschede, Netherlands

[3]Play and Civic Media, Amsterdam University of Applied Sciences, Amsterdam, Netherlands

Corresponding Author:
Tamara Veronica Pinos Cisneros, MSc
Digital Life Centre
Amsterdam University of Applied Sciences
Wibauthuis (WBH) | 06A02
Wibautstraat 3-b
Amsterdam, 1091 GH
Netherlands
Phone: 31 621157005
Email: t.v.pinoscisneros@utwente.nl

Abstract

Background: Innovative technologies such as game consoles and smart toys used with games or playful approaches have proven to be successful and attractive in providing effective and motivating hand therapy for children with cerebral palsy (CP). Thus, there is an increased interest in designing and implementing interventions that can improve the well-being of these children. However, to understand how and why these interventions are motivating children, we need a better understanding of the playful elements of technology-supported hand therapy.

Objective: This scoping review aims to identify the playful elements and the innovative technologies currently used in hand therapy for children with CP.

Methods: We included studies that design or evaluate interventions for children with CP that use innovative technologies with game or play strategies. Data were extracted and analyzed based on the type of technology, description of the system, and playful elements according to the Lenses of Play, a play design toolkit. A total of 31 studies were included in the analysis.

Results: Overall, 54 papers were included in the analysis. The results showed high use of consumer technologies in hand therapy for children with CP. Although several studies have used a combination of consumer technologies with therapeutic-specific technologies, only a few studies focused on the exclusive use of therapeutic-specific technologies. To analyze the playfulness of these interventions that make use of innovative technologies, we focused our review on 3 lenses of play: *Open-ended Play*, where it was found that the characteristics of ludus, such as a structured form of play and defined goals and rules, were the most common, whereas strategies that relate to paidia were less common. The most commonly used *Forms of Play* were physical or active form and games with rules. Finally, the most popular *Playful experiences* were control, challenge, and competition.

Conclusions: The inventory and analysis of innovative technology and playful elements provided in this study can be a starting point for new developments of fun and engaging tools to assist hand therapy for children with CP.

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KEYWORDS

technology; cerebral palsy; play; children; hand therapy

Introduction

Background

Children with hand motor skills deficiencies face challenges daily. They may have difficulties with daily activities such as eating, getting dressed, or socializing with friends and families. Physical and occupational therapies can ameliorate the motor skills of these children [1]. One group with hand motor skills deficiencies is children with cerebral palsy (CP). Despite therapists' efforts, the interventions available for this group are repetitive and thus perceived as demotivating [2]. Providing therapy via a motivating activity positively impacts improving motor skills, as patients are more willing to take part and adhere to the treatment. Therefore, rehabilitation researchers and therapists constantly look for ways to innovate and improve existing therapies.

Challenges of current therapy at home include lacking the means for personalization, monitoring of progress of the exercises, and high cost of devices. Children with CP present with a diverse degree of motor function, and no 2 children will be affected in the same way. Therapists therefore adjust the exercises according to each child; however, this type of personalization is challenging if the therapy is to be performed at home. In addition, therapists need to provide tailored and timely feedback for the child to sustain motivation and increase adherence when performing therapy at home. Trying to provide this help at home can increase the workload and pressure on the therapists and caregivers.

New technologies, such as the E-link, the HandTutor, or the surface electromyography, present advantages in hand rehabilitation such as data analysis, customization, feedback, and adaptability to the home environment [3]; however, their high cost means that families cannot make use of them easily. Two known approaches to increase motivation are the use of new technologies and play. The benefits of play in the development of children have been widely studied, showing that the motivational nature of play encourages children to participate and learn. Thus, one of the approaches that therapists have successfully used in rehabilitation centers is to perform exercises through play [4]. One successful example of play-based therapy is Pirate Therapy [5], which highlights the importance of motivating children to work toward a goal through playful activities. Researchers have also studied the use of new technologies, such as virtual reality (VR), augmented reality, game consoles, and robots, which are familiar and appealing to children because they provide opportunities for play via interactive games while enriching the therapeutic experience [3].

Furthermore, these new technologies provide monitoring and automatic feedback on performance, the opportunity for repetition to improve motor skills, and sharing experiences between children and others. These are also financially accessible technologies that require low technical support, making them appropriate for use at home. Some examples of successful studies on hand therapy for children with CP and other motor disabilities are the studies conducted by Reid [6] and analyzed in the review by Pereira et al [7]. They concluded that VR is suitable for supporting hand therapy. Koutsiana et al [8] concluded in their review that serious games are an alternative to provide motivation in therapy. Moreover, Winkels et al [9] showed positive results in participants' usability, user satisfaction, and enjoyment in gaming with the Nintendo Wii sports games, boxing, and tennis. In their review, Ayed et al [10] highlighted that the interest in the field of VR systems for rehabilitation is increasing. However, none of these studies provide an overview of the extent and range of the research on playful technological interventions. There does not seem to be a systematic approach to how and when we use technology and play in therapy for children. Many studies have experimented with available technologies that can be adjusted for therapy without paying much attention to the play elements that can be applied. Therefore, there is a need to have an overview of what the field has been doing for the last decade and to deepen our understanding of the use of play in therapy.

Objectives

The range of playful technological interventions can be studied along multiple dimensions. First, the type of technology (motion sensing, game consoles, etc) can be used to categorize the research. Second, the type of playful elements (competition, rules, fantasy, etc) can help structure the analysis. Therefore, in this scoping review, we aim to identify which innovative technologies are part of playful hand therapies and what are the playful elements used in these interventions. This information will provide researchers, designers, and practitioners with an overview of current therapies for children with CP that make use of innovative technologies and play. Furthermore, we aim to provide starting points to design new therapies that are supported by innovative technology and play (which makes them suitable for other environments than just the rehabilitation center) and that engage and motivate children.

Designing Playful Interactions

To analyze and determine whether and which playful elements have been applied in technology-supported hand therapies for children with CP, we used the Lenses of Play [11]. The Lenses of Play is a design toolkit used to create playful interactions. For example, Almahmoud [12] used the Lenses of Play to design a toy for children with autism. We have chosen to use it as our framework because it provides multidimensional examination of play beyond traditional therapist-centered approaches, making a distinction between games and free play [13] and providing a diverse set of playful elements such as control and competition among others. Other frameworks or models used in therapy, such as Theraplay [14] or SCOPE-IT [15], refer more to the behavior of children in connection with their caregivers and occupational performance. Although play is an essential element, these frameworks lack the focus on what makes an activity or object playful for children. The Lenses of Play focus on the object, game, and user interaction. This framework will help us to better understand how playfulness is used and identify the necessary ingredients to design new playful experiences for therapy. In the future design of playful therapies, this can lead to a common and more specific language to be used by the different stakeholders involved in innovative, technology-supported therapies, including clinicians, children, and their parents, as well as technology developers.

First, we briefly describe the technologies used in this review. Subsequently, identifying the playful elements used within therapies that use new technology will support a more systematic reflection and understanding of the potential benefits of using these technologies.

Methods

A scoping review aims to compile the relevant literature and map the critical concepts of a specific topic. For this scoping review, we used the five-stage framework proposed by Arksey and O'Malley [16]: (1) identifying the research questions; (2) identifying relevant studies; (3) study selection; (4) charting the data; and (5) collating, summarizing, and reporting the results.

Identifying the Research Questions

In line with the main objectives of this scoping review, we aim to answer the following research questions:

- Question 1. Which innovative assistive technologies are used in hand therapies for children with CP?
- Question 2. Which playful elements are embedded in the technology-supported therapy to motivate children with CP?

Identifying Relevant Studies

To identify relevant studies, we performed comprehensive searches in the Scopus, Web of Science, and CINAHL databases for medical and human-computer interaction studies published in English between January 2009 and December 2022. The final search was performed on January 17, 2023. The keywords used were as follows: "cerebral palsy OR cerebral paresis OR cerebral palsies; AND play* OR game OR gamification OR toy; AND child OR children; AND therapy OR rehabilitation OR treatment; AND hand OR upper limbs." The queries that were run on all the databases are presented in Multimedia Appendix 1.

Study Selection

After removing duplicates, the titles and abstracts were analyzed according to the inclusion and exclusion criteria set by 2 reviewers (AB and TVPC). The inclusion criteria for the analyzed articles were as follows: (1) study participants were children (aged 0-18 years) with spastic CP; (2) the therapy described was focused on hands or upper limbs motor skills; (3) the therapy used innovative technology (ie, electronic tools, systems, and devices); (4) the therapy used playful elements such as video games or toys; and (5) the publications consisted of peer-reviewed academic articles or conference proceedings that were published between 2009 and 2022. The exclusion criteria included (1) insufficient information about the game or play activity or referred to traditional therapies without the support of technologies (eg, bimanual, constrained-induced movement, and Pirate Therapy), (2) lack of focus on the treatment used, (3) written in a different language than English, (4) unavailability to access the full text at the time of analysis, and (5) incomplete inclusion criteria. Disagreements between reviewers with regard to the exclusion criteria were resolved through discussion.

Charting the Data

The data extracted from the selected studies included authors, date of publication, research questions or aim, sample size, frequency, time and duration of therapy, hand movement, intended environment (home or rehabilitation center), the technology used, description of the system, and playful elements according to the Lenses of Play.

Collating, Summarizing, and Reporting the Results

The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines [17] were followed for reporting the results; the PRISMA-ScR checklist is included in Multimedia Appendix 2. The protocol was registered with the Open Science Framework. The authors (TVPC, BK, BS, and GL) met to determine the categories of technologies, evaluate the playful elements of the Lenses of Play, and analyze the extracted data. To determine the categories of technologies, we investigated their functionality and determined commonalities. For example, Kinect and Leap Motion are used to detect movement; hence, we created a motion sensor category. To identify the playful elements used in the interventions, we analyzed the information provided for each intervention through each of the Lenses of Play. To do so, we examined the design principles, play mechanisms, and goals that were included in the interventions and described in the paper. For commercially available games and technologies, we also investigated the information provided on the developers' websites [18-23]. For example, when analyzing a study with the Lens of Play *Playful experiences*, if the intervention described a game where the player had to grab a specific number of virtual butterflies and place them in a jar, the game will be categorized under the playful experience *completion* because the player must complete a task. The same was performed with the other lenses by following the definitions of each element of the Lenses of Play.

Results

Overview

The total number of studies found on Scopus was 166, whereas 126 studies were found on Web of Science (including MEDLINE) and 58 studies were found on CINAHL, resulting in 350 studies, including duplicates. The first author (TVPC) removed duplicate studies, resulting in 239 studies. The first 2 authors (TVPC and AB) conducted the analysis of titles and abstracts based on the inclusion and exclusion criteria. This yielded a total of 66 studies whose full text were reviewed for data extraction by 1 of the authors (TVPC). Figure 1 depicts the number of studies identified at each process stage following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. Finally, 54 studies were included in the study (Table 1).

In recent years, there has been an increase in the interest in developing and researching hand therapies that use innovative assistive technology and playful elements. Figure 2 shows the distribution of the selected papers from 1999 to 2022.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of search process.

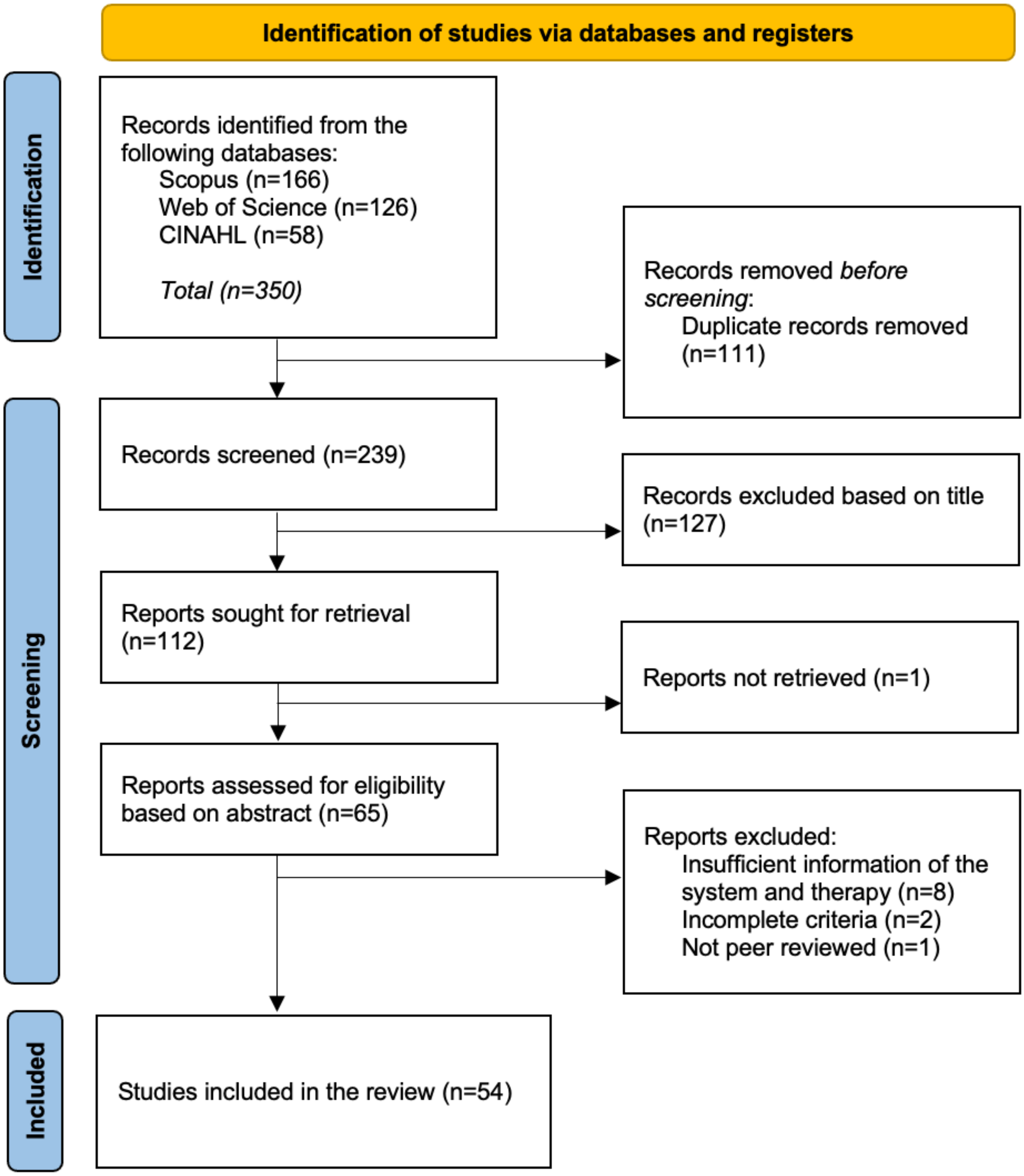


Table 1. Summary of analyzed studies and assistive technology (original purpose of the technology and type of hardware).

Study, year	Study		Technology
	Goal	Participants	Category and system
Category 1: therapeutic-specific technology			
Bian et al [24], 2020	To develop toy modules in combination with Lego blocks to support hand and arm training	5 children, aged 5-10 years; 1 with amentia and 4 with hemiplegia	• Category: Smart Tangibles (smart blocks) • System: path building with the smart blocks and Lego blocks
Guberek et al [25], 2009	To evaluate the level of cooperation and satisfaction of children when practicing arm and hand movements during play-like activities in a physical environment	Children aged 5-12 years	• Category: Motion Sensing (IREX[a]) • System: the IREX system with the game Zebra Crossing, the child attempts to touch as many stars as possible while advancing the crosswalk
Mandil et al [26], 2015	To use a tangible user interface in designing tabletop activities to help motivate children with motor disabilities to increase the number of exercises and improve the motor proficiency and quality of life	4 children with CP[b], aged 6-14 years; 3 physiotherapists	• Category: Smart Tangibles (PhysiTable) • System: PhysiTable with 3 different paths defined with LEDs. Music and color used for feedback. The player uses a cube to trace the path.
van Delden et al [27], 2012	To study the use of tangible, interactive games for the repetitive training of upper limbs in the therapy of children with CP	4 therapists; 16 children with CP, aged 2.5-8 years; 14 non-CP children aged 8-9 years	• Category: Smart Tangibles (smart toys and TagTiles) • System: the smart toys are used to manipulate the TagTiles
Wu et al [28], 2022	To develop an Interactive Story Box to facilitate rehabilitation of speech, cognition, and motion	4 children with CP, aged 4-8 years	• Category: Smart Tangibles (interactive story box) • System: Raspberry PI, RFID[c] readers, and tangible objects to create an interactive box. Story maps are controlled with characters in the shape of a puzzle.
Category 2: consumer technology			
Acar et al [29], 2016	To investigate the efficiency of Nintendo Wii games in addition to neurodevelopmental treatment in patients with CP	30 children with CP, 16 female participants, aged 6-15 years	• Category: game consoles • System: Nintendo Wii, with the VR[d] games (tennis, baseball, and boxing)
Avcil et al [30], 2021	To compare the effects of neurodevelopmental therapy and video game–based therapy for upper extremities	30 children with CP, aged 6-15 years	• Category: game consoles (Nintendo Wii) and motion sensing (Leap Motion) • System: 2 video games to improve hand and grip functions. "CatchAPet" to touch rabbits with repetitive wrist flexion or extension movements and "Leapball" to grasp a virtual ball with all fingers and throw it by finger extension.
Chen et al [31], 2021	To evaluate the feasibility of a Kinect-based constraint-induced therapy	10 children with CP in phase 1 and 8 children with CP in phase 2	• Category: motion sensing (Kinect), computers • System: video game where the child is a warrior defending their island. The Kinect detects the hand movements to throw cannonballs.
Chiu et al [32], 2014	To investigate whether Wii Sports Resort training is effective and if any benefits are maintained	62 children with hemiplegia aged 6-13 years	• Category: game consoles (Nintendo Wii) • System: Nintendo Wii, with Wii Sports Resort games, from easiest to hardest: bowling, Air Sports, Frisbee, and Basketball. 10 minutes per game.

Study, year	Study		Technology
	Goal	Participants	Category and system
de Oliveira et al [33], 2016	To develop a VR game using Unity 3D to aid motor and cognitive rehabilitation in children with CP	8 clinical experts	• Category: computer (PC), motion sensing (Leap Motion), and wearables (Mind wave) • System: 6 phases of a video game in a PC controlled by Leap Motion. Mind wave used to keep track of player's attention.
El-Shamy and El-Banna [34], 2020	To investigate the effect of Wii training on hand function	40 children with hemiplegic CP, aged 8-12 years	• Category: game consoles (Nintendo Wii) • System: playing 4 Wii games: tennis, boxing, bowling, and basketball
Elsaeh et al [35], 2017	To develop a high-level control in which the human brain is stimulated by the visual, audio, and tactile sensation to transmit instructions to the affected upper limb's joints	2 children with hemiplegia, 1 7 years old female participant, and 1 10 years old male participant	• Category: computer (PC), controller (Novint Falcon) system: 3 video games on a PC using the Novint Falcon controller
Garcia-Hernandez et al [36], 2021	To examine how the subjective experience of seeing and controlling a half-body avatar or an abstract hand representation in a virtual environment for training upper limb movements may affect motor performance	19 children aged 7-9 years	• Category: computer and motion sensing (Kinect) • System: a video game with body or hand representation where participants have to reach and grab a ball
Gieser et al [37], 2015	To recognize and classify static gestures from Leap Motion by comparing classification techniques, decision trees, support vector machines, and k-nearest neighbors. Create and evaluate a game to detect hand gestures.	Volunteers and experts	• Category: computer (PC) and motion sensor (Leap Motion) • System: virtual game developed on Unity for PC and controlled via Leap Motion.
Golomb et al [38], 2009	To describe the learnings of providing home telerehabilitation to people with CP and to suggest ways to address some of the barriers to home telerehabilitation in this population	3 adolescents with CP	• Category: console (PlayStation 3) and controller (5DTD Ultra sensing glove). • System: custom games programmed in Java3D for PlayStation 3 and controlled with a 5DT5 Ultra sensing glove.
Golomb et al [39], 2010	To investigate whether in-home remotely monitored VR video game–based telerehabilitation in adolescents with hemiplegic CP can improve hand function and forearm bone health and demonstrate alterations in motor circuitry activation	3 patients with severe right hemiplegic CP, aged 13-15 years	• Category: console (PlayStation 3) and controller (5DTD Ultra sensing glove). • System: the 5DT5 Ultra sensing glove has 5 fiber optic sensors in each of the 5 fingers; it is connected to a PlayStation 3 with Linux, and the games were programmed using open source Java3D API[e].
Goyal et al [40], 2022	To report the use of a VR gaming system and haptic feedback and its effectiveness	1 child, aged 6 years	• Category: game consoles (PlayStation) • System: a driving simulation game with PlayStation 4
Gregory et al [41], 2012	To enable play for children with CP that continuously entertains, which will allow extended play over long durations	N/A[f]	• Category: smart tangibles (Pleo) and controller (Wii Nunchuk) system: a Wii Nunchuk is used to teach dance movements to Pleo.
Hernández et al [42], 2018	To test the usability of the gaming station with clinicians and children with CP and to establish the feasibility in a 12-week clinical trial	6 therapists and 6 children with CP, aged 7-16 years	• Category: controller (Novint Falcon) • System: force feedback Novint Falcon game controller, custom grips, arm and wrist supports, and software to be used with mainstream games
Hsieh et al [43], 2020	To improve hand performance while playing with Chinese puppets modified with Lego robots	42 children with CP	• Category: smart tangibles (Lego Mindstorms NXT) • System: modified puppets with Lego, using servo motors, sensors, and connecting cables

Study, year	Study		Technology
	Goal	Participants	Category and system
Hung et al [44], 2018	To study the feasibility and possible efficacy of a suite of motion-controlled games designed for upper-extremity training in children with CP using Kinect2Scratch	13 children with CP; mean age 6.9 years	• Category: computer (PC), motion sensor (Kinect) system: 3 video games in a PC with a screen with a Kinect sensor • Scratch visual programming and Kinect2Scratch software
Kassee et al [45], 2017	To compare a Nintendo Wii intervention to single-joint resistance training for the upper limb	6 children with spastic hemiplegic CP aged 7-12 years	• Category: game Consoles (Nintendo Wii) System: experimental group: Nintendo Wii controllers, and selected games. Control group: TheraBand, Elite band and squeeze ball with a list of exercises.
Kottink et al [46], 2017	To assess the feasibility, in terms of gaming experience, a mixed-reality system for rehabilitation of the arm and hand function	5 children aged 7-12 years with CP and 10 adults aged 30-70 years with stroke or brain injury	• Category: motion sensing (Kinect), computers (PC) • System: HandsOn game—reaching, grasping, and releasing a physical object to control a PC video game using Kinect
Leal et al [47], 2020	To verify if there was any performance improvement in a task performed in a virtual environment and if it is transferable to the real environment	28 children with CP, aged 6-15 years	• Category: motion sensing (Kinect), computers, and smart tangibles (touchscreen) • System: Check Limit Game, pop bubbles with the touchscreen or gestures
Li et al [48], 2009	To assess if a low-cost VR therapy home-based system can promote movements of the hemiplegic upper extremity that the child finds difficult	5 children with CP aged 8 years	• Category: motion sensing (EyeToy) and game console (PlayStation2) • System: VR therapy home-based system that consists of video games (Secret Agent and Mr Chef) for PlayStation2 and controlled with EyeToy
Macintosh et al [49], 2020	To assess the feasibility of an intervention that combines a cocreated gaming technology with biofeedback and coaching	19 children, aged 8-18 years	• Category; wearables (MYO Armband) and computers • System: Dashy Square video game played with the use of electromyography and an MYO armband
Macintosh et al [50], 2022	To describe the design and evaluation of a biofeedback virtual game	9 children	• Category; wearables (MYO armband) and computers • System: Dashy Square video game played with the use of electromyography and an MYO armband
Nai et al [51], 2019	To analyze the use of Vive trackers to estimate forearm axial rotation for the purpose of supporting interaction with serious games	8 healthy participants aged 21-31 years	• Category: motion sensing (HTC Vive trackers) and computers (PC) • System: HTC Vive trackers attached to a wrist bracer to control a serious game system on a PC. One tracker used around the palm and another around the center of the forearm.
Pruna et al [52], 2017	Evaluate the use of a haptic device and VR games in upper limb rehabilitation in children	5 children with mild spasticity, aged 7-12 years; 4 children with Down syndrome and difficulty of movement in upper limbs, aged 9-12 years	• Category: controller (Geomagic Touch) and VR headsets (Oculus Rift) • System: 2 interactive virtual environment games (watering plants and order objects). The haptic device (Geomagic Touch) acquires the movement generated by the user, and an Oculus Rift provides immersion in the use of the system.
Stansfield et al [53], 2015		1 boy aged 10 years	

Study, year	Study		Technology
	Goal	Participants	Category and system
	To further investigate whether improved measures of motor performance will be seen with the use of motion-based VR gameplay		• Category: computers (PC) and wearables (Polhemus Liberty) • System: PC with the Polhemus Liberty tracking sensor, a screen, and a memory game played alone, in cooperation or competition
Tarakci et al [54], 2020	To study the potential efficacy of an 8-week program with the Leap Motion controller-based training as a therapeutic method for upper-extremity rehabilitation in comparison with conventional rehabilitation programs in children with CP, juvenile idiopathic arthritis and brachial plexus birth injury.	Group 1 (CP: n=15; JIA[g]: n=18; and BPBI[h]: n=9). Group II (CP: n=15; JIA: n=25; and BPBI: n=10). Aged 5-17 years.	• Category: motion sensing (Leap Motion) and computers (PC) • System: 2 rehabilitative video games on PC using Leap Motion: Fizyosoft CatchAPet and Fizyosoft Leapball
Winkels et al [9], 2013	To explore the effect of the Nintendo Wii training on upper-extremity function in children with CP	15 children with CP	• Category: game consoles (Nintendo Wii). System: children played the boxing and tennis games provided in the Nintendo Wii Sports video game console.
Yildirim et al [55], 2021	To investigate the effect of leap motion–based exergame therapy	20 children with CP, aged 8-15 years	• Category: motion sensing (Leap Motion) and computers • System: 2 video games controlled with a leap motion. Leap Ball: grab a ball and throw it into a box of matching color. Catch a Pet: touch the moles in a certain order
Zoccolillo et al [56], 2015	To investigate the effectiveness of video game therapy with respect to conventional therapy in improving upper limb motor outcomes	22 children with CP, aged 4-14 years. GMFC[i] between I and IV.	• Category: game consoles (Xbox) and motion sensing (Kinect) • System: a videogame of the console Xbox using the Kinect device for motion capture. Six games available: “Space pops,” “20.000 Leaks,” “Rally Ball,” boxing, volley, and bowling.
Category 3: therapeutic and consumer technology			

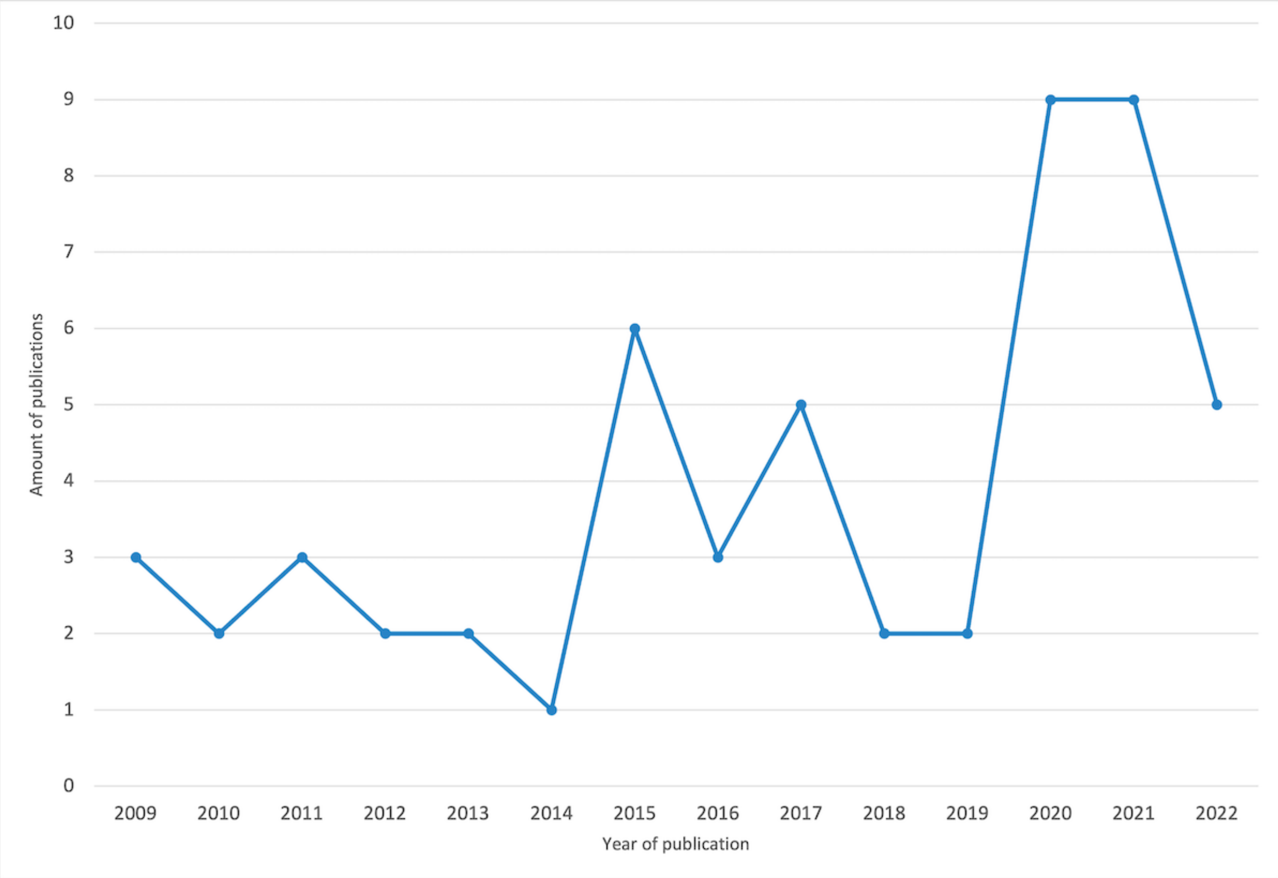
Study, year	Study		Technology
	Goal	Participants	Category and system
Amonkar et al [57], 2022	To evaluate the feasibility of implementation, acceptance, and perceived efficacy of a joystick-operated ride-on-toy intervention to promote upper-extremity function	11 children with CP, aged 3-14 years; 11 caregivers; and 6 clinicians	• Category: joystick ride-on-toy • System: children rode the ride-on-toy (car) navigating with the spastic hand and performing a task throughout the path (collecting objects, throwing balls, and avoiding obstacles)
Bortone et al [58], 2020	To determine the efficacy of immersive virtual environments and wearable haptic devices	8 children with CP or developmental dyspraxia	• Category: wearable (haptic device for the fingertip) and VR headsets (Oculus Rift VK2) System: collecting coins in a VR environment and placing them in a moving piggy bank. Slide a token out of a virtual labyrinth with the finger. Difficulty changes with time.
Choi et al [59], 2021	To investigate the efficacy of a VR rehabilitation system of wearable multi-inertial sensors for upper limb	80 children, aged 3-16 years with brain injury including CP	• Category: wearable (Neofect Smart Kids) and computers • System: games with activities of daily living promoting wrist and forearm articular movements using wearable inertial sensors.
Cifuentes-Zapien et al [60], 2011	To study if a video game can be used as an interface for a robot for the rehabilitation of the pronation and supination movements of children with CP	1 healthy right-handed child aged 11 years.	• Category: computers (PC) and robotics (robotic arm). • System: a PC video game developed for an upper limb rehabilitation robot for children with CP. The video game simulates a formula one race car on a racetrack. The car's horizontal position is controlled by the pronation and supination motions.
Crisco et al [61], 2015	Evaluate play activity recorded by the controller for 2 toys and 3 computer games.	20 children aged 5-11 years	• Category: controller (arm and elbow remote), smart tangibles (smart toy: car and dog), and computers (PC). • System: a specially designed arm and elbow remote controller was used to interface wirelessly with 2 smart toys. • System: A specially designed arm and elbow remote controller was used to interface wirelessly with 3 video games.
Crisco et al [62], 2015	To develop and evaluate the measurement accuracy of innovative, motion-specific play controllers that are engaging rehabilitative devices for enhancing therapy and promoting neural plasticity and functional recovery in children with CP	6 typically developed children (3 male participants and 3 female participants aged 5-11 years)	• Category: controller (arm and elbow remote) and smart tangibles (smart toy: car) • System: the play arm and elbow remote controller was designed with a conformable, ergonomic handle to accommodate varying levels of contractures among children with CP and control a car.
Dunne et al [63], 2010	To describe the hardware platform, present the design objectives derived from iterative design phases and meetings with clinical personnel, and discuss the current game designs and identify areas of future work	Expert clinicians on CP	• Category: wearables (accelerometer) and smart tangibles (multitouch display, tangible objects). • System: 3 games played (Find the bone, Spelling, and Catch the butterflies); the tangible objects control the game in a multitouch display. An accelerometer measures body changes and modifies the game, for example, butterflies fly off the jar.

Study, year	Study		Technology
	Goal	Participants	Category and system
Fu et al [64], 2020	To determine if children could tolerate 9 laboratory treatment sessions and administer up to 7.5 h/wk of CCFES[j] video game therapy at home	3 children aged 8-11 years with hand hemiplegia	• Category: computer, wearables (arm sensors and electrical stimulation electrodes) • System: 4 video games (Paddle Ball, Sound Tracker, Skee-Ball, and Marble Maze)
Hernandez et al [65], 2021	To explore the effectiveness of interactive computer play with haptic feedback	13 children with CP, aged 7-16 years	• Category: controllers (Novint Falcon and Custom levers) and computers • System: 4 commercial video games to train wrist movement: Crazy Rider, Swooop, Funky Karts, and Lil Mads and the Gold Skull. 5 video games to train elbow and shoulder movement: Looney Tunes Dash, Heroes of Loot, Bird Brawl, Pac-Man, and Save the Day.
Minh et al [66], 2021	To test a design of 2 interactive toys and an open game	4 children with CP, aged 2-3 years	• Category: computers and smart tangibles (smart toys) • System: a stuffed stick toy with a 6-DOF inertial measurement unit (IMU) and force sensor–incorporated gloves to squeeze a ball used to play “Catch the worms in the garden”
Mirich et al [67], 2021	To assess the efficacy of VR rehabilitation	1 child aged 4 years	• Category: wearables (Neofect Smart Kids) and computers • System: a functional activity game with different activities such as turn pages, painting, wiping a table, and playing ping pong selected based on the needs of the patient
Mittag et al [68], 2020	To present the design and implementation of a tangible device for hand training	N/A	• Category: wearables (arm sensors) and computers • System: a video game controlled by the sensors and interactions with the tangible controller.
Parmar et al [69], 2021	To improve rehabilitation programs for children and adults with neurodevelopmental disorders in a game-based telerehabilitation.	6 children with CP; 10 adults recovering from a stroke	• Category: wearables (motion therapy mouse) and computers • System: the motion mouse is attached to different objects such as a ball, to control movement in a commercial video game (Big Fish Game).
Peper et al [70], 2013	To examine the potential effects of the training on bimanual coordination and identify if the training had beneficial effects on the affected arm’s performance	6 children with CP aged 7-12 years	• Category: controller (custom levers) and computers (laptop) • System: 2 horizontal levers, a laptop computer, and an additional monitor. Left-hand movements produce vertical displacements, and right-hand movements produce horizontal displacements.
Preston et al [71], 2016	To study the feasibility of using computer-assisted arm rehabilitation computer games in schools, their preference for single player or dual player mode, and changes in arm activity and kinematics	9 boys and 2 girls with CP aged 6-12 years; mean age 9 years	• Category: robotics (robotic arm) and computers (PC) • System: an assistive robotic arm connected to a computer with cooperative and competitive games
Psychouli et al [72], 2017		Non-CP children and 3 groups of CP children (CIMT, RT[l], and CIMT+RT), aged 5-11 years	

Study, year	Study		Technology
	Goal	Participants	Category and system
	To propose a system that can enhance children's motivation during the implementation of a CIMT[k] session and that could explore differences in compliance rates, motivation levels, and intervention feasibility		• Category: wearables (arm sensors) and smart tangibles (smart toys) • System: arm and hand with sensors (accelerometer, magnetometer, gyroscope for upper and lower arm, and flex sensors on the wrist and fingers) that control the 4-wheeled robotic vehicle (DFRobot Cherokee)
Sabry et al [73], 2020	To develop a low-cost VR rehabilitation system with a data glove and virtual games	8 children with CP, aged 5-12 years	• Category: wearables (data glove) and computers • System: a data glove is used to play video games: "Grasp the ball"
Stroppini et al [74], 2022	To determine the feasibility and efficacy of the MusicGlove to motivate hand function	3 children with hemiparetic CP, aged 6-17 years	• Category: wearables (MusicGlove) and computers • System: a video game is controlled with the glove. The patients tap their fingers to make musical notes according to the notes that show up on the screen.
van Loon et al [75], 2011	To test a set of video games, developed to loosen the coupling between the hands of children with CP	7 children with spastic unilateral CP, aged 7-12 years	• Category: controller (custom levers) and computer (PC) system: 3 computer games that challenged the participants to move their hands according to 6 different bimanual coordination patterns executed with custom levers.
Weightman et al [76], 2011	To compare upper limb kinematics of children with CP using a passive rehabilitation joystick with adults and able-bodied children to better understand the design requirements of computer-based rehabilitation devices	9 adults (aged 23-30 years), 9 children (aged 7-9 years), and 7 children with CP (aged 5.5-7 years)	• Category: a controller (joystick) and computers (PC) • System: a computer game in which the child controlled a "spaceship" collecting "satellites" with the use of a joystick.

[a]IREX: immersive rehabilitation exercise.
[b]CP: cerebral palsy.
[c]RFID: radio frequency identification.
[d]VR: virtual reality.
[e]API: application programming interface.
[f]N/A: not applicable.
[g]JIA: juvenile idiopathic arthritis.
[h]BPBI: brachial plexus birth injury.
[i]GMFC: gross motor function classification.
[j]CCFES: contralaterally controlled functional electrical stimulation.
[k]CIMT: constraint-induced movement therapy.
[l]RT: robot-assisted therapy.

Figure 2. Publications per year.



Innovative Assistive Technology

The authors identified 2 ways to classify the innovative assistive technologies used in the analyzed studies: the original purpose of the technology and the type of hardware.

Original Purpose of the Technology

This first type of classification refers to therapeutic-specific technology, consumer technology, and the combination of therapeutic and consumer technology. Table 1 shows the details of the studies per category. Therapeutic-specific technology was developed for the sole purpose of being used in hand therapy and has been used in 5 studies. An example of this type of technology is the immersive rehabilitation exercise, which is a video gesture control technology that allows patients to be immersed in a video game where users can exercise by interacting with the elements of the game [25]. Consumer technology is a commercially available technology used in entertainment or other fields but that has been modified to be used in hand therapy, consumer technology was used in 29 studies. The authors of the included studies identified this type of technology as potentially beneficial and motivating because of its existing functionalities, interactions, familiarity, and lower costs [54]. For example, Acar et al [29] investigated the efficiency of Nintendo Wii games together with neurodevelopmental treatment in patients with CP. They analyzed “out-of-the-box” games, such as tennis, baseball, and boxing, focusing on the upper extremities. In addition to the observed improvements in speed and functional independence, the children perceived the use of the Nintendo Wii as a reward.

The rest of the studies (20 in total) made use of a combination of therapeutic-specific technology and consumer technology; an example is presented in the studies by Golomb et al [38,39], where custom games were developed to be used with the PlayStation 3 console (consumer technology) in combination with the 5DT Ultra sensing glove (therapeutic-specific technology). The games encouraged hand movements such as opening and closing or thumb extension; speed was also trained by challenging the player to chase a butterfly by flexing or extending the fingers rapidly.

Types of Hardware

This second type of classification refers to a more general category of hardware or technologies, such as VR headsets, game consoles, wearables, motion sensing, controllers, smart tangibles, and robotics (Table 2). When analyzing the types of hardware, it was found that the most common technologies used were computers (32/54, 59%), as they were often used to deploy a video game and to connect with other types of technology. Wearables were one of the most used technologies (19/54, 35%); wearables are continuously in close contact with the body to capture the movement of the hand or arm while they can provide direct haptic feedback. Some of these technologies include gloves such as 5DT Ultra sensing gloves, the Neofect Smart Kids, the Data glove, and the Music glove. Smart tangibles were used in 15 studies, including smart toys such as the TagTile, a device similar to an electronic board game [27], and the dancing dinosaur Pleo! Dance! [41]. Motion-sensing technology was also frequently used (14/54, 25%); a device that belongs to this category is the Kinect, which was used in the studies by Hung et al [44], Kottink et al [46], and Zoccolillo et al [56] because of its ability to capture the upper extremities and movements of the users from a distance. Another widely used type of hardware was controllers (11/54, 11%), for example, the Novint Falcon, a haptic device that acts as a controller similar to a computer mouse but with a shape that allows for higher degrees of freedom. This device, which allows for resistive force feedback on the spastic hand, was used by Elsaeh et al [35] and Hernández et al, [42,65], where limitations of movements and direction are adapted to the interactions needed in the virtual games used and the possibilities of the spastic hand. The full list of types of hardware used in the studies can be found in the Multimedia Appendix 3 [9,24-76]. Some studies focused on using only one type of innovative assistive technology. In contrast, most studies (43/54, 80%) used a combination of ≥1 type, such as PCs with robotic arms [60], smart toys with an arm and elbow remote controller and a PC [61], wearables and smart tangibles [63], and custom levers with a PC [75]. The complete list of studies that used a combination of different types of hardware is provided in Multimedia Appendix 4 [27,30,31,33,35-39,41,42,44,46-76].

Table 2. Technology classification based on type of hardware.

Type of hardware and name	Value, n (%)
Computers (n=32)	
PC	26 (81)
Laptop	4 (17)
Tablet	2 (6)
Controllers (n=11)	
Custom levers	3 (27)
Geomagic Touch	1 (9)
Joystick	2 (18)
Motion Therapy mouse	1 (9)
Novint Falcon	3 (27)
Wii Nunchuk	1 (9)
Game consoles (n=11)	
Nintendo Wii	6 (55)
PlayStation	4 (36)
Xbox	1 (9)
Motion sensing (n=14)	
EyeToy	1 (7)
HTC Vive trackers	1 (7)
IREX[a]	1 (7)
Kinect	6 (43)
Leap Motion	5 (36)
Robotics (n=2)	
Robotic arm	2 (100)
Smart tangibles (n=15)	
Interactive Story Box	1 (7)
Lego Mindstorms NXT	1 (7)
Multitouch display	2 (13)
Pleo!	1 (7)
PhysiTable	1 (7)
Ride-on-toy	1 (7)
Smart blocks	1 (7)
Smart toys	5 (33)
TagTiles	1 (7)
Tangible objects	1 (7)
VR[b] headsets (n=2)	
Oculus Rift	2 (100)
Wearables (n=19)	
5DT sensing gloves	2 (10)
Accelerometer	1 (5)
Arm and elbow remote	2 (10)
Arm sensors	4 (21)

Type of hardware and name	Value, n (%)
Electrical stimulation electrodes	1 (5)
Data glove	1 (5)
Mindwave	2 (10)
Music glove	1 (5)
MYO Armband	2 (10)
Neofect Smart Kids	2 (10)
Polhemus Liberty	1 (5)

[a]IREX: immersive rehabilitation exercise.
[b]VR: virtual reality.

Lenses of Play

Overview

Bekker et al [11] defined the Lenses of Play as a toolkit that includes different perspectives on play that can inform design decisions throughout the design process. Initially, 4 lenses were defined: *Open-ended Play*, *Forms of Play*, *Stages of playful interactions*, and *Playful experiences*. In a later publication, Bekker et al [77] introduced a fifth lens, *Emergence*, which relates to the system's perspective and how it can provide meaningful interactions. This analysis focuses on the *Open-ended Play*, *Forms of Play*, and *Playful experiences* (Figure 3) lenses, and the *Stages of playful interactions* and *Emergence* lenses have been omitted because little information was provided about these aspects of play in the studies included in this review. It was possible to identify the playful elements used in the proposed interventions for the other lenses (Table 3).

Figure 3. Lenses of Play; the size of the circles represents the frequency of use of the play element in the publications.

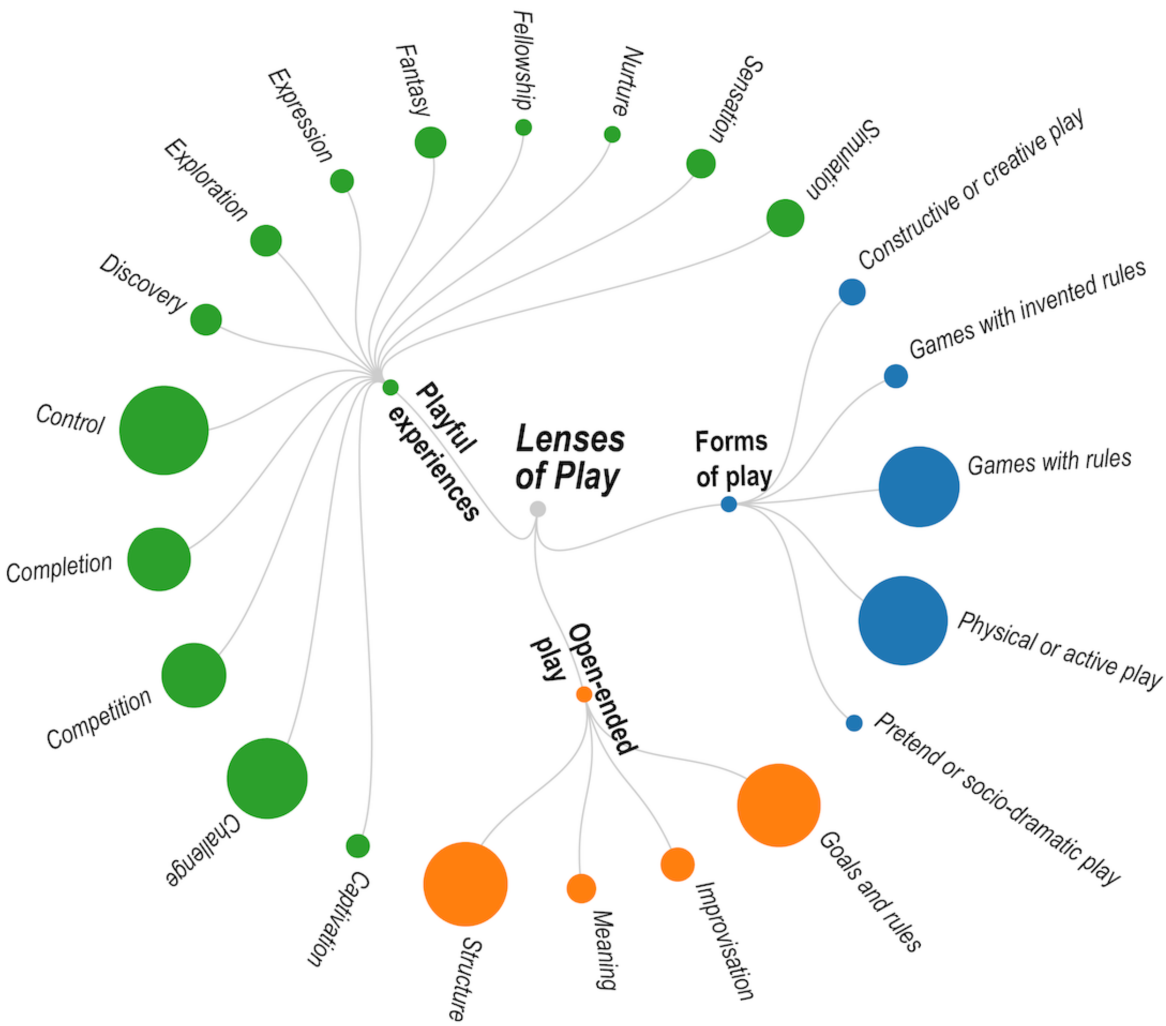


Table 3. Summary of analyzed studies by Lenses of Play.

Lens and play element	Categories		
	Therapeutic-specific technology	Consumer technology	Therapeutic and consumer technology
Open-ended Play			
Improvisation	[24]	[41,43]	[57,61,62,67,72]
Structure	[25-28]	[9,29-40,42,44-56]	[57-61,63-71,73-76]
Goals and rules	[25-28]	[9,29-40,42,44-56]	[57,58,60-65,67-71,73-76]
Meaning	[24]	[41,43,52]	[61,72]
Forms of Play			
Constructive or creative play	[24,28]	[41,43]	[74]
Pretend or sociodramatic play	—[a]	[41,43]	—
Physical or active play	[24-28]	[9,29-56]	[57-76]
Games with rules	[25-27]	[9,29-40,42,44-52,54-56]	[57-61,63-65,68-71,73-76]
Games with invented rules	—	[28]	[61,62,72]
Playful experiences			
Captivation	[28]	[41,43,52]	
Challenge	[25-27]	[9,29-39,42,44-56]	[57-61,63,64,67-76]
Competition	[24-27]	[9,29-34,40,42,44,45,47,48,51,53,55,56]	[58,61,63-65,67-71,74]
Completion	[26-28]	[30,31,35-37,40,47,49-53,55]	[57-59,64-67,69,71,74-76]
Control	[24-28]	[9,29-56]	[57-76]
Discovery	[24,28]	[33,43]	[61,62,72]
Exploration	[24,26]	[33,41,43,46]	[61]
Expression	[24]	[41,43]	[72]
Fantasy	[28]	[41-44]	[70,76]
Fellowship	—	[53]	[71]
Nurture	—	[41]	[70]
Sensation	—	[35,42]	[58,59,72,74]
Simulation	—	[35,40,42,44,45,48,56]	[60,63,74]

[a]No articles in this category make use of this play element.

Lens 1: Open-Ended Play

According to Bekker et al [11], “Open-ended play can be positioned somewhere between paidia and ludus.” In paidia or free play, there is no end goal; it is chaotic, and there is space for improvisation and spontaneity, allowing for expression, meaning, and playing for its sensation. At the same time, ludus refers to games with fixed rules, structure, end goals, and challenge or competition. The *Open-ended Play* lens refers to the 4 properties that characterize paidia and ludus: improvisation, structure, goals and rules, and meaning, as defined by de Valk et al [78]. Players can create their own game during *improvisation* without preparation, whereas *structure* leaves little room for chaos or spontaneity in a game. If *goals and rules* have been defined, the game will have a finite status with a fixed process. Finally, players can add *meaning* to the interaction possibilities that the designers have established.

As shown in Table 3, most interventions presented in the articles have characteristics that refer to ludus, a structured form of play (49/54, 90%) with defined goals and rules (48/54, 88%). In contrast, elements that refer to paidia, such as improvisation (8/54, 15%) and meaning (6/54, 11%), were found in fewer studies. For example, Dunne et al [63] used 3 video games—Find the bone, Spelling, and Catch the butterflies—on a multitouch screen where tangible objects are used to play the games. An accelerometer measures body changes that indicate changes in inclination and use of compensatory movements. Changes in body posture modify the game, for example, butterflies fly off the jar. The 3 games have a clear structure and set of rules (ludus) that the player must comply with to reach a goal, such as catching all the butterflies inside a jar.

In contrast, Crisco et al [61] proposed a system where a robotic car and a robotic dog were controlled using a play controller. Children can play with the toys by performing different wrist motions in this system. There is no set of rules (paidia) besides the type of movements the controller allows. The interaction with the toys is not fixed and can rapidly change according to the children's interests (improvisation and meaning).

Lens 2: Forms of Play

This lens refers to children's development of skills through different forms of play. There are 4 primary forms of play according to Bekker et al [11]; a description of the forms is provided in Table 4. All the analyzed papers refer to an intervention with a physical or active form of play as they all aim to provide physical therapy for the players. Most interventions also presented games with rules (45/54, 83%); the only interventions that did not have games with rules were those that had more of an open-play approach assisted with a toy for example [24,28,41,61,62]. The intervention proposed by Gregory et al [41] contains 3 forms of play, constructive or creative play, pretend or sociodramatic play, and physical active play, where the player interacts with Pleo! Dance! the dinosaur and teaches it to dance using a remote control.

Table 4. Properties of Play Lens 2: Forms of Play.

Forms of play	Description [11]
Constructive or creative play	Creating and constructing something from objects.
Pretend or sociodramatic play	Acting out roles, often using toys and props.
Physical or active play	Sensory motor play with objects. In preschool years, this may involve rough-and-tumble play. Older children engage in play with a more vigorous component to test strengths and skills.
Games with rules	Playing games in social groups with fixed predetermined rules
Games with invented rules	Playing games with modified or rule sets invented

Lens 4: Playful Experiences

According to the Play Lens 4: *Playful experiences*, there are 20 different types of playful experiences: captivation, challenge, competition, completion, control, discovery, eroticism, exploration, expression, fantasy, fellowship, nurture, relaxation, sadism, sensation, simulation, subversion, suffering, sympathy, and thrill. We identified 13 out of the 20 playful experiences in the included studies, as described in Table 5. Control was the most used playful experience (the complete summary can be seen in Table 3). Control could be found in interventions that relied on structure and rules and in those with a more open-play form. For example, the study by Gregory et al [41] consisted of playing and teaching a dinosaur to dance, where playful experiences of captivation, control, exploration, expression, fantasy, and nurture could be found. At the same time, other interventions relied on more competitive (29/54, 54%) and challenging (45/54, 83%) experiences against avatars in the system, another player, or oneself, similar to those in Wii Sports [9,29,30,32,34,45].

Table 5. Properties of Play Lens 4: Playful experiences.

Type of Playful experiences	Description
Captivation	Experience of forgetting one's surroundings
Challenge	Experience of having to develop and exercise skills in a challenging situation
Competition	Experience of victory-oriented competition against oneself, opponent, or system
Completion	Experience of completion, finishing and closure, in relation to an earlier task or tension
Control	Experience power, mastery, control, or virtuosity
Discovery	Experience of discovering a new solution, place, or property
Exploration	Experience of exploring or investigating a world, affordance, puzzle, or situation
Expression	Experience of creating something or expressing oneself in a creative fashion
Fantasy	Experience of make-believe involving fantastical narratives, worlds, or characters
Fellowship	Experience of friendship, fellowship, communality, or intimacy
Nurture	Experience of nurturing, grooming or caretaking
Sensation	Meaningful sensory experience
Simulation	Experience of perceiving a representation of everyday life

Discussion

Principal Findings

This scoping review aimed to provide an overview of the innovative technologies used in hand therapies for children with CP and to identify the playful elements used in such interventions. The 54 analyzed studies showed that therapists and researchers are investigating a broad diversity of technology combined with play to make therapy more pleasant, engaging, and effective for children and to overcome some of the challenges and needs encountered in hand therapy such as the lack of personalization; monitoring of progress; high cost of devices; and the need for tailored feedback, increased adherence, and motivation.

The results of this study show high use of consumer technologies such as the Nintendo Wii, PlayStation, Leap Motion, and several smart toys, to name a few, as a response to the need for financially accessible technology for therapy. This can help lower the therapy costs while allowing to practice in different contexts, such as at home or at school. In addition, considering the familiarity and interest children already have with these types of technology, they could be more easily accepted and adopted. Another important finding was the variety of technologies used; we identified at least 41 different devices. These devices come with a diversity of characteristics such as motion tracking (Kinect, Leap Motion, immersive rehabilitation exercise, etc) and haptic feedback (smart tangibles, TagTiles, Geomagic Touch, controllers, etc) or can be more general support systems (PC, laptop, and game consoles) that can easily be used to deploy a video game. Interestingly, 80% (43/54) of the studies used a combination of hardware; for example, de Oliveira et al [33] used Leap Motion in combination with Mindwave and custom software developed for the explicit purpose of therapy. The combination of commercial and custom hardware brings together the strengths of a robust technology that requires low technical support and can be used at home without extensive financial burden, with the requirements that specific treatments can bring.

From our analysis of play elements, we see different approaches to how play has been implemented and the type of technology used to enhance motivation and adherence: via video games, where the participants had to execute an action with their hands to advance in the game, and via toys or other types of tangible devices that allowed for a more open form of interaction to engage the user while performing the exercises. The findings show that under Play Lens 1: *Open-end Play*, “structure” and “games and rules” were most used in video games. The opposite can be observed in games with toy-like tangibles such as Pleo [41], TagTiles [27], Lego Mindstorm [43], and PhysiTable [26], which allow for a more open-play approach, where there is a structure of the game in terms of narrative. Yet, there is plenty of space for the players to explore and create their own rules, adding space for improvisation and meaning. Although not all the studies reported on motivation and improvement of skills, those that did showed that play has a vital role in motivating children to do their therapy while helping them improve their motor skills. This further supports the idea that *play* is a valuable factor in therapy because it appeals to children. Once they are in a state of flow or immersion in the game, they can perform different hand movements with repetition without becoming burdensome. Moreover, they can share their experience and create bonds through play with other children and family members.

One anticipated finding was that all the studies fit into the Play Lens 2: *Form of Play*, “physical or active play,” which refers to sensory motor play with objects and the test of strength and skills, which is paramount in physical therapy. Furthermore, there should be a flexibility in this “physical or active play” to be personalized to the skill level of children with CP and the use of technology can provide this personalization through the use of sensors and intelligent systems. The other *Form of Play* that was identified the most was “games with rules,” where participants often encounter a predefined goal and a clear set of rules that they had to comply with to play the game. Control (54/54, 100%) and challenge (45/54, 83%) were the most commonly used Play Lens 4: *Playful experiences*. They are often characteristics of video games and are also found in traditional therapy with toys guided by a therapist. The commonality of these approaches is that the participant had to accomplish a task by controlling an object in the virtual environment or a physical object. This control was strongly linked with the exercise that had to be performed with the spastic hand. In the case of therapy at home, it is challenging to achieve the guidance that therapists provide, but the use of technology can help solve this problem [31].

Design New Therapies Supported by Innovative Technology and Play

From this analysis, we cannot draw strict conclusions regarding the impact of using one technology over another. We are also left with questions on how best to use open play or games with goals (Play Lens 1) and how to choose a specific play experience (Play Lens 4). Nonetheless, the playful elements and technology inventory gathered here can be a starting point for designers, researchers, and clinicians who wish to develop new interventions for children with CP. Researchers and designers should first be aware of the consequences and affordances of using one specific technology and the type of play they want to provide with the intervention. The analyzed interventions present toys and video games that offer different types of play and play experiences with their advantages and disadvantages. Although commercially available video games can be easier to develop and access, they might not fit the child’s specific level of disability.

In some cases, combining such technology with specialized software can provide better training. In contrast, toys can provide haptic feedback, allow object manipulation with both hands, and provide more freedom in the type of play, giving room for creativity. When designing new interventions, it is essential to consider certain aspects such as the type of play experience, level of challenge, competition, and physical activity. This kind of play experience could be games with rules or open play. The level of challenge should not frustrate the child but keep them motivated. With competition, we can provide the possibility to compete against themselves or someone else.

Further research can include comparing the effectiveness of different play strategies (for motivation and improvement of motor skills) and designing new interventions that use smart toys or other physical and digital play tangibles to broaden the knowledge base. Another interesting area of focus would be to study in more depth how hand therapy for children with CP can benefit from using new technologies, including artificial intelligence. The possibilities of using artificial intelligence in this area are broad; four examples are as follows: (1) the application of artificial intelligence for personalization (tailored to the skills of the user), (2) adaptive play complexity (changing complexity depending on the progress made in therapy or skills),

(3) balanced play (the skills of different participants are leveled out), and (4) the use of data to help the therapists and caregivers to provide adequate support to the patients or create competition within a community to develop a shared experience. Many opportunities can make the experience of hand therapy more entertaining for children, and the combination of technology and play is a direction that can help achieve this.

Strengths and Limitations

This paper provides a comprehensive review of the current state of hand therapy for children with CP, with a focus on the use of innovative technologies and playful elements. With this review, we have synthesized a wide range of the literature and identified key technologies and approaches in the field. We are also proposing a novel approach by including the Lenses of Play to analyze and understand the application of playful elements in technology-supported hand therapy. This framework provides a new perspective on play and offers a diverse set of elements that can inform the design of new therapies.

We acknowledge that this scoping review has limitations, and first is the lack of details of the interventions. The Lenses of Play allowed us to examine the papers from different perspectives. However, because the main goal of the research papers was to study the effectiveness of the interventions or propose new types of interventions, they did not contain a complete description of all the features of the games or toys, their design process, and the play experience. This could have added bias because we relied on the limited information provided in the studies and on the experience and knowledge of our team and the publicly available information of some of the technologies. Another limitation is the lack of scientific publications on other games, toys, and commercially available technology that therapists include in their program. A further limitation is that we only included studies written in English, excluding studies published in other languages.

Conclusions

With this scoping review, we found that the role of play in the interventions that use innovative technologies in hand therapy for children with CP is to create an enjoyable activity for children that can also help them improve their motor skills. We have provided an overview of how and which technologies are available and which playful elements are part of the interventions. Currently, the field shows diverging strategies and a variety of playful experiences that are supported by technology. Whether via a video game or a toy, with rules and structure, or open play, repetition becomes fun and engaging. While playing, children enjoy the activity and forget that they are performing repetitive hand movements. Technology is an appealing medium to support play; it provides advantages such as measuring hand and arm movement and integrating them in the interaction with the games. In addition, it has functionalities for personalization according to the degree of spasticity of the child and their personal preferences. Technology can also provide feedback to guide the therapy and the game and improve the play experience while collecting valuable data for the therapists, the caregivers, and the children. The implementation of personalized and adaptive therapies in the home or school environment can help relieve the workload on the caregivers and rehabilitation centers. Together with play, innovative, assistive technologies provide an intrinsic incentive to exercise and continue with therapy.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search queries.
[DOCX File , 13 KB - games_v11i1e44904_app1.docx]

Multimedia Appendix 2
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.
[DOC File , 50 KB - games_v11i1e44904_app2.doc]

Multimedia Appendix 3
Types of hardware and studies.
[DOC File , 491 KB - games_v11i1e44904_app3.doc]

Multimedia Appendix 4
Studies that use a combination of different types of hardware.
[DOC File , 208 KB - games_v11i1e44904_app4.doc]

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Abbreviations

CP: cerebral palsy
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
VR: virtual reality

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Original Paper

Effects of Commercial Exergames and Conventional Exercises on Improving Executive Functions in Children and Adolescents: Meta-Analysis of Randomized Controlled Trials

Jinlong Wu[1*], MA; Zhuang Xu[1*], MA; Haowei Liu[1], MA; Xiaoke Chen[2], MA; Li Huang[1], MA; Qiuqiong Shi[3], PhD; Linman Weng[4], MA; Yemeng Ji[1], MA; Hao Zeng[5], MA; Li Peng[1], PhD

[1]College of Physical Education, Southwest University, Chongqing, China
[2]Department of Physical Education, Tsinghua University, Beijing, China
[3]Laboratory for Artificial Intelligence in Design, Hong Kong, China
[4]Faculty of Psychology, Southwest University, Chongqing, China
[5]College of Physical Education, Nanchang University, Nanchang, China
[*]these authors contributed equally

Corresponding Author:
Li Peng, PhD
College of Physical Education
Southwest University
2 Tiansheng Road, Beibei District
Chongqing
China
Phone: 86 13699878189
Email: 804455169@qq.com

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Abstract

Background: Exergames are promising exercise tools for improving health. To the best of our knowledge, no systematic review has compared the effects of commercial exergames and conventional exercises on improving executive functions (EFs) in children and adolescents.

Objective: This study aimed to investigate the effects of commercial exergames and conventional exercises on improving EFs in children and adolescents.

Methods: Following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, 5 randomized controlled trial (RCT) databases (PubMed, Web of Science, Scopus, PsycINFO, and SPORTDiscus) were searched from their inception to July 7, 2022, to identify relevant RCTs. The Cochrane Collaboration tool was used to evaluate the risk of bias for each study. GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) was used to evaluate the overall quality of evidence.

Results: In total, 8 RCTs including 435 children and adolescents were included in the analysis. Commercial exergames had no significant benefit on overall EFs compared to conventional exercises (Hedges g=1.464, 95% CI –0.352 to 3.280; P=.06). For core EFs, there was no evidence to suggest that commercial exergames are more beneficial for improving cognitive flexibility (g=0.906, 95% CI –0.274 to 2.086; P=.13), inhibitory control (g=1.323, 95% CI –0.398 to 3.044; P=.13), or working memory (g=2.420, 95% CI –1.199 to 6.038; P=.19) than conventional exercises. We rated the evidence for overall EFs, cognitive flexibility, inhibitory control, and working memory as being of very low quality due to inconsistency (large heterogeneity) and imprecision (low number of people). Additionally, no effects of the intervention were observed in the acute and chronic groups.

Conclusions: We do not have strong evidence to support the benefit of commercial exergaming on EFs because we did not observe a Hedges g close to 0 with tight CIs. Further research is needed to confirm this hypothesis.

Trial Registration: PROSPERO CRD42022324111; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=324111

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KEYWORDS

commercial exergames; exergame; randomized controlled trial; RCT; conventional exercises; executive function; children; adolescent; pediatric; youth; exergaming; randomized; meta-analysis; meta analyses; review method; systematic review

Introduction

Background

Executive functions (EFs) are top-down cognitive processes that control and regulate other cognitive processes while performing intricate cognitive tasks [1]. EFs include 3 core functions, namely, inhibitory control, working memory, and cognitive flexibility [2]. Studies have found that EFs are closely associated with mental health [3,4], academic performance [5], and sleep quality [6] in children and adolescents.

It is well-established that adequate and regular exercise can improve EFs in healthy children and adolescents [7,8]. Exergames (or active video games) are emerging and promising technology-based exercise programs that refer to movement-based interactive video games requiring whole-body exercise [9-11]. Common exergames include Wii Fit, Xbox Kinect, Wii Sports, and Dance Dance Revolution [12]; these exergames platforms and devices comprise a class of commercial exergames [13]. These commercial exergames can increase motivation and engagement from users [14-16] due to their special challenge and interest in games and aim to encourage users to exercise [17]. Commercial exergames have recently become a popular exercise activity with which children and adolescents spend their spare time [18,19]. Previous findings have demonstrated the potential benefits of commercial exergames for both physical health (eg, improving muscle strength [20], balance [21], and cardiopulmonary function [22,23]) and mental health (eg, improving mood states [24], self-esteem [25], and self-efficacy [25]) in children and adolescents.

One systematic review showed that commercial exergames can improve cognitive skills (eg, EFs) in children and adolescents [26]. The main reason that commercial exergames have a positive effect on EFs is that they include several games related to cognitive challenges [26]. However, because the systematic review used passive controls in their comparisons, which hindered the evaluation of the effectiveness of commercial exergames compared to traditional methods, it is still not clear whether exergames offer more advantages for improving EFs than do conventional exercises. Another study performed a meta-analysis to compare the effects of commercial exergames and conventional exercises on the cognitive skills of older adults, and the results did not find that commercial exergames offered better benefits for improving EFs (assessed, for example, using the Stroop task) than conventional exercises [16].

Objective

To our knowledge, no systematic reviews have compared the effects of commercial exergames and conventional exercises on improving EFs in children and adolescents. This knowledge gap needs to be filled because younger participants have a close affinity for commercial exergames and are also the main beneficiary group [27]. There could be a role for exergames in improving EFs when children (eg, those with neurodevelopmental disorders) are unable or less inclined to engage in conventional exercise. Therefore, this meta-analysis aimed to compare the effects of commercial exergames and conventional physical activity on EFs in children and adolescents.

Methods

Design

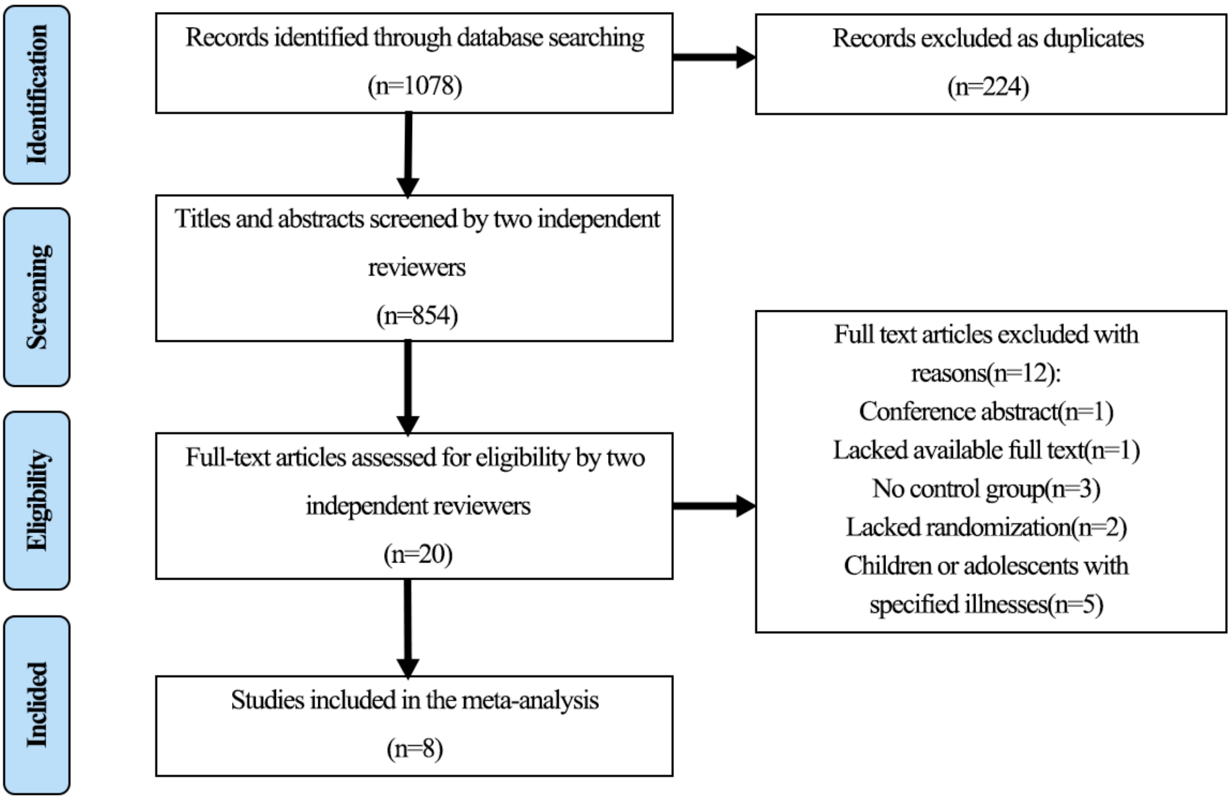
This meta-analysis was performed in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement and its accompanying checklist [28] and was registered with PROSPERO (CRD42022324111).

Study Identification

We searched 5 databases, including PubMed, Web of Science, Scopus, PsycINFO, and SPORTDiscus, for randomized controlled trial (RCT) studies published in English from inception until July 7, 2022, to identify all relevant published articles regarding the effect of exergames on EFs in children and adolescents. The initial search was performed using the following 3 key terms: child/adolescent, exergame, and executive functions. A detailed keyword search strategy can be found in Multimedia Appendix 1. The search keywords for each main term were developed from the search strategies of previous reviews related to commercial exergames, EFs, and children or adolescents [1,29]. Additional literature was identified by searching and reviewing the reference lists of relevant studies.

A total of 1078 records were retrieved from all databases. After removing duplicates and screening titles and abstracts, 854 records were analyzed for eligibility. After full-text screening, 13 articles met the inclusion criteria and were included in this systematic review, and 8 articles were included in the meta-analysis. The article screening process is illustrated in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) study selection diagram.



Eligibility Criteria

All inclusion criteria followed the PICOS (Participants, Interventions, Comparators, Outcomes, and Study design) framework and included the following criteria: (1) studies that targeted children and adolescents up to 18 years of age [28], (2) the primary intervention was exergames with any modality and the control group underwent conventional exercises, (3) the outcomes involved cognitive performance assessments of overall or core (ie, inhibitory control, cognitive flexibility, and working memory) EFs assessed using questionnaires or computer tasks, and (4) the study design was an RCT published in English in a peer-reviewed journal.

Study Selection and Data Extraction

Two researchers independently scanned the titles and abstracts, and studies that satisfied the inclusion criteria were retrieved for full-text assessment. Differences between the two researchers were resolved through discussion. If an agreement could not be reached, the final decision was made through discussion with a third researcher. The data were independently extracted by two researchers. The extracted data were related to the document characteristics (first author, publication year, and country or region), participant description (number and age of participants), details of the interventions (exergame group and conventional exercise group), and outcomes measured. If there were multiple control groups in one study, only the data for the control group receiving the conventional exercise were extracted.

Risk of Bias

We used the revised risk of bias tool described in the Cochrane Handbook version 5.1.0 [30] to categorize the risk of bias of each study, which includes 7 domains, namely, sequence generation, allocation concealment, blinding of assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. The items were rated as having a low, unclear, or high risk of bias. Based on the risk of bias in the individual domains, studies were classified as having a low, unclear, or high risk of bias. Disagreements regarding the risk of bias were resolved by discussion or by consulting a third researcher. The risk of bias for blinding of the outcome assessment was based on the method of outcome assessment (objective or subjective).

Quality of Evidence

GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) was used to evaluate the quality of evidence [31]. GRADE includes 5 subtraction items, namely, risk of bias, inconsistency, indirect evidence, imprecision, and publication bias. According to the results, the quality of evidence was divided into 4 categories: high, medium, low, and very low. In the GRADE evaluation, there was no evidence of a downgrade to high quality, 1 item was downgraded to medium quality, 2 items were downgraded to low quality, and 3 or more items were downgraded to very low quality. The GRADE assessments were applied independently by two reviewers to judge the certainty of the evidence. If there were disagreements, an experienced researcher made the decision [32].

Data Analysis

All analyses were implemented using Comprehensive Meta-Analysis version 3 (Biostat). Specifically, when different instruments were used to measure outcome variables, the effect size in each study was calculated using Hedges *g* with 95% CIs between the groups. Hedges *g* was calculated and weighted through inverse variance, thereby accounting for the respective sample sizes, varying outcomes, and cognitive measures [33]. The magnitude of Hedges *g* values was interpreted as trivial ($g<0.2$), small ($0.2<g<0.5$), moderate ($0.5<g<0.8$), and large ($g>0.8$) effect sizes. Heterogeneity across studies was evaluated and graded using the I^2 statistic (very low: $I^2<25\%$; low: $25\%<I^2<50\%$; moderate: $50\%<I^2<75\%$; and high: $I^2\geq75\%$) [34]. If $I^2\leq50\%$, the research results were considered homogeneous, and a fixed model was used for the meta-analysis. If $I^2>50\%$, then there was heterogeneity among the research results, and a random model was used for the meta-analysis [34]. In addition, the influence of each study on the pooled effect size estimates was examined using a sensitivity analysis. A sensitivity analysis (ie, wherein 1 study was removed) was used to inspect the impact of the retention or removal of outliers and their influence on the overall effect size. As fewer than 10 studies were included in each analysis, publication bias was not investigated. After conducting a meta-analysis for overall EFs, subgroup analyses were performed based on the 3 specific EF domains (inhibitory control, working memory, and cognitive flexibility).

Additional statistical analyses included the following: (1) when studies used ≥2 tests to measure the same variable, the average effect size was calculated; (2) when studies reported ≥2 measurements, only the last measurement was considered; and (3) for studies that reported multiple results on one cognitive task, the result of the more executive demanding condition was included (eg, incongruent trials in the Stroop task) [35].

Results

Descriptive Characteristics

Table 1 summarizes the characteristics of the included studies. In total, we analyzed 8 RCT studies [36-42] involving 435 children and adolescents that investigated the difference in effect between commercial exergames and conventional exercises on improving the EFs of healthy children and adolescents. All included studies were published in peer-reviewed English journals. The trials were conducted in the United States (n=4) [37,38,40,41], China (n=3) [39,42,43], and Spain (n=1) [36]. In all studies, the intervention involved the use of commercial exergames to improve EFs. The exergames devices used included Nintendo Wii (n=4) [37,38,42,43], Xbox Kinect (n=3) [36,39,41], and LeapTV console (n=1) [40]. All participants in the control group underwent conventional exercises. There were 2 acute [36,37] and 6 chronic [38-43] interventions. For the 2 acute exergames interventions, the lengths of the single intervention sessions were 15 and 20 minutes. For the chronic exergames intervention, the intervention durations ranged from 4 to 8 weeks, with a frequency between 1 and 5 times per week. The duration of each intervention session ranged from 10 to 30 minutes. Conventional exercises in the control group mainly included conventional exercises [37,40,42,43], running [36,39], and school-as-usual exercises [41].

Table 1. Summary of the characteristics of the studies included in the meta-analysis.

Study (country)	Participant description					Exergame group		Control group training	Outcome measured
	Recruited from	Age (years), mean (SD)	Female (%)	Intervention group, n		Platform	Intervention duration		
				Exergame	Control				
Flynn et al [38] (US)	Neighborhoods	13.7 (1.4)	48	70	10	Nintendo Wii	120 min (30 min/session, 1 session/week for 4 weeks)	Exercises	EF[a]: D-KEFS[b]
Benzing et al [36] (Spain)	Secondary schools	14.5 (1.1)	0	21	23	Xbox Kinect	15 min	Running	EF: D-KEFS
Flynn and Richert [37] (US)	NR[c]	Range: 6.8-12.9	48	35	36	Nintendo Wii	20 min	CE[d]	IC[e]: Flanker task
Xiong et al [42] (China)	Childcare center	Range: 4-5	50	30	30	Nintendo Wii	800 min (20 min/session, 5 sessions/week for 8 weeks)	CE	CF[f]: DCCS[g]
Gao et al [40] (US)	Neighborhoods	4.7 (0.7)	59	18	14	LeapTV console	1800 min (30 min/session, 5 sessions/week for 12 weeks)	CE	CF: DCCS
Gai et al [39] (China)	Kindergartens	5.7 (0.5)	NR	32	28	Xbox Kinect	360 min (20 min/session, 3 sessions/week for 6 weeks)	Running	WM[h]: Backward digit; IC: Flanker task, CF: DCCS
Layne et al [41] (US)	Primary school	Range: 8-9	23	19	21	Xbox Kinect	200 min (10 min/session over 4 weeks)	School-as-usual exercises	IC: Go/No-Go
Liu et al [43] (China)	Preschools	4.9 (0.3)	52	24	24	Nintendo Wii	600 min (30 min/session for 20 sessions over 4 weeks)	CE	IC: Go/No-Go; CF: DCCS; WM: "Mr. Ant"

[a]EF: executive function.

[b]D-KEFS: Delis-Kapan executive function system.

[c]NR: not reported.

[d]CE: conventional exercise.

[e]IC: inhibitory control.

[f]CF: cognitive flexibility.

[g]DCCS: dimensional change card sort.

[h]WM: working memory.

Methodological Quality

All the included studies had a low risk of bias in random sequence generation, incomplete outcome data, selective reporting, and other biases. We awarded a high risk of bias for allocation concealment and blinding. Allocation concealment and blinding are difficult in many exercise intervention trials (Figure 2). The overall quality of evidence according to the GRADE approach is presented in Table 2. We rated the evidence for overall EFs, cognitive flexibility, inhibitory control, and working memory as very low quality due to inconsistency (large heterogeneity) and imprecision (low number of people). Details of the GRADE criteria are provided in Multimedia Appendix 2.

Figure 2. Risk of bias graph. Percentages represent the risk of bias.

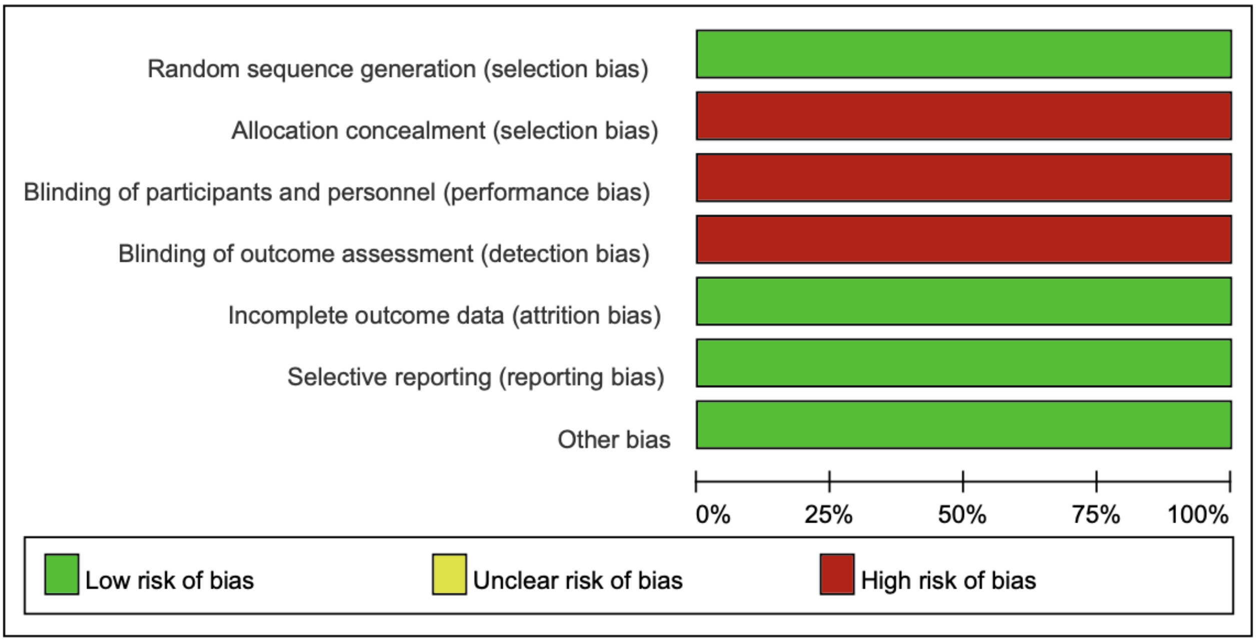


Table 2. Summary of GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) assessment of the effect of exergames on executive functions (EFs).

EF	Certainty assessment						Participants, n		Effect, absolute SMD[a] (95% CI)	Certainty
	Studies[b], n	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Experimental	Control		
Overall EF	4	Not serious	Serious[c]	Not serious	Serious[d]	None	147	85	1.464 (–0.352 to 3.280)	Very low
CF[e]	5	Not serious	Serious[c]	Not serious	Serious[d]	None	125	119	0.906 (–0.274 to 2.086)	Very low
IC[f]	3	Not serious	Serious[c]	Not serious	Serious[d]	None	77	75	1.323 (–0.398, 3.044r)	Very low
WM[g]	2	Not serious	Serious[c]	Not serious	Serious[d]	None	56	52	2.420 (–1.199 to 6.038r)	Very low

[a]SMD: standardized mean difference.

[b]All studies were randomized controlled trials.

[c]Large heterogeneity was observed among the included studies (I^2 >75%).

[d]The overall number of individuals included in the trials was low (<400 individuals in both treatment groups).

[e]CF: cognitive flexibility.

[f]IC: inhibitory control.

[g]WM: working memory.

Meta-Analysis of Effects on Overall and Core EFs

The results of the meta-analysis are shown in Figure 3 [36,38-40,42,43]. Of the 8 studies included, 4 [36,37,39,43] examined the effects of commercial exergames on overall and core EFs. The EF tasks from the 2 included studies were integrated into 3 core EF domains. We used the random effects model for all comparisons because of the high heterogeneity among the included studies. Specifically, the pooled Hedges *g* for overall EFs was 1.464 (95% CI –0.352 to 3.280; *P*=.06), with large heterogeneity (I^2=76%). The subgroup results showed a nonsignificant effect size on cognitive flexibility in 5 studies [36,39,40,42,43] (*g*=0.906, 95% CI –0.274 to 2.086; *P*=.13), inhibitory control in 3 studies [36,39,43] (*g*=1.323, 95% CI –0.398 to 3.044; *P*=.13), and working memory in 2 studies

[39,43] (g=2.420, 95% CI –1.199 to 6.038; P=.19), with large heterogeneity (I^2=94%, 96%, and 98%, respectively). Sensitivity analyses were carried out for overall EFs and cognitive flexibility, and 1 study [39] was found to be an outlier (z=11.272 and 13.141, respectively); thus, a "one study removed" test was performed. The single effect size score specified a change of –0.533 and –0.874, respectively, but was significant (P=.11 and P=.15, respectively) and within the 95% CI.

To further analyze the effect of exergames on overall and core EFs between acute and chronic interventions, we calculated the effect size for these 2 types of interventions (Table 3). The results showed that these findings were not statistically significant among acute and chronic interventions. Notably, the results have high heterogeneity and wide CIs, which can downgrade the consistency and precision of the evidence.

Figure 3. Forest plot for the meta-analysis of the effect of commercial exergames and conventional exercises on improving EFs. EF: executive function.

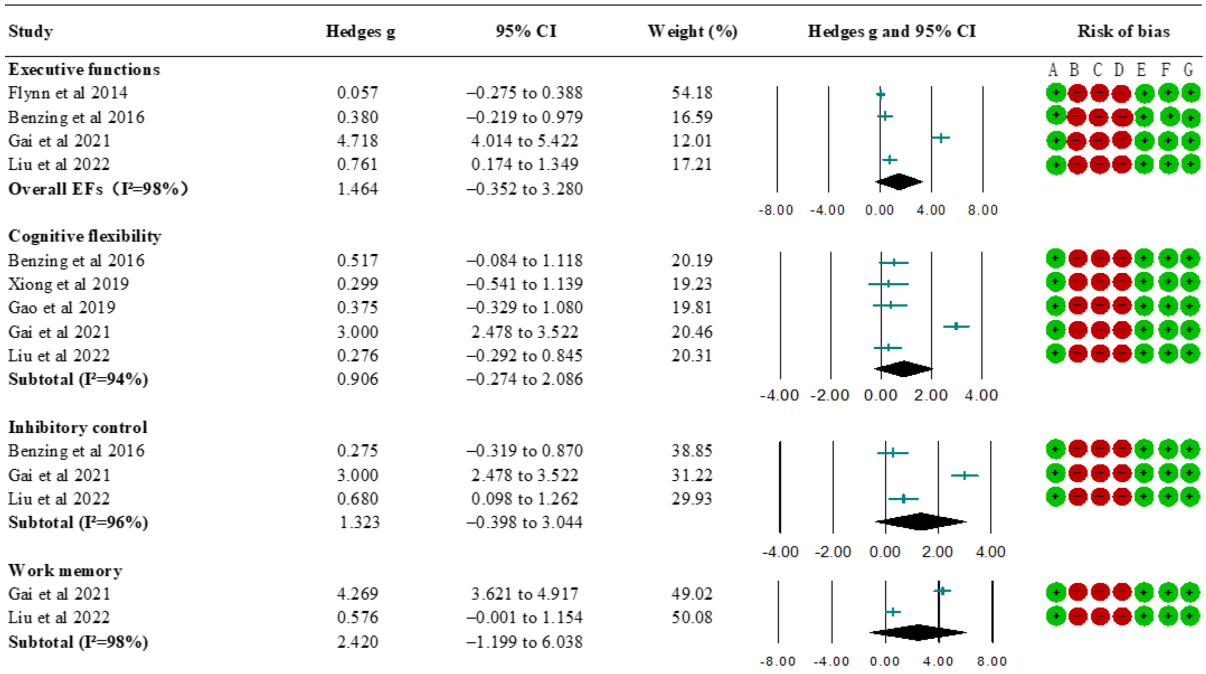


Table 3. Summary of acute and chronic subgroup analyses.

Subgroup	Studies, n	Hedges g (95% CI)	I^2 (%)	P value
Executive functions				
Acute intervention	2	0132 (–0.155 to 0.420)	0	.36
Chronic intervention	2	2.713 (–1.147 to 6.574)	98.602	.17
Cognitive flexibility				
Chronic intervention	4	0.989 (–0.488 to 2.465)	95.483	.19
Inhibitory control				
Chronic intervention	2	1.828 (–0.438 to 4.094)	97.047	.11

Discussion

Principal Findings

The current review investigated the effects of comparing commercial exergames and conventional exercises on improving EFs in children and adolescents based on the outcome data of 8 studies. However, there is a lack of evidence supporting the benefit of commercial exergaming on EFs because of the very high heterogeneity and wide CIs in our results.

To some extent, our results are consistent with those of previous studies. Sala et al [44] performed a reanalysis of a recent meta-analysis in which Stanmore et al [45] claimed that exergames exert a positive effect on cognition, explained the impact of exergames on cognition as small or null, and found no evidence that exergames improve cognitive ability. Notably, the study population was not restricted. Another 2 studies with meta-analyses of RTCs examined the effectiveness of exergames in improving EFs for older people and found that exergames were not superior to conventional exercises in improving EFs among older adults [46,47]. Our findings are consistent with these reviews.

Soares et al [16] conducted a meta-analysis and explained that the difference between exergames and conventional exercises may be related to the intervention of the control group (conventional exercises) with regard to cognitive demand.

Specifically, exergames appear to be more effective for global cognitive performance than conventional exercises with low cognitive demand, in contrast with no advantages in improving cognitive performance when comparing exergames versus conventional exercises with higher cognitive demand. Another study [48] compared virtual reality–based exercises with high versus low cognitive demand and found that exercises with high cognitive demand were more beneficial for EFs than ones with low cognitive demand. Although some studies found that cognitive training with exercise can improve cognitive performance [49,50], it is noteworthy that we only included studies using commercial exergames as the intervention; most commercial exergames platforms and devices (eg, Xbox Kinect and Wii Sports) were not designed to improve one particular cognitive function. Commercial exergames have fewer cognitive components than do professional cognitive training programs. This might be one reason why there was no significant difference between commercial exergames and conventional exercises in improving EFs in children and adolescents in our study.

Another reason may be related to the subjects included in our study. Our study only included healthy children and adolescents rather than children and adolescents with EF impairments (eg, autism spectrum disorder and attention-deficit/hyperactivity disorder). The intervention duration was only 4 to 8 weeks, and based on commercial exergames with low cognitive demands, healthy children and adolescents may require a longer intervention duration to achieve the expected improvement [51]. When the time available for the intervention is limited, healthy children and adolescents may receive the same benefits from commercial exergames and conventional exercises. This may be another reason for the lack of significant differences.

Although these results were not consistent with our expectations, we believe that they are highly encouraging. Given their benefits and advantages (eg, emotional experiences, high feasibility, and usability), exergames can attract children and adolescents to gameplay, keep them physically active, and may play an important role in improving cognitive functions in children or adolescents who are unable or less inclined to engage in conventional exercise. Engaging in exergames is considered a more active lifestyle; thus, we should encourage the development and design of exergame platforms, particularly customized exergames, that is, exergame interventions or platforms designed based on the training or rehabilitation aims of different populations. Studies are needed to examine whether the customization of exergames can help target populations obtain more benefits in cognitive performance.

Limitations

This study had several limitations. First, only 8 RTCs reporting the effectiveness of exergames compared with conventional exercise in improving EFs were included in this study, which may have impacted the precision and variability of the estimates. Second, there was large heterogeneity between the included studies in this meta-analysis, the source of which was not found due to data limitations. These heterogeneities might be related to intervention programs, exergame platforms, or other aspects of the included studies, which may have reduced the quality of evidence and negatively impacted the precision and variability of the estimates.

Finally, because only a limited number of studies were included in this review, we could not identify potential moderators (eg, age). This suggests that more work is needed in the field to further examine and confirm the findings of this study.

Conclusions

There is a lack of evidence of the benefits or harms of commercial exergaming because we did not find a Hedges *g* close to 0 with tight CIs. Further research is needed to confirm this hypothesis.

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Authors' Contributions

JW and LP conceived and designed the study. JW, ZX, HL, and XC selected the articles and extracted the data. JW, LH, and QS contacted the original investigators. JW and ZX analyzed the data. JW and ZX wrote the first draft of the manuscript. LH, YJ, LW, HZ, and LP revised the manuscript. All the authors agree with the results and conclusions of this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed search strategy.
[DOCX File , 13 KB - games_v11i1e42697_app1.docx]

Multimedia Appendix 2
Details of GRADE Criteria.
[DOCX File , 17 KB - games_v11i1e42697_app2.docx]

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Abbreviations

EF: executive function
GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
PICOS: Participants, Interventions, Comparators, Outcomes, and Study design
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial

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Review

The Use of Gamification in the Self-Management of Patients With Chronic Diseases: Scoping Review

Xiting Huang[1], MM; Xinyue Xiang[2], MSN; Yang Liu[1], MM; Zhiqian Wang[1], MSN; Zhili Jiang[1], MSN; Lihua Huang[1], MBBS

[1]Nursing Department, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China

[2]Department of Respiratory Medicine, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China

Corresponding Author:
Lihua Huang, MBBS
Nursing Department
The First Affiliated Hospital
Zhejiang University School of Medicine
Building 17, 3rd Floor
79 Qingchun Road
Hangzhou, 310003
China
Phone: 86 13867129329
Email: lihuahuang818@zju.edu.cn

Abstract

Background: Chronic disease self-management is a public health issue of worldwide concern, and gamification is an emerging strategy to improve patients' participation in chronic disease self-management. Some studies have summarized designs for the gamification of chronic disease self-management from the perspective of eHealth technology, but they have not mentioned differences in design methods, functions, and evaluation methods of gamified designs for self-management in different chronic diseases.

Objective: This scoping review aims to synthesize the characteristics of realization forms, functions, and evaluation methods in chronic disease self-management gamification to improve self-management among the chronic disease population.

Methods: We applied a methodological framework for scoping reviews and the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist. As of January 7, 2023, we systematically searched 9 databases for relevant studies from January 2012 to December 2022. Related data were extracted based on the research questions. We calculated the frequencies, charted the quantitative data, and coded the extracted material for qualitative content analysis.

Results: We retrieved 16,221 records, of which 70 (0.43%) met the eligibility criteria. In the included research, the target populations for gamified designs for self-management of chronic diseases included patients with stroke, cancer, diabetes, chronic obstructive pulmonary disease, coronary heart disease, obesity, and hypertension. Almost all studies mentioned technical support for gamification (68/70, 97%), mainly in the form of active video games (58/70, 83%); however, less than half of the studies mentioned the theoretical basis for gamification (31/70, 44%). There were 37 concepts or theories relevant to gamification design, most of which were in the field of psychology or were cross-disciplinary (n=33, 89%). Gamification for the self-management of chronic diseases has been widely recognized, including for promoting physical exercise and rehabilitation training (48/99, 48%), increasing initiative for symptom management (18/99, 18%), providing psychological support (14/99, 14%), improving cognitive function (12/99, 12%), and improving medication adherence (7/99, 7%). A total of 39 studies mentioned the gamification effect; however, we did not find a unified evaluation standard.

Conclusions: This scoping review focuses on gamification designs for chronic disease self-management and summarizes the realization forms and functions of gamification in self-management for different patient populations. With practice in a gamified internet-based environment, patients can not only master the knowledge and skills of self-management in fascinating scenarios but also benefit from gaming experience and make better health-related decisions in real life. It is worth noting that a comprehensive evaluation of the users as well as a personalized and targeted intervention should be developed before gamification.

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KEYWORDS
gamification; chronic diseases; self-management; scoping review; mobile phone

Introduction

Background

Most chronic diseases have obvious behavioral risk factors including smoking, physical inactivity, and unhealthy diet [1]. Therefore, the treatment and management of these diseases increasingly involve cooperation with patients, relying on self-management. Barlow et al [2] defined self-management as the ability to manage symptoms, treatment, physical and psychosocial changes as well as lifestyle changes that patients develop in coping with chronic diseases. However, poor self-management compliance of patients with chronic diseases, such as nonprescribed medication, lack of regular physical activity, and unhealthy eating habits, is a common clinical problem worldwide [3,4]. People with chronic diseases not only cannot see the benefits of self-management in the short term but also endure repeated and monotonous training or changes in past health habits, which is a struggle between low impulses and high cognitive control [5]. With the rapid development of technology, mobile health (mHealth) and telemedicine based on the internet and mobile electronic devices can provide internet-based health services for acute and chronic care, intervention, counseling, and social support for patients with chronic diseases [6]. The process of motivating individuals to find joy in monotonous, repetitive, or uninteresting tasks in a planned, selective way and guiding individuals to make positive changes is called "gamification."

Gamification refers to the application of game design elements to nongame contexts [7]. The specific practice is to integrate game design elements such as points, badges, leaderboards, and avatars into nongame contexts such as marketing [8] and classroom teaching [9] to realize "meaningful play," that is, to achieve serious purposes other than entertainment in an interesting process [10]. When gamification emerges in the field of health care, its serious purposes include, but are not limited to, helping patients with chronic diseases adhere to self-management [11], promoting their basic needs of autonomy, and balancing the unidirectional and paternalistic relationships between doctors and patients [12]. The core of gamification design lies in human-computer interaction and instant feedback, which conforms to the abovementioned difficulties and pain points in the self-management of patients with chronic diseases and is an important measure to break the failure of patients with chronic diseases to adhere to long-term self-management.

Since 2011, there has been an intense discussion about gamification, and the literature on gamification in the health care field has grown rapidly. In the field of rehabilitation and behavioral sciences, gamification attracts patients with cardiovascular disease [13-15], diabetes [16,17], and stroke [18-20] to participate more actively in the management of their long-term health problems with the application of mHealth, virtual reality (VR) technology, and robots.

Objectives

Gamification in the field of chronic disease self-management is at an emerging stage. However, in some studies on gamification design in the field of health care, there is a lack of understanding of gamification as a design strategy, narrowly limiting its application to the use of video games [21] or blindly adding game design elements solely to encourage certain behaviors (such as physical activity) [22]. At present, the theoretical framework design of gamification is a hot topic [23]. Therefore, based on the evidence-based methodologies and from the perspective of gamification design, we integrated the forms, functions, and effect evaluation of gamification in the self-management of patients with chronic diseases to explore the mechanics, dynamics, and experience of gamification design of users with chronic diseases.

Considering the heterogeneity of scientific research design and measurement methods of different studies, we believe that a scoping review is a method of knowledge synthesis that is suitable for discussing large-scale, diverse, and complex heterogeneity themes. For these reasons, a scoping review could be a better choice than a systematic review to quickly describe the research progress of a certain field, showing the scope, depth, breadth, and deficiency and providing more information for the future [24]. Therefore, this scoping review aimed to classify, compare, and synthesize gamification in chronic disease self-management.

Methods

Overall Framework

This study was designed according to the framework developed by Arksey and O'Malley [25]. The five main stages are as follows: (1) identify the research question (RQ), (2) identify relevant studies, (3) search strategy and study selection, (4) chart the data, and (5) summarize and report the results. This scoping review is reported according to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.

Research Question

This scoping review aimed to describe how gamification design has been implemented in self-management promotion for patients with chronic diseases and how to evaluate the effect of gamification in the self-management of patients with chronic diseases. We articulated the study objectives using the following RQs:

- RQ1: How is the gamification of chronic disease self-management implemented?
- RQ2: What role does gamification play in the self-management of chronic diseases?
- RQ3: How do existing studies evaluate the gamification design of chronic disease self-management?

Eligibility Criteria of Relevant Studies

The research team used brainstorming to establish the eligibility criteria for relevant studies. According to the definition of chronic disease by the Centers for Disease Control and Prevention, we retrieved synonyms for chronic disease and specific disease names for cardiovascular diseases, chronic pulmonary diseases, metabolic syndrome, and cancer. On the basis of the widely accepted definition of gamification [7], relevant studies should apply games or game design elements to promote self-management needs with joyful experiences of patients with chronic diseases. We retrieved cognates and synonyms of gamification, game based, game design elements, game component, game design, and game principle. Given the inseparable connection between the application of gamification and electronic devices, we also retrieved synonyms of video games, computer games, exergames, and VR.

Information Sources and Search Strategy

PubMed, Web of Science, CINAHL, APA PsycINFO, Embase, Cochrane Library, China National Knowledge Network, Wanfang (Wanfang Data), and VIP (CQVIP) were used as the data sources. In the past decade, there has been an increase in health-oriented gamified clinical research and applications [11]. Considering the speed of electronic technology changes, the technology before 2012 does not have a reference value, and we searched for the literature on gamification of chronic disease self-management from January 2012 to December 2022.

The retrieval strategy was based on the combination of subject terms and keywords, and the retrieval scope was the titles and abstracts. The search strategy did not limit any inclusion based on the affiliation of the authors, but the publication language was limited to English and Chinese to ensure an accurate understanding of the research. All databases were run on March 18, 2022, and updated on January 7, 2023. Refer to Multimedia Appendix 1 for the detailed search strategy.

Inclusion and Exclusion Criteria

Under the guidance of an academic librarian, along with a brainstorming session, the research team set the following inclusion and exclusion criteria.

Inclusion criteria were as follows: (1) the research participants or targets were patients diagnosed with chronic diseases aged >18 years; (2) the gamification design in this study must include game design elements; and (3) the study was published in Chinese or English.

Exclusion criteria were as follows: (1) patients with diseases that require long-term rehabilitation owing to trauma (eg, patients with fractures or brain injuries); (2) special research participants such as high-risk groups of people with chronic diseases; groups people with genetic diseases; groups of people with occupational diseases; and special groups such as those who are disabled, sexual minorities, and pregnant women; (3) conference abstracts, patents for an invention, and so on, which only have descriptions but no experimental data; (4) studies for which the full texts are not available.

Synthesis of Results

In total, 2 reviewers (XH and XX) independently screened abstracts and full-text articles with EndNote (version X9; Thomson Corporation) software. In case of conflicting opinions, a third reviewer was consulted (YL) to reach a consensus. The following information was extracted from the articles included in the review: first author, country, publication year, types of study design, objective population (chronic disease type), (if any) sample size and gender distribution, gamification realization forms, theoretical frameworks, game design elements, roles of gamification in chronic disease self-management, and gamification design evaluation tools. All data are presented with data charts suggested by Arksey and O'Malley [25].

To describe the sample and study characteristics, the first author coded papers for the following information using Excel (version 2019; Microsoft Corporation) software: publication year and country of publication (extracted from the paper metadata); types of study designs (extracted from the Methods section); number of patients with chronic diseases and their disease types (extracted from the Results section); and sample characteristics (extracted directly from the Results section or calculated mean value of all sample data).

To describe the application of gamification in chronic disease self-management, the first author coded the paper for following factors: gamification realization (extracted the description of the research tool from the Methods section); gamification evaluation (extracted related outcome measurements from the Methods section); gamification function (extracted verbatim from the "aim" or "objective" statements of each paper).

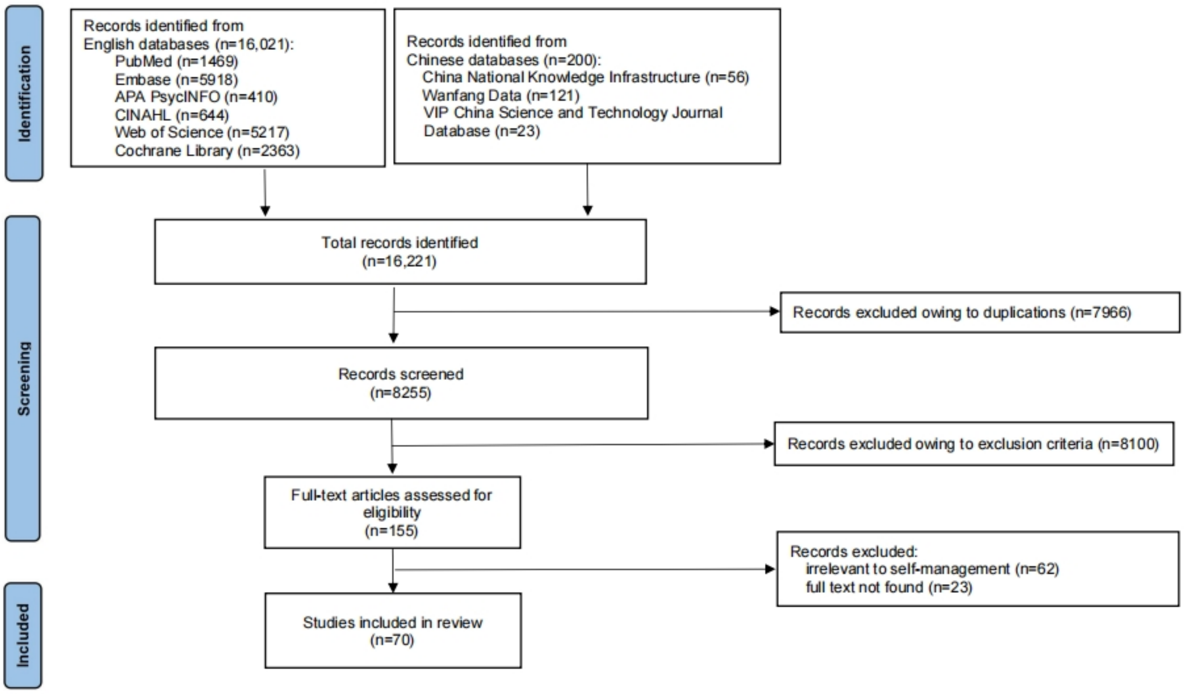
After data extraction, the fourth author calculated the frequencies of the quantitative data and charted the data. The first author coded the extracted material for qualitative content analysis. After 2 coding cycles, subthemes of "gamification forms" emerged, including "technical support" and "theoretical support," and subthemes of "gamification function" emerged, including "symptom management," "medication management," "physical activity and rehabilitation," "cognitive function rehabilitation," and "psychological support."

Results

Search Results

The initial search yielded 16,221 results, of which 7966 (49.11%) were duplicates and 8100 (49.94%) were excluded by reading the titles and abstracts. Of the remaining 155 articles, 70 (45.2%) met the inclusion criteria. The PRISMA-ScR flowchart (Figure 1) shows more detailed information [26].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of study selection.



Basic Information

A total of 70 articles included in this review were mainly from 22 countries. Most studies (56/70, 80%) were concentrated in developed countries. The United States was the country with the most research (18/70, 26%), followed by the United Kingdom (6/70, 9%). There were 5 relevant studies in Canada and Australia and 3 relevant studies in China, Norway, Germany, Spain, Brazil, and Switzerland. The remaining 18 studies were conducted in 12 countries (South Korea, Greece, Iran, France, Malaysia, Portugal, Pakistan, Denmark, Japan, Singapore, Israel, and Indonesia).

Among the included studies, studies within the last 3 years accounted for half of the included studies (35/70, 50%). There were no restrictions on the study designs or chronic diseases in this review. The study design included experimental studies (27/70, 39%), literature studies (18/70, 26%), observational studies (13/70, 19%), and other types of studies (12/70, 17%). Survivors of stroke accounted for the largest number of studies (29/70, 41%), followed by patients with unclassified or multiple chronic diseases (11/70, 16%; Table 1). Except for some studies that only reported the development of gamification designs without data on research participants (26/70, 37%), the review extracted data from 2193 participants, most of whom were female (n=1423, 64.89%). The age distribution of the patients ranged from 33 to 85 years, with the mean age of 55.56 (SD 8.69) years (26/70, 37%). Details are provided in Multimedia Appendix 2 [13-20,27-87].

Table 1. Basic characteristics of the included studies (N=70).

Characteristic	Studies, n (%)
Publication year	
2012-2015	9 (13)
2016-2019	26 (37)
2020-2022	35 (50)
Study design	
Experimental study	27 (39)
Randomized controlled trial	10 (14)
Pilot study	10 (14)
Mixed research	5 (7)
Quasi-experiment	1 (1)
Paired experiment design	1 (1)
Literature study	18 (26)
Systematic review	11 (16)
Scoping review	4 (6)
Review	3 (4)
Observational study	13 (19)
Qualitative research	9 (13)
Cross-sectional descriptive research	3 (4)
Retrospective research	1 (1)
Other studies	12 (17)
Introduction of the gamification design	6 (9)
Expert testimony	6 (9)
Patient population	
Hypertension	2 (3)
Obesity	2 (3)
Coronary heart disease	3 (4)
Chronic obstructive pulmonary disease	6 (9)
Diabetes	8 (11)
Cancer	9 (13)
Unclassified or multiple diseases	11 (16)
Stroke	29 (41)

Realization Forms of Gamification in Chronic Disease Self-Management

Overview

In this study, the gamification of chronic disease self-management cannot be achieved without advanced electronic and information technology but also requires a design supported by the theoretical model.

Technical Support

In this review, the gamification practice of chronic diseases requires the joint support of software (such as applications, active video games, websites, and emails) and hardware (game joysticks, computers, electronic displays, robots, and VR technology devices).

Owing to the derivation of gamification from games, gamification is a methodological approach that enables active video games (AVGs) to be given a purpose other than entertainment. In this study, AVGs were the most common form of gamification practice (58/70, 83%). AVGs are video games that require players to use a certain part of their body as a controller to interact with the game system [13,27]. They can be used as apps for smartphones, tablets, and desktops as well as in combination with hardware facilities such as game joysticks, electronic displays, robots, and VR technology to present AVG content. The top 3 diseases with the highest use rate for AVGs are stroke (28/58, 48%), cancer (8/58, 14%), and unclassified or multiple chronic diseases (7/58, 12%).

As AVGs rely on users' activities in human-computer interaction, most studies (41/58, 71%) mentioned that users can physically interact with avatars in games through various physical activities, such as jogging and boxing, to promote physical activity and extremity function rehabilitation. According to whether AVGs are designed to serve the health care field, AVGs can be divided into commercial games for the general population and experimental games for patients with chronic diseases. The former ones aim for commercial profit, and their rule design and game operation do not have any therapeutic purposes, which has become a limitation in this type of clinical research [28]. In total, 4 qualitative interviews mentioned the gamification needs and preferences of patients with chronic diseases. Patients paid more attention to the health benefits of gamification than AVG points [29,30]. They hoped to integrate more social mechanisms to gain company from relatives and friends in the self-management process [31]. For older patients with chronic diseases, the AVG interface should be as simple as possible, and sound along with video can be used to replace excessive text and button functions [32]. One expert suggested that AVG design for stroke can use a storyline with a sense of purpose to alleviate the impact of significant physical and psychological changes after stroke, thus encouraging patients to participate in rehabilitation [33].

In addition, many hardware or software match (10/70, 14%) with communication media and integrate the game design elements to realize gamification of chronic disease self-management. The form of gamification of "hardware plus communication media" is specifically manifested as a wearable activity tracker combined with email and SMS text messaging [34,35] to provide feedback on exercise steps, which is used for postdischarge activities of patients with cancer [34], exercise, and weight loss for patients with diabetes [35]. The gamification forms of "software+communication media" include web-based interactive community websites [36], self-made mobile apps [37], and mHealth [14,16,38-41], which play an important role in knowledge education and symptom management of chronic obstructive pulmonary disease (COPD), diabetes, hypertension, and other diseases. In a qualitative interview, middle-aged and older patients with chronic diseases were asked how they felt about game design elements. They believe that the first encouragement from family and friends will determine their internal motivation for self-management, and the appropriate frequency of badges, likes, and other reward elements can motivate them to change their daily life habits [40]. Some experts have pointed out that different game design elements are interrelated; therefore, it is necessary to combine the characteristics of patients with their health and well-being and create a relatively stress-free game environment. Let patients enter the state of flow and improve the self-efficacy of self-management.

Theoretical Support

In this review, some studies (31/70, 44%) indicated that relevant theories or concepts guided their gamification practices in the self-management of patients with chronic diseases. A total of 37 concepts or theoretical frameworks were mentioned in the included articles, most of which originated from psychology and cross-disciplinarity (n=33, 89%), such as self-determination theory [38,40,42-44], flow theory [33,45-49], social cognition theory [27,50-52], goal-setting theory [34,43], information-motivation-behavioral technology model of behavior change [32,43], intrinsic motivation [16,53], self-efficacy [17,45], persuasion system design model [54], inhibitory control [55,56], patient-reported outcome [32], co-design approach, and participatory design [57].

Individual studies have started with game design, regarding gamification as a design strategy, and have developed frameworks, such as "mechanics-dynamics-aesthetics" frameworks [33,58], "mechanics-dynamics-emotions" frameworks [23], and "dynamics-mechanics-components" framework [88]. As the theoretical research of gamification is in an emerging direction, the terms are constantly changing.

In the abovementioned theoretical frameworks, the mechanics dimension is central to what defines a game, representing the rules, purpose, and scope of gameplay. The mechanics dimension is the fundamental process that drives game progress and player engagement, such as challenge mechanism [32,58], random mechanism [15,38,59], collaboration mechanism [15,31,37,59,89], and win-or-lose state. In contrast to the concept of mechanics, the dynamics dimension is not a concrete element directly applied to gamification design but rather an abstract motivation that promotes the achievement goals of targeted behavior. The dynamics dimension defines the nature of player interaction within a game, which gives rise to a change in the game state, both in the underlying data and the game's interface. Common dynamics dimension in gamification design includes emotion (evoking players' curiosity, excitement, happiness, or competitive motivation), narration (starting with a series of storylines), progression (recording the development and growth of players), and relationships (promoting family affection, friendship, and other emotions generated in the interaction) [89]. The aesthetics dimension emphasizes the relationship between a player's game experience and their emotional or intellectual response to the game experience. In the included articles, graphics, audio, and haptics can provide sensory feedback and a fun experience for patients with chronic diseases, helping to promote the self-efficacy and response-efficacy of chronic disease self-management [90]. Along with users interacting with the gamified system, they will have emotional responses such as excitement, regret, pleasure, and thrill [23]. Some scholars have changed the word of "aesthetics" to the word of "emotion" (mechanics-dynamics-emotions) [23]. Each component of the gamification frameworks mentioned earlier is causally linked by the game designers and provides the users with pleasure and fun perceptions [91]. In the "dynamics-mechanics-components" framework, points, badges, and leaderboards were concrete game design elements, which only belong to the basic design of the component level in the gamification design. To achieve the maximum value of gamification, game design elements should be applied from the mechanical level preferably to the dynamic level [89].

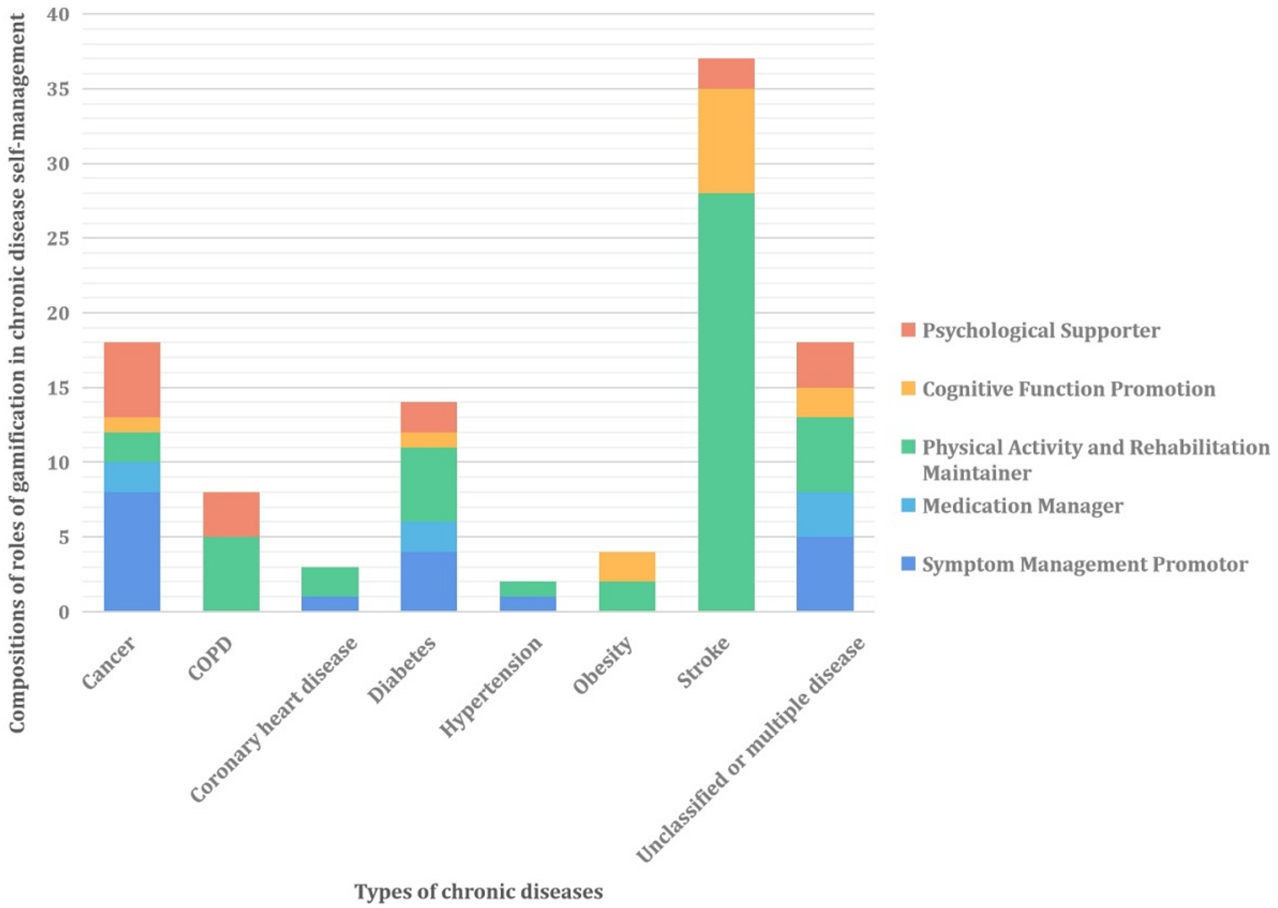
Some studies have discussed the framework of gamification design in the self-management of patients with chronic diseases based on their gamification practice. "The wheel of Sukr" framework was proposed based on the self-management needs of people with diabetes, and the topic definition was summarized through expert interviews, providing practical guidelines for the gamification of chronic disease self-management. This theoretical framework combines behavior change methods and game technology with chronic disease self-management, emphasizing the close correlation among 8 themes: fun, esteem, growth, motivation, sustainability, socializing, self-representation, and self-management. "The wheel of Sukr" framework plays a synergistic role with the game design elements represented under each theme [60]. "The Ayogo model" was derived from the management evidence of patients with diabetes and established patients' self-efficacy and belief in self-management through 3 mechanisms of "narrative," "progression," and "social interaction" [61].

In summary, the gamification design has achieved the purpose of promoting patients gain confidence in self-management through role-playing in games [58], encouraging patients to persist in rehabilitation with relatives or fellow patients [37,88], mastering disease knowledge and skills in an enjoyable and more engagement way [15,31]. For designers, gamification is about designing mechanics that create an aesthetic experience. However, for players, it is about having fun and then figuring out the rules and nonentertaining goals behind the form of game experience. Therefore, the gamification design of chronic disease self-management should be based on game design concepts, psychological or interdisciplinary terms, and immersive technologies such as VR and apply game design elements to provide users with a game experience to better support them in creating overall value in self-management.

Roles of Gamification in Chronic Disease Self-Management

Gamification in the self-management of patients with chronic diseases helped to manage symptoms, improve medication compliance, maintain physical activity and rehabilitation motivation, and provide psychological support (Figure 2).

Figure 2. Roles of gamification in chronic disease self-management. COPD: chronic obstructive pulmonary disease.



Symptom Management Promotor

Within the scope of this review, cancer and diabetes management were prominent in gamification.

For patients with cancer, gamification enhanced the connection between patients with cancer and others through human-computer interaction and social mechanisms [29,32,34,45,51], providing support from health care professionals, relatives, and friends. The progress bar element was applied to record their health condition, self-management measures, and psychological progress [28,34,62], giving users a sense of disease control. In the management of side effects and symptoms after cancer chemotherapy, the project iManageCancer offered survivors of cancer an opportunity to play the role of a mayor with the avatar element. They could master strategies for handling chemotherapy-induced nausea and vomiting after chemotherapy by managing the "Anticancer City" in the game [62]. The avatar element enabled survivors of cancer to better immerse themselves in a virtual environment while playing games and mastering skills to relieve helplessness about chemotherapy-induced nausea and vomiting and other side effects after chemotherapy and alleviate the anxiety about death of survivors of cancer [51,63].

For people with diabetes, game design elements were applied for blood glucose management education. In a study that collected data on 14 gamification practices of diabetes self-management [89], the avatar element was mainly used to simulate insulin injection and diet management to maintain normal blood sugar levels. Take The Didget game for example, the source of AVG points was each reading of the glucose meter, users could exchange these points for game props, characters, and levels to promote timely measurement of blood glucose levels in people with diabetes [89]. It can internalize users' behavior into personal goals during repeated training, improving their self-efficacy and promoting active participation in symptom management in the real world.

In symptom management, the avatar element enabled patients to learn more knowledge about disease management through role-playing [17,57,61-64]. Users were allowed to self-manage trials and errors in the virtual environment with an immersive experience, which cultivated the self-efficacy of self-management in repeated training. Finally, patients with chronic diseases should be guided to apply the disease management methods learned from the virtual environment in the real world and achieve the purpose of secondary prevention of disease.

Medication Manager

This review on medication adherence focused on survivors of cancer, patients with diabetes, and patients with other unclassified chronic diseases.

In the homemade mobile game iLoveBreast, the storyline element promoted patients with breast cancer to gradually complete self-education. The mean value of medication compliance of patients in the game group was higher than in the control group (7.6, SD 0.7 vs 6.5, SD 0.5; $P<.001$). This was because involvement in game medication and reminder alerts had improved users' knowledge of the disease and medication safety [64].

For people with diabetes, insulin use had been taken as a routine [89], so even simple rewards (eg, cumulative points in the form of grades and badges) encouraged people with diabetes to practice glycemic control [40,89]. The time-limited mechanism was convenient for patients with diabetes to play repeatedly at their leisure and constantly consolidated the clinical diabetes education content in repeated processes [52,89].

Among other unclassified chronic diseases, a study retrospectively observed the compliance rate of medication time and dosage in patients with multiple chronic diseases who used the app ("Perx Health") for 3 months and 6 months. This study found a slight downward trend in the 3-month group from the first month to the third month and in the 6-month group from month 4 to month 6 (P=.73) but found no significant differences in medication adherence rates over time (P>.05). In timing adherence subanalysis, the median medication adherence for the first month in the 6-month group was 77.3% (IQR 52.0%-93.1%) and 77.4% for the sixth month (IQR 36.2%-94.4%) [38]. This showed that gamification intervention can promote patients' internal motivation and maintain long-term stability of medication adherence.

Although the number of studies on drug compliance in this review was limited, the results showed that medication education for patients with chronic diseases required a simple gamification design to avoid information overload [40,49]. However, it was necessary to inform the users when to terminate gamification intervention if the gamification design used the element of "points and levels" to record the growth of users. Unless users are intrinsically motivated to stick to medication, missing out on rewards could impair their compliance [38].

Physical Activity and Rehabilitation Maintainer

On the basis of Nintendo Wii series products, Kinect sensors, Microsoft Xbox system, and other mature somatosensory game products and research designs, there were a large number of studies (47/70, 52%) on physical activity and rehabilitation training, including patients with COPD [27,37,65-67], coronary heart disease [13,59,68], diabetes [16,28,35,89], cancers [34,51], and stroke [18-20,30,33,44,47-49,53,54,70-85], making physical activity and rehabilitation training enjoyable.

With the support of AVGs, patients with COPD could meet the exercise requirements of medium- to high-intensity resistance exercise [65,67], and the specific movements of the AVG could be regarded as a therapeutic exercise for patients with cardiovascular disease [13], which improved the compliance of pulmonary rehabilitation and cardiac rehabilitation [13,65,67]. With consideration of the characteristics of exercise intolerance of patients with COPD and coronary heart disease, safety for home use, different levels of difficulty and warm-up exercises were shown in some studies [66,68]. In physical activity interventions for people with diabetes, gamification design mainly promotes walking. Pokemon Go was a good example; its fascinating storyline and the user's devotion to animation inspired the intrinsic motivation of users to use Pokemon Go, which attracted users to increase their steps, walking time, and training intensity during the 24-week intervention period [16]. Thus, gamification design was helpful in maintaining their physical activity, but it was difficult to completely replace therapeutic skills training such as pulmonary rehabilitation [66].

The gamification of rehabilitation for survivors of stroke was one of the breakthroughs in the field of health care, with a specific focus on the rehabilitation of upper limb function (22/70, 46%). For the rehabilitation of the upper arm and shoulder joint, motion sensors were worn to record the range of motion of the shoulder and the amount of shoulder movement, so as to help health care professionals and users judge in a timely manner whether the rehabilitation action was effective [20,30,47,69,70,73,76,78,83,85]. For hand function rehabilitation, game joystick, game gloves, and touch screen could be used to practice grasping, releasing, and pointing

[53,71,73,78] while completing game tasks. For users with weak hand strength and small torso roll angles, commercial game devices cannot record subtle movement changes. Gloves with infrared technology [71] and tangible robots [18,20,44,80] emerged, capturing subtle movements invisible to the naked eye, providing timely feedback on every bit of rehabilitation progress to users, and empowering them to continue. As for functional rehabilitation of the lower limbs, gamification design focused on improving balance functions [42,69,74,84] and activity endurance [48,75,84]. In addition to AVGs, VR technology was combined to construct virtual scenes to train the spatial orientation and cognitive abilities of patients with stroke [18,49,73,74,82].

Overall, “human-computer interaction” was an important game design element in the gamification design of the physical activity and rehabilitation training, providing timely feedback data for both health care professionals and patients such as training duration, intensity, and training action; allowing patients to see physical function changes with exercise rehabilitation; and improving their compliance with exercise and rehabilitation [13,16,19,20,28,30,33,35,37,42,44,46-49,51-56,58-60,64-66,69-83,85].

Cognitive Function Promotion

The studies on cognitive function in the included studies were all conducted in the form of AVGs, which was applied to the attention training of obese patients and the rehabilitation of cognitive function after stroke and cancer chemotherapy.

AVGs come with the effect of cognitive function training. This is because the user learns the rules of the game and processes them quickly and accurately in the game, which keeps the brain active to avoid cognitive decline [45] and improves cognitive control and attention [42]. The time-limited game design element was used to train attention and goal-oriented behavior in obese patients, control the frequency of their consumption of a high-carbohydrate diet (eg, dessert), and strengthen their adherence to a healthy diet [55,56]. Users who received the gaming intervention were more concerned about daily food intake than those who received regular weight management (65.3% vs 33.6%), and the average weight loss in the intervention group was greater than that in the control group (3.4% vs 2.5%) [56].

On the basis of neuroplasticity, rehabilitation of cognitive impairment is possible for survivors after cancer chemotherapy or stroke [19,45,53,86]. A literature review on AVGs in older patients with chronic diseases mentioned that AVGs helped to improve executive functions such as naming, memory, and sense of direction [42]. One neurocognitive learning application was also effective in improving the speed and accuracy of information processing in survivors of cancer with chemotherapy-related cognitive impairment, and the effects could be sustained for some time (at the end of intervention: the average score of perceived cognitive impairment was −7.47, 95% CI −10.80 to −4.13; $P<.001$ and 6 months later: the average score was −6.48, 95% CI −9.85 to −3.11; $P=.001$) [45]. In terms of improving attention and perception, gamification design combined with VR could provide users with an immersive experience with the first-person perspective of game characters [19,49].

It is worth noting that technical interaction should avoid complex design for patients with cognitive dysfunction, which was preferably set as the default setting for self–decision-making (eg, group decision-making and social decision-making) [19,52,77,82,86]. It was also necessary to avoid eye fatigue caused by the long-term use of electronic screens and be aware of the uncanny valley effect of VR [33,72,73].

Psychological Supporter

Patients with chronic diseases usually experience loneliness [29,36], anxiety [33,41,46,63], depression [32,33,42,45,51,60,63,71,80,81], boredom, and pain [17,79] during the rehabilitation process. Some patients with chronic diseases tend to self-isolate [45]. Gamification design provided interesting experiences to distract patients with chronic diseases from negative emotions and provided support and encouragement from friends [14,27,35,37,77], other patients [36,37,44,53], and health care professionals [14,27,29,32,34,36,79].

Owing to the disease characteristics, survivors of cancer have a stronger fear of death than patients with other chronic diseases. They often focus on a vicious cycle of negative conditions and have difficulty getting rid of negative thoughts, leading to further anxiety and depression. One qualitative study mentioned that the points element was used to provide timely feedback on cumulative progression and improve motivation and positive emotions to disperse the fear of death, thus fundamentally shaking the foundation of negative emotions [32]. Another study introduced a web-based community platform (“COPD360 social”), allowing patients with COPD to exchange self-management experiences through the social mechanism and seek help from health care professionals. It enhanced the empowerment of patients with COPD and their caregivers, encouraged them to use the platform actively, created a sense of belonging in web-based communities, and promoted the dissemination of health knowledge [36].

The psychological effects of the gamification interventions were not independent. A systematic evaluation indicated that physical activity games were important components of the effective management of depression in the older adults, significantly reducing the degree of depression in older adults (SD mean difference=−0.60, 95% CI −0.95 to −0.25; $P<.001$) [87]. However, the psychological effects of gamification interventions were limited. If the patient had been diagnosed with depression, the intensity and frequency of the AVG-based intervention were not effective [42].

Evaluation of Gamification Design in Chronic Diseases Self-Management

This review did not find a unified evaluation criteria for the gamification design of chronic disease self-management. The evaluation indicators of gamification design mentioned in the literature have been compiled into Table 2.

Table 2. Evaluation of gamification design (n=39).

Evaluative dimensions and evaluation methods	Studies, n (%)
User satisfaction	
User Satisfaction Evaluation Questionnaire [78]	1 (3)
Self-designed questionnaire [52,61,62]	3 (8)
One-dimensional subjective score [35,51,55]	3 (8)
User experience	
User Experience Questionnaire [58]	1 (3)
Game Experience Questionnaire [53]	1 (3)
Self-designed questionnaire [32,44,49,74,78,91]	6 (15)
Interview [13,16,27,29-31,37,49,58,63,65,69,78,80]	14 (36)
User preference	
User interface features [58]	1 (3)
Self-designed questionnaire [41,77,78]	3 (8)
Interview [13,40,57,58,73,78]	6 (15)
Completion or participation	
Statistical results [55,56,62,68]	4 (10)
Self-designed questionnaire [14]	1 (3)
Accessibility	
Ease of Use Scale [32]	1 (3)
Acceptance Questionnaire (based on Technology Acceptance Model) [14]	1 (3)
Usability	
System Usability Scale [32,37,84]	3 (8)
Feasibility	
Recruitment rate or retention rate [51,56]	2 (5)
Safety	
Adverse events [35,68,73]	3 (8)
Self-management behavior record	
System log files [14,16,19,20,44,47,65,69,81,91]	10 (26)
Economic cost	
User Satisfaction Evaluation Questionnaire [78]	1 (3)

Of the 70 articles, 39 (56%) reported the evaluation indicators of the chronic disease self-management gamification system. Of the 39 articles, 9 (23%) used existing scales, including the System Usability Scale [32,37,85], Ease of Use Scale [32], Acceptance Questionnaire [14], User Experience Questionnaire [58], User Interface Features Questionnaire [58], User Satisfaction Evaluation Questionnaire [80], and Game Experience Questionnaire [53]. Of the 39 articles, 12 (31%) used self-designed scales to evaluate users' satisfaction [52,64,65], experience [32,44,49,63,76,80], engagement [14], and preference [41,79,80]. Of the 39 articles, 10 (26%) with gamification design through AVGs used system log files to record symptom management strategies [14,63] and their duration [16,20,59,71], activity and rehabilitation training intensity, and related data of users [19,44,47,83].

In total, 17 studies showed user experience and preferences through interviews.

Most users mentioned experiencing pleasure and effectiveness when using gamified systems [29,58,59,66,68,71,80,82]. They could receive timely feedback for error correction or affirmation with human-computer interaction [58,82], stimulate self-efficacy of self-management with the competition mechanism [49,57], and realize personal progress visualization and internal motivation promotion with game design elements such as points and the progress bar [40]. On the basis of mobile devices, users' physical activities and rehabilitation training could be free from the limitations of time, location, weather, or other medical activities, achieving self-management liberalization and confidentiality [16,30,37,66,71]. Using the internet, users could obtain support and supervision from health care professionals and patients more conveniently [27,31,37]. However, some users were older adults, and obstacles in technology and health status were inevitable [75]. They stated that they were unfamiliar with electronic technology and required accompaniment or technical support from their family members or health care professionals [13,27,31,66,71,75]. Owing to the severity of the disease, individual differences in participation and challenge difficulty among different users made it difficult for the gamification design to achieve absolute fairness [27,57]. Therefore, the gamification design of the system interface required comprehensive consideration of users' cognitive and physical functions. This could be simplified by reducing the number of buttons instead of background music to prevent visual information overload [49,57]. Security preparedness was the most important issue when AVG was used for physical activity or rehabilitation training. Without it, users would not have the motivation to use the gamification system [77]. It would be helpful to present action guidance from the first perspective in AVG so that users can operate better and increase their interest, thereby entering a flow state [49]. In terms of competition mechanism and goal setting of gamification design, user engagement and actual situations showed individual differences, preferably allowing users to set their own goals to avoid physical exhaustion and disrupting the fun of exercise itself [27,29].

Overall, the evaluation focused on the experience of patients with chronic diseases, reflecting the self-management motivation, technical novelty, fun of the game experience, and the degree of personalization related to the motivation for self-management [30,82]. Only a few studies reported safety-related outcomes [35,70,75] and adverse events triggered by individual exercises with a gamification system (such as knee pain and low back pain) [70]. We suggest that to promote gamification in chronic disease self-management, health care professionals should pay attention to the safety protection and emergency plan for patients' home use.

Discussion

Principal Findings

This scoping review identified 70 gamification studies on chronic disease self-management conducted from 2012 to 2022. Stroke was the leading disease in gamification research (29/70, 41%), and the field of physical activity and functional rehabilitation was the central research content of chronic disease self-management gamification. In all studies, gamification practice was dominated by AVGs (58/70, 83%), and its theoretical support was mainly derived from existing psychological and cross-disciplinarity concepts or theories. The main functions of gamification were promoting physical exercise and rehabilitation training in patients with chronic diseases (48/99, 48%), especially in the field of poststroke rehabilitation; AVGs have become a rehabilitation tool for survivors of stroke [48] and are used for symptom management (18/99, 18%), psychological support (14/99, 14%), cognitive exercise (12/99, 12%), and medication management (7/99, 7%). Evaluation indicators and qualitative text showed that the use of gamification in chronic disease self-management was widely recognized by patients.

Reflection

Compared with traditional self-management methods, the combination of gamification design and mobile technology has broken through the traditional medical mechanism and experience of patients with chronic diseases, allowing them to have more autonomy in the choice of rehabilitation training time and rehabilitation forms. Therefore, gamification enabled patients with chronic diseases to maintain a high motivation for self-management for 6 months [38], meeting the requirements of disease self-management such as physical activity, symptom management, and disease cognition. In addition, patients with chronic diseases who coexisted with diseases for a long time often had negative emotions such as anxiety and depression, which had a negative impact on their health outcomes, disease management, and quality of life [87]. Gamification used game design elements to create enjoyable experiences, allowing patients to better immerse themselves and complete self-management in a state of flow [46,57,73]. When patients reacted as the requirements of self-management, the gamification would provide timely praise through human-computer interaction, like points accumulation. This timely positive feedback helped to improve the self-efficacy of patients with chronic diseases engaged in self-management, and they sincerely felt happy [79], thereby reducing the conflict between long-term health goals and previous unhealthy habits [50,60], fostering sustainable long-term self-management.

We suggest that health care professionals, developers, and researchers of gamification design should take ethnic characteristics, personal lifestyles, personality, interests, and hobbies into consideration when applying gamification. The most controversial game design element in this study was the competitive mechanism. Competition is bound to result in winners and losers. It is undoubtedly an incentive for patients who win and lead the leaderboard, but if the patient is far behind others, it may make the user give up [57]. This could be a disease characteristic of the susceptibility to fatigue. Patients with cancer and patients with COPD believe that game design elements should be used to build confidence, and even if they want to compete, they should constantly challenge and surpass themselves, rather than emphasizing the competition for patient performance. Patients with different disease severity levels have different perceptions of difficulty in completing the same challenge. For those with severe disease, failure to challenge, especially over a long period, may even lead to depression and a lack of self-efficacy [27,29,45]. For people with diabetes, the fun of competition lies in the fast-paced disease knowledge competition [52,89]. Therefore, the application of game design elements should be related to the frequency of interactions between users and the system or the degree of participation between users and the community to gamify the experience of chronic disease self-management. In addition, patients with chronic diseases of different ages have different preferences for game design elements. Among middle-aged and older adults, users do not want too many rewarding elements such as badges and likes, avoiding making the gamification system of chronic disease self-management like a children's game [40]. Technical barriers should be considered when older patients with chronic diseases use electronic products, which reminds the gamification designer to simplify the game interface and game rules without affecting the user's fun [46,49,52,58,61,77,79].

Therefore, successful gamification design cannot be separated from the following four universal gamification design rules: (1) focus on incentive mechanism, (2) do not terminate games at will, (3) not overemphasizing specific gamification mechanism, and (4) link games with health and happiness [39]. Before the gamification design of chronic disease management, 4 core questions are recommended to be based on the following: Can it provide a good motivation for chronic disease self-management? Is the set target activity meaningful and interesting? Is there a structured pattern of the expected activity behavior? Does the gamification mechanism use potentially conflict with the target behavior?

Future Research

Although this review found that gamification had a positive and universal effect on chronic disease self-management, we still need to view the results dialectically. Most of the gamification intervention periods in the included studies were all within 1 year, and most interventions were within 6 months; therefore, we cannot rule out the novelty effect of technology. We also need to consider that the users included are themselves interested in the study, which inevitably leads to a selection bias. In addition, the gamification of chronic disease self-management involved multiple environments such as clinical settings [73,80] and family settings [30,44,77], which interferes with the effectiveness of gamification interventions. To better explore how gamification promotes self-management in patients with chronic diseases and promotes their expected long-term outcomes, the consistency of the research setting should be controlled, the sample size should be expanded, and the follow-up period should be extended in the future, and more methodological research is encouraged to investigate the extent to which various forms of gamification impact chronic disease self-management.

Limitations

Unfortunately, this review retrieved only the literature published in Chinese or English, omitting valuable data from relevant articles published in other languages. Gray material and unpublished studies were not included in this review. Many health-related applications were privately operated, and their development and evaluation information were not disclosed. The sample sizes of some diseases in the included studies were insufficient and could not represent the entire population. Therefore, in the future, we will expand the search to focus on the literature published in other languages and further study the heterogeneity of disease populations.

Conclusions

This review was based on a definition of gamification, without limiting the type of research, that focused on gamification designs for chronic disease self-management; the study synthesized the differences in the gamification realization forms and functions in self-management of different disease populations, which helped the researchers to completely understand the use experience and opinions on gamification for the self-management of patients with chronic diseases. Before using gamified interventions for chronic disease self-management, researchers must conduct a comprehensive survey of the target group, clarify the shortcomings of the self-management and game preferences of patients with chronic diseases, and stimulate internal motivation through appropriate game design elements. At the same time, it is also necessary to consider the multidisciplinary expert qualifications of the research team and the cost of research interventions, developing attractive chronic disease self-management plans based on the definition of gamification to be applicable to chronic disease management in developing countries.

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Data Availability

All data generated or analyzed during this study are included in this paper and the multimedia appendices.

Authors' Contributions

XH was the principal investigator. XH was involved in conceptualization, study design, data collection, data curation, formal analysis, writing the original draft, and editing the revised draft. XX was involved in conceptualization, data collection and curation, review, and editing. YL was involved in conceptualization and participated in discussions of study selection if the first 2 authors had conflicting opinions. ZW and ZJ were involved in conceptualization and data visualization. LH was involved in conceptualization, methodological guidance, data validation, formal analysis, writing—review and editing, and supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Searching strategies of this scoping review.
[DOCX File , 14 KB - games_v11i1e39019_app1.docx]

Multimedia Appendix 2
Data extraction of the references.
[XLSX File (Microsoft Excel File), 42 KB - games_v11i1e39019_app2.xlsx]

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Abbreviations

AVG: active video game
COPD: chronic obstructive pulmonary disease
mHealth: mobile health
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
RQ: research question
VR: virtual reality

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Original Paper

Gamification and Soft Skills Assessment in the Development of a Serious Game: Design and Feasibility Pilot Study

Luca Altomari[1*], BEng; Natalia Altomari[2*], PhD; Gianpaolo Iazzolino[1*], PhD

[1]Department of Mechanical, Energy and Management Engineering, University of Calabria, Rende, Italy

[2]Department of Mathematics and Computer Science, University of Calabria, Rende, Italy

[*]all authors contributed equally

Corresponding Author:
Luca Altomari, BEng
Department of Mechanical, Energy and Management Engineering
University of Calabria
Ponte Pietro Bucci
Rende, 87036
Italy
Phone: 39 3932671847
Email: luca.altomari@gmail.com

Abstract

Background: The advent of new technologies has had a profound impact on the labor market, transforming the way we work and interact with each other. With the rise of digital tools and platforms, gamification has emerged as a powerful technique for enhancing productivity and engagement in various fields, including human resource management. In particular, gamification has been found to be effective in developing and assessing soft skills, which play a critical role in determining the success of individuals, teams, and organizations.

Objective: We present a serious game that identifies the most sought-after skills in the job market and offers feedback, and we provide a set of guidelines for the creation of serious games.

Methods: We present the serious game Among the Office Criticality (AOC). The AOC game structure involves a set of sequence analysis techniques, which is known as process mining.

Results: The pilot study findings indicate that the game is both engaging and beneficial to subjects, suggesting that the results align with current theoretical perspectives. Furthermore, the study suggests that the obtained data can be extended to the broader population.

Conclusions: This study illustrates a serious game structured according to the needs of the labor market and developed to put the user at the center, using evaluation techniques consistent with the literature, with the aim of constituting an interdisciplinary approach suitable for adequately assessing users and creating value for them.

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KEYWORDS

gamification; soft skills; recruitment; serious games; assessment; process mining; work-life skills

Introduction

Background

The field of human resources has transformed traditional and outdated personnel selection methods through technological advancements, paving the way for more technologically advanced methods that reduce hiring costs and optimize the evaluation of candidates during the recruitment process. This is particularly relevant when it comes to millennials and Generation Z. Gamification is among these methods. It can be defined as “a package of services in which a basic service is enhanced by rule-based service systems that provide the user with feedback and interaction mechanisms that aim to facilitate and support users’ global value creation” [1], and in recent years, it has become an increasingly popular trend in nongaming contexts [2] to increase motivation and engagement [3]. Gamification involves the use of structured rules and competitive conflicts to achieve specific goals, and in which a person is fully engaged with the context, losing track of time and experiencing the thrill of doing rather than achieving external rewards [4]. Research has shown that play and games can be linked to positive social behavior [5], the development of important skills such as self-regulation and empathy [6], and the promotion of teamwork [7].

Gamification is often used to enhance services and test gaming experiences and can be a powerful tool for influencing behavior [1]. However, some studies have examined issues related to gamification [8]. This technique is applied in settings related to learning, business, or promoting a product or service [9]. Through elements, such as competition, goal achievement, and reward, gamification can increase users' motivation, engagement, and satisfaction in an activity [10,11].

Many researchers have suggested that gamification and game-based assessments could predict work performance as an alternative to traditional selection methods [12,13]. Fetzer et al [13], according to the concept of "stealth assessment," highlighted the potential of game-based assessments for predicting work performance. Invisible evaluation can accurately and efficiently detect a subject's level of competence, can continuously extract data on their performance during the game [14], and is almost undetectable, reducing test anxiety while maintaining validity and reliability [15]. In this context, a gamified assessment environment could distract candidates from being assessed, promoting unconscious rather than desirable or socially acceptable behavior. Assessment and learning tools that may be created through the use of gamification are known as serious games [16], which are games designed for a primary purpose other than pure entertainment [17], like supporting human capital development [18]. Serious games are designed for educational, training, or informational purposes that combine the playful experience with learning specific skills and competencies [19]. Unlike traditional games, serious games were created to impart knowledge and teach players how to apply those skills in real life by creating engaging and entertaining experiences that prompt users to perform certain actions, improving the effectiveness and efficiency of those activities.

Various sectors, such as education [20], health care [21], mobility [22], marketing [23], and the environment [24], have been equipped with this innovation, simulating situations in which the player must make decisions, solve problems, or develop specific skills. Moreover, owing to the interactive nature of serious games, players can learn actively, receiving immediate feedback on their progress and the correctness of their actions [25].

If the game is user-friendly and realistic, it tends to generate positive responses from candidates [26]. Thus, one of the cornerstones of these games (as well as an aspect this paper will focus on) is the development of awareness related to one's skills, particularly those skills called "soft skills," which are indispensable in the world of work [27].

In relation to the connection between gamification and transversal skills, game elements, such as textures, feedback, avatars, visual effects, and voiceovers, can be effectively used to assess candidates' soft skills [28].

Problem-solving skills, strategic thinking, and adaptation to new contexts are soft skills, also known as "behavioral skills." They are non-technical skills (as opposed to hard skills) important for personal and professional success. Using game mechanics, gamification can make learning these skills more engaging and effective. Serious games play a key role in developing soft skills (such as problem solving, planning, and analytical thinking) in the world of work [27]. Certain elements, such as a risk-free environment, predispose users to a setting conducive to experimentation and exploration, activating stimuli, such as curiosity, learning by discovery, and perseverance [29].

Serious games are playful and interactive tools often used in education with pedagogical goals, which are designed to teach skills, notions, and strategies [30,31]. Serious games offer active involvement, immediate feedback, experiential learning, collaborative learning, and learning personalization, which enhance positive learning effects [32]. The scenarios designed for serious games have a positive relationship with student engagement and academic performance [33]. Despite their potential, serious games still pose a challenge to the educational world, and there is a need for more emphasis on less formal and traditional models that are suitable for teaching today's generation of students [34]. Serious games are an important resource for the world of training and education, facilitating the learning of specific disciplines.

Transversal skills often overlap with digital skills, which have become increasingly necessary for performing tasks due to the growth of technology in recent years. Digital skills involve the use of information and communications technology (ICT) tools and can be classified as operational, formal, informational, or strategic skills [35].

Based on these premises, this research proposes an innovative method for addressing an issue dear to companies, the recruitment process. Recruiting an unsuitable candidate can be very costly, both in terms of money and nonproductive time. Therefore, many companies are looking for innovative ways to improve their recruitment process to attract and identify the most suitable candidates for available positions. This involves the use of cutting-edge recruiting techniques and an increased focus on assessing candidates' skills and qualities [36].

Psychological tests that measure cognitive abilities and personality tests, which are traditional selection methods, can somewhat predict job performance [37]. As previously mentioned, the game is an attractive and valid alternative to traditional selection methods, and gamifying these tests can be a way to assess candidates with the benefits stated above.

The COVID-19 pandemic has prompted a shift in the labor market toward Industry 5.0 to the New Normal Era, a time of collaboration between advanced technology and human creativity to address business, social, and environmental challenges [38]. This has had an impact on the labor market, affecting both demand and requirements, as well as leading to the emergence of the "great resignation" phenomenon, in which individuals across countries and industries are exhibiting a heightened awareness of work conditions and opportunities [39,40].

To successfully adopt artificial intelligence (AI), organizations and individuals must embrace transformative changes in their practices, recognizing the foundational role of connected technologies in driving increased digitization in business and management worldwide. Key factors for successful AI adoption include team coordination, organizational culture, governance strategy, and AI-employee integration strategies. Furthermore, the integration of serious games and AI provides new computational tools for social research. Soft skills, such as communication, problem solving, critical thinking, and creativity, are crucial for successful AI adoption, while leadership plays a vital role in setting a vision and strategy for its implementation [41,42].

Recent studies have emphasized the importance of soft skills and talent in the New Normal Era, where work has changed significantly and new methodologies, such as smart working and remote working, are becoming increasingly prevalent. As a result, soft skills are now a top organizational priority [43].

State of the Art

Industry 5.0: Impact of Emerging Technologies on Gamification and the Labor Market

With the increasing adoption of new technologies, such as AI, virtual reality, metaverse, blockchain, augmented reality, and collaborative robots, it is crucial to understand the transition from Industry 4.0 to Industry 5.0 for creating sustainable business and management practices. Industry 4.0 was characterized by automation technologies, the Internet of Things, and smart factories, while Industry 5.0 involves the collaboration between advanced machinery and human creativity to solve business, social, and environmental issues. The adoption of transformative changes in practices is essential for organizations and individuals to understand as these connected technologies provide the foundation for increased digitization in business and management worldwide. While the use of serious games and gamification has become increasingly popular in recent years, some of these emerging technologies, particularly AI, have the potential to be disruptive for the world of work and have a significant impact on human resources, recruitment, and corporate life [38].

Team coordination and organizational culture are also crucial elements that organizations must consider when adopting AI. Effective coordination between team members is essential for successful AI implementation, and organizational culture plays a critical role in supporting this coordination. An innovation mindset is also necessary to foster a culture of experimentation, learning, and continuous improvement, which are all essential for successful AI adoption.

Governance strategy is another key area that organizations must consider when adopting AI. Effective governance ensures that AI is being used ethically, responsibly, and in compliance with legal and regulatory frameworks. AI-employee integration strategies are also important, as they help to ensure that employees feel comfortable working with AI systems and are equipped with the necessary skills to do so [41].

Pérez et al [42] suggested that the integration of serious games and AI offers new computational tools for social research. By developing and applying gamification with an eye toward both design and efficacy, organizations can increase productivity and promote better decision-making processes in the workplace. The use of gamification and serious games in the workplace can be a promising tool to enhance motivation, engagement, and decision-making processes among employees.

An evidence-based approach to gamification considers its effectiveness to be dependent on the use of scientifically proven principles and tactics that can impact outcomes [44]. Optimistic results have been found in the integration of some of the newest technologies, as AI, virtual reality, and serious games are being increasingly used in several industries, such as the healthcare industry where there was a great effort concerning new technologies and research during the COVID-19 pandemic, yielding favorable outcomes for the treatment of various health conditions as well as for medical education and training [45-47]. Moreover, Schönbohm and Zhang [48] revealed the effectiveness of serious games in facilitating strategic decision-making in the context of the COVID-19 pandemic.

In the era of the new normal, the global workforce is experiencing an unprecedented phenomenon known as the “great resignation.” This phenomenon is characterized by individuals in various countries and industries exhibiting a heightened awareness of work conditions and opportunities, which is indicative of an overall increase in people’s awareness of work. However, this phenomenon has also brought about uncertainty, challenges, and opportunities for organizations due to external factors such as the gig economy and the implementation of technology [39,40].

Recent research by Duch-Brown et al [49] investigated the relationship between market power, AI, and online labor markets. They showed that market-designing platform providers can influence labor demand and supply elasticities on online labor markets by setting specific terms and conditions on the platform. The study also revealed a significantly higher demand for AI-related labor and a significantly lower supply of AI-related labor, indicating the need for further exploration of the role of AI in online labor markets. Similarly, Deranty and Corbin [50] highlighted the potential societal impacts of AI deployment in work, particularly in the areas of technological unemployment and wealth polarization.

This presents new challenges and opportunities for soft skills [51], as well as technical skills and fusion skills [52], which are those skills and attributes required for individuals to thrive in the fusion environment of the 21st century. Therefore, staying updated with technological advancements and market-specific demands is essential for individuals employed in data science–related fields (more so than others) to enhance and maintain their employability, especially in the digital renaissance. Additionally, real-time identification of market demands plays a crucial role in balancing the adequate supply and demand of talent in this era [53].

The Future of Work Relies on Soft Skills in the New Normal Era

A new technological revolution is going on, and many organizations are eager to adopt new technologies in order to gain a competitive advantage. However, implementing new tools, like AI-based tools and technologies, is not enough to achieve success. A recent review on human resource management conducted in March 2023 revealed that organizations need to look beyond technical resources and focus on developing nontechnical resources as well [41]. The review highlights several nontechnical resources that are critical to successful AI adoption. These include human skills and competencies, such as communication, problem solving, critical thinking, and creativity, which are essential for effective collaboration with AI systems. Additionally, leadership is vital for setting a vision and strategy for AI adoption and ensuring that it aligns with the organization's overall goals and values. In conclusion, the review underscores the importance of developing nontechnical resources in addition to technical resources when adopting AI. By investing in human skills and competencies, leadership, team coordination, organizational culture, innovation mindset, governance strategies, and AI-employee integration strategies, organizations can fully realize the benefits of AI adoption and gain a competitive advantage in the marketplace [41].

The 2023 Pulse of the Profession report by Project Management Institute highlights that power skills, which are soft skills built upon a solid foundation of technical skills, are a top organizational priority [43]. Developing these skills can lead to delivering results that add value to both the organization and its customers.

Redefining work requires more than skill development, as skills have inherent limitations. Simply retraining workers to perform different routine tasks or adapting to new technologies to complete the same tasks does not address the underlying challenges for workers or capture the potential benefits for companies. The vision of redefined work involves shifting workers' focus from routine tasks to identifying and resolving hidden issues and opportunities. While automation can facilitate this shift, it is not just about automating tasks or using technology. It does not involve changing the workforce composition or retraining employees for different domains, and it does not require employee suggestion boxes, 20% work time for innovation or entrepreneurship, or innovation centers. Workers must develop and use their human abilities to identify issues, solve problems, implement solutions, and iterate to recognize and resolve hidden issues and opportunities. A key characteristic of this work vision is its continuous evolution. Problem identification and solution methods are typically used to correct processes, address deviations, or eliminate inefficiencies, with the goal of incorporating feedback into more structured and defined work. Loosening the structure is only a temporary measure to advance the process [51].

The job market has undergone a significant transformation due to the pandemic, which has been expedited by the emergence of new technologies. To thrive in this new era, possessing soft skills, such as communication, problem solving, creativity, and collaboration, as well as the ability to adapt to change, is crucial [54], even if digital and technological skills are vital for enhancing a firm's performance. Moreover, Akrim [55] stressed that while knowledge is important, soft skills cannot be overstated when it comes to securing one's future.

To gain a competitive edge in the job market, integrating talent and knowledge management strategies is imperative [56], and to succeed in the future of work, prioritizing soft skills and talent management strategies in recruitment and training processes is essential. Identifying unique talents and skills is crucial to gaining a competitive advantage. High demand for soft skills, such as creativity, emotional intelligence, critical thinking, and problem solving, necessitates their recognition and prioritization in organizations' development efforts [57].

The Pedagogical Side of Serious Games

Serious games serve as an effective and result-oriented medium, utilizing interactive and playful forms of engagement [30]. They represent tools designed with the goal of teaching something, such as skills, notions, and strategies, and offer the possibility for the user to identify with learning and formative situations, and thus, it can be said that they pose pedagogical goals [31]. Serious games are associated with multiple advantages from pedagogical and formative points of view, including active involvement, as the player becomes the protagonist of learning and is stimulated to explore, experiment, and reason independently [29]. Another advantage is immediate feedback, as they provide a timely and accurate response on the player's actions, allowing learning based on error and its correction. Other advantages include experiential learning related to scientific literacy [58], as they allow for real-world situations to be experienced and simulated, providing a direct and engaging educational experience; collaborative learning, as they can be used to foster cooperative learning, stimulating participation and information sharing even in educational settings between teachers and students [59,60]; and learning personalization [61], as they can be designed to adapt to each player's cognitive needs and abilities, sparking and maintaining player interest and motivation and enhancing positive learning effects [32]. In addition, there is a positive relationship between the scenarios designed for serious games and the expected outcomes of the learning experience [62] considering, as part of this process, student engagement and academic performance [33].

Despite the potential of these tools, they still pose a challenge to the educational world [34]. It is important to place more emphasis on less formal and traditional models that are more suitable for teaching, which can be projected to the generation of students experiencing school today. Serious games, according to this perspective, represent an important resource for the world of training and education, and are facilitators for learning specific disciplines.

Soft Skills in the Labor World

Soft skills refer to a range of personal attributes, social abilities, and communication competencies that are necessary for success in the workplace. These skills, which are distinct from technical skills, include qualities such as positive attitudes, good communication, and strong interpersonal skills. They are also described as the “human skills” or “people skills” needed to effectively use technical knowledge and expertise in a professional setting [63].

Several studies have focused on identifying the key soft skills that are valuable in the labor market [64]. Several international studies have shown that soft skills are critical to our future success, and their importance is recognized by education providers, academics, human resource departments, and businesses [65-68].

This research aims to understand how companies and economic organizations that recruit, hire, and develop professionals at a medium to high-level view and value soft skills in their human resource development process [69].

According to the study, the most important soft skills for different groups, determined based on criteria such as significance, relevance, availability in the job market, and negative impact if lacking, are as follows: problem solving (for the group focused on achieving results), team working (for the group focused on mastering social skills), and time management (for the group focused on making progress in the workforce).

In order to examine the testability and relevance of certain soft skills, it is also useful to analyze communication and decision-making in greater depth. Additionally, problem solving may be linked to self-directed learning and communication for goal orientation, and both of these skills may be considered when discussing digital skills [70]. Therefore, it is advisable to carefully analyze these 5 skills, which were identified through a classic assessment. To assess communication [71], the communicative style (aggressive, passive, or assertive) [72-74] was adopted, and for problem solving, models, such as DMAIC (Define, Measure, Analyze, Improve, and Control) [75] and Problem Solving Inventory (PSI) [76], were used. Team working and related skills developed in group environments are highly sought after by recruiters when hiring [77]. The research was inspired by the Comprehensive Assessment of Team Member Effectiveness (CATME) [78], and for decision-making, the cognitive style (a person’s preferred way of thinking and tendency to adopt certain strategies more frequently) [79] was evaluated using the General Decision-Making Styles (GDMS) scale [80]. Time management, as theorized by Lakein [81] and others, was assessed using the time management behavior scale [82]. Soft skills are increasingly recognized as critical to future success and are valued by those in education, academia, and human resource departments. They also help organizations gain new customers, increase revenue, and reduce employee turnover, which is why employers are placing an increasing emphasis on these skills [66].

Purpose of the Study and Origins

This study was conceived within the scope of the SWAG (Skills in Work-life Analysis Game) project. SWAG sets out to democratize the human resource world, through the use of intergenerational language, and it is inclusive and comprehensive of the needs, complexity, and peculiarities of today’s and tomorrow’s talents, connecting the right person to the right position. The SWAG team (involving Altomari Luca, Altomari Natalia, and Vigliaturo Daniele) was created in the context of the first cycle of “UniCaLab” (Contamination Lab of the University of Calabria) in 2019 (path concluded among the 3 winners) and achieved victory in Invitalia’s “#IoRestoAlSudHackathonTour*” contest in the same year.

In this work, a new assessment framework is presented that takes into account the needs of the labor market and is based on gamification, with a focus on the concept of “recrutainment” (a term combining “recruitment” and “entertainment”), which integrates cognitive and aptitude assessment methods into the personnel selection process [83] and is not only partially conceived as a subset of gamification, but also goes beyond it [84]. In this study, a serious game that assesses the most in-demand skills in the job market and provides feedback is illustrated, proposing a set of guidelines for the development of serious games while describing the game design process. The first trial of the game was conducted and positive results were achieved, paving the way for further studies.

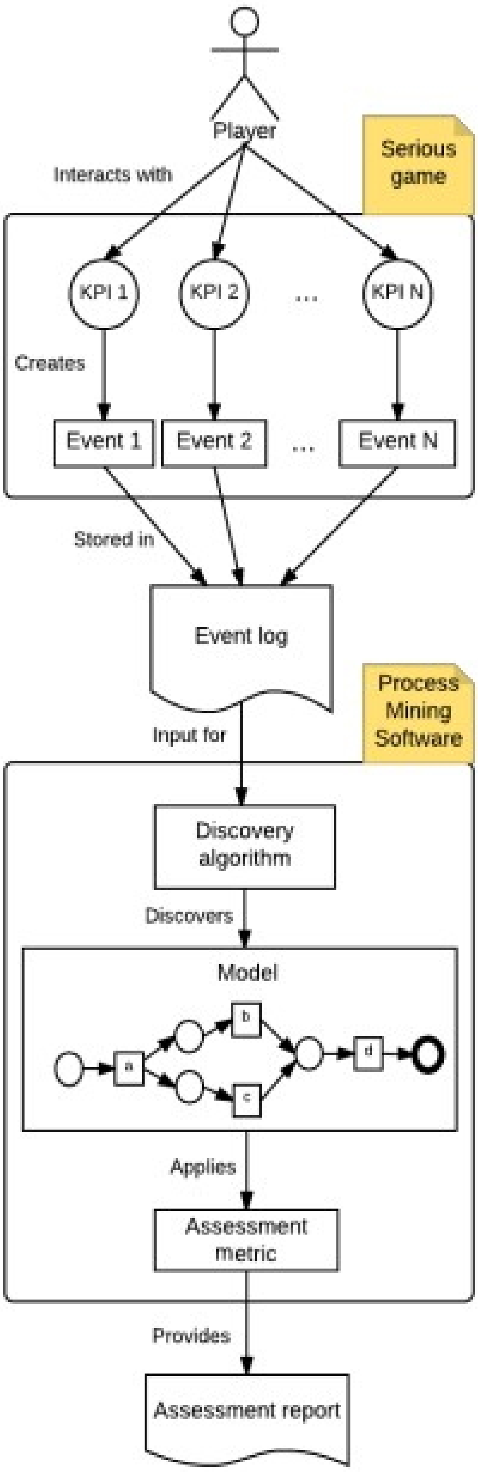
The serious game Among the Office Criticality (AOC) was developed by the SWAG team as a desktop version with the technical support of Artémat.

Methods

Research Methodology and Proposal of a Serious Game

The purpose of this study was to develop a model that can identify and evaluate certain work-life skills (in this case, 5 soft skills that are in high demand in the job market) and provide feedback to the user who uses the tool. Gamification is particularly suitable for this purpose because it allows for the creation of tools that can provide quick, objective, and standardized assessments [85] after an initial design and implementation effort, while also allowing for a more informal approach to the person being evaluated [12,13]. The study presents the AOC serious game, which is able to detect the 5 soft skills mentioned above. The AOC serious game uses a set of sequence analysis techniques, which is known as process mining, to overcome the limitations of traditional skills assessment methods [85]. The user interacts with the game, which tracks key performance indicators (KPIs) based on the user’s choices at each decision point and saves them in an event log at the end of the game. These events and values are processed by process mining software, which generates an output (Figure 1) [85].

Figure 1. Architecture for skill assessment in serious games based on event sequence analysis. KPI: key performance indicator.



The software that analyzes the event log uses an algorithm to read the data in the log and create a model. This model is then used to apply the metrics of the specific evaluation tool to produce the final report.

AOC is a serious game that is structured as a tree graph, with decisional moments represented as nodes. Analyzing the user's choices within the game involves identifying the pattern arcs that connect the nodes. However, analyzing all user actions within the game can cause scalability issues. To address this, the event log only records data related to decisional moments and the duration of the game, rather than all interactions. In this case, sequence analysis can be helpful in solving or mitigating the problem [85]. In the AOC game, metrics are based on a data set of fixed-length numerical vectors and an overall rating formula. These vectors are added together based on the entries in the event log to create a final vector, the values of which are then used in the formula to produce a numerical result. This result, as well as the individual values, can be easily translated into a final report that is provided to the user in both graphical and narrative forms. The design of serious game processes can be performed in 2 steps: context analysis and iterative concept use. The first step involves using user-centered design methods, which focus on the user's intent, situation, activity, and characteristics. The second step involves testing the tool, once it has been defined and materialized as a prototype or mock-up, in order to improve it with a focus on attractiveness, motivation, and support for activities [86]. It is important to keep in mind some fundamental principles of gamification, such as freedom of choice, benefits and relevance, personalized experience, long-term interaction, unwanted side events, and ethical and legal elements [86]. The tree graph structure containing the decisions should also be considered.

AOC Serious Game

AOC is a serious game that assesses 5 soft skills by immersing users in a simulated game context where they can use various tools as needed. The game context places the player directly into a company through a specific delivery at the beginning of the game. In the simulation, the player, who is starting their work experience, begins their journey at a fictious firm with an apprenticeship contract. At the start of the simulation, the user is presented with an organizational chart, and graphic and textual descriptions of the business context. Over the first 6 months of the game, the player must interact with other characters to complete tasks, deal with unexpected events, and make decisions, choosing the means of communication and working with superiors and other team members in order to achieve the best possible result at the end of the simulation. At the end of the game, based on the choices made, the user is presented with a scenario that reflects the path they took. The contract can be converted into permanent employment, extended for an additional 6 months, or terminated.

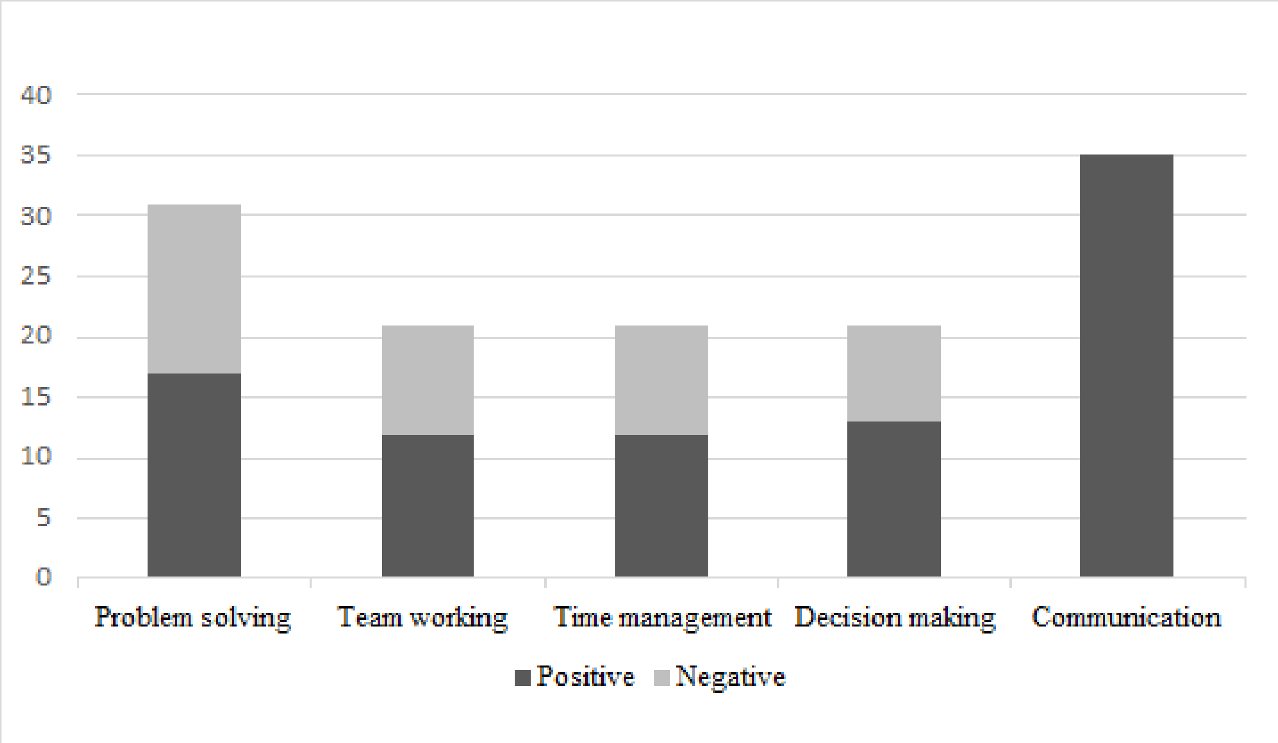
Serious Game Output

In the alpha version of the game, the user is presented with a series of decisions that are related to values for various soft skills. These values are individual variables that are combined into a resultant vector, denoted as R. The R values are then input into the overall evaluation formula, which produces a numerical result, designated as x. This result corresponds to an outcome that is related to the objective of the game. As the user makes decisions, the events of the game progress according to the graph. Each event occurs consecutively and presents the user with contextual choices that are as visual and immediate as possible (eg, a choice between 3 interactive texts). The values assigned to each decision are based on data from previous studies and the literature used to construct the game [87]. The game has a maximum duration of 30 minutes, after which the available time (displayed as a countdown) reaches zero. If the simulation is not completed at this point, the final result is the R vector, which does not consider any subsequent decisional moments and includes a penalty for time management. The "first-person" perspective is intentionally designed to increase the user's engagement and encourage active interaction.

In 2017, van Laar et al [88] conducted a study that examined 75 studies on 21st century skills and found that problem solving and communication were the most commonly mentioned skills, with 24 and 22 quotes, respectively. In this study, communication was defined as the ability to transmit information effectively, while problem solving was defined as the ability to use ICT to understand and process problems and actively use knowledge to find solutions.

The structure of the graph, the assignment of scores, and the analysis of these scores are all built using techniques from the Theory of Graphs, in line with theory and market research that emphasizes the importance of problem solving, which is tested in greater detail than the other skills. This is evident in the analysis of paths that maximize and minimize the variables associated with the skills, which has shown a range of 33 possible values for problem solving. The skills of team working, time management, and decision-making have 21 possible values and make up a total of 48% of the testing (Figure 2). The remaining 52% is composed of problem solving and communication, with this last skill requiring more attention as it is divided into 3 categories: passive communicative style, aggressive communicative style, and assertive communicative style. Variables used to identify the communicative style are also included in this percentage.

Figure 2. Positive and negative possible scores concerning every skill assessed by the serious game Among the Office Criticality. The ranges show the number of possible final resulting skill values.



The slight differences in amplitude within the ranges can be attributed to both psychobehavioral factors and mathematical advantages. The psychobehavioral reason is that each communication style has the potential to generate unexpected events within interpersonal relationships (ordered: aggressive, passive, and assertive). The mathematical advantage is that the 3 variables can never be equal in any of the possible combinations. The outcome for the user consists of a final report that includes both graphical and narrative components (Table 1).The graphical component consists of a 2D diagram that incorporates a polygon, with each vertex representing the user's scaled final scores in the four soft skills: team working, time management, decision-making, and problem solving. This polygon describes a surface of amplitude that is directly proportional to the x value resulting from the overall evaluation formula. The textual component includes a result relating to the final goal (3 possible scenarios) and different sections describing the user's score in each individual skill (low, medium, and high). In the graphical component, the dominant communication style is also explicitly highlighted (aggressive, passive, or assertive).

Table 1. Range width comparison showing "how much" a single skill is assessed.

Skill	Assessment, %
Problem solving	25.19
Team working	16.03
Time management	16.03
Decision-making	16.03
Communication	26.72

Ethics Approval

Ethics approval for the research project, "Innovation in Teaching Methods" was granted by the Ethics Committee of the University of Calabria (COMITATO ETICO DI ATENEO - CEA) on May 9, 2019. The project, which was conducted within the University of Calabria, aimed to assess soft skills using the tool developed by SWAG, alongside human tutors. Adhering to the approved ethical guidelines, the research team ensured participant confidentiality and privacy throughout the data analysis process.

Results

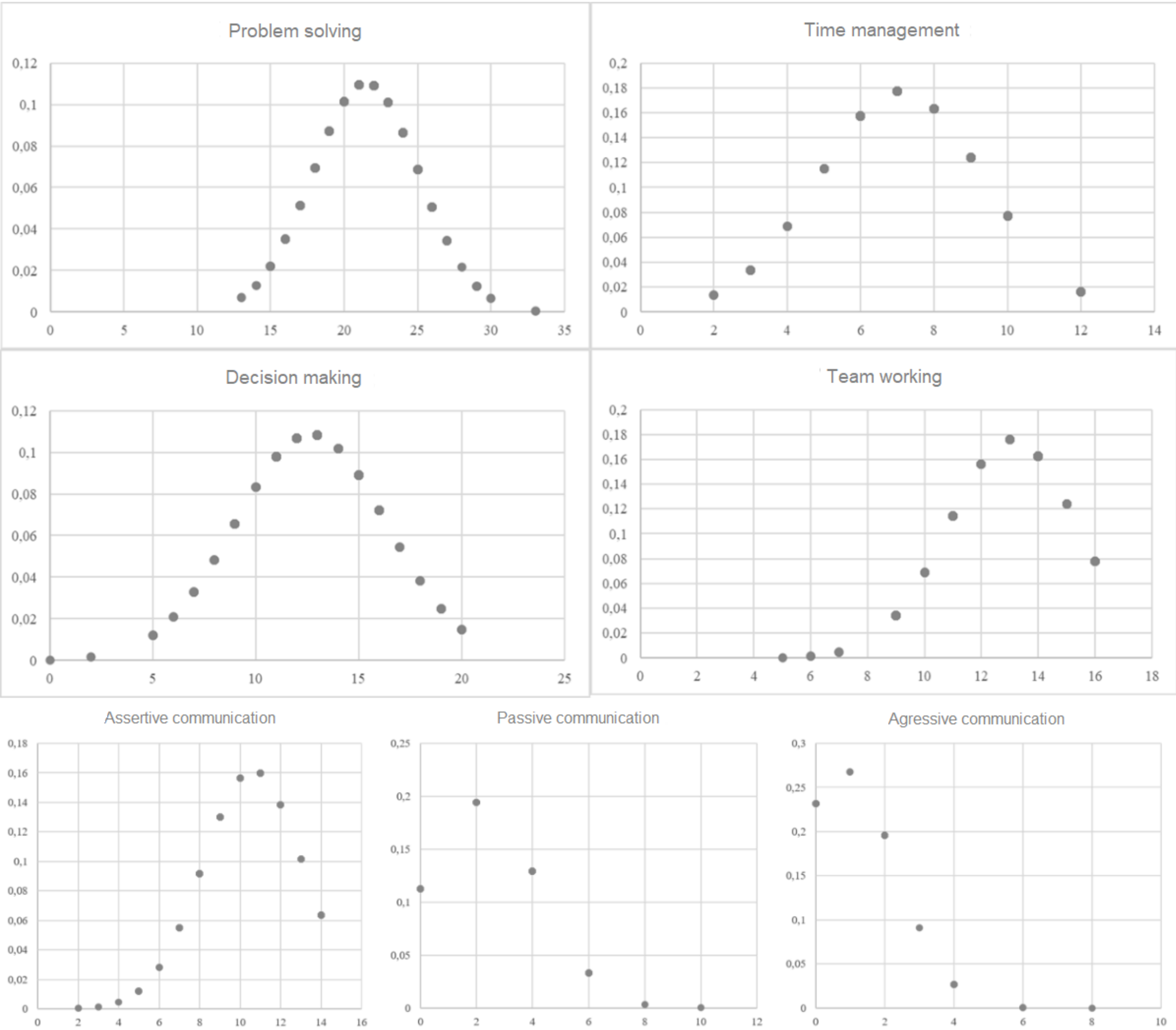
Elaboration and Descriptive Statistical Analysis

To test the serious game, the researchers conducted a pilot study with 160 subjects from the University of Calabria (Italy) who were enrolled in the 2018/2019 academic year. Table 2 and Figure 3 show the results of the preliminary data screening and the normal curve of the collected data. According to the criteria of Curran, West, and Finch [89] (asymmetry greater than |1|=severe nonnormality; kurtosis greater than |3|=moderate nonnormality), the value for aggressive communication was close to being severely nonnormal in terms of asymmetry. This may be due to a small number of data points for individuals who had this type of communication as a result. While only 1 item showed these values, the results of the descriptive analyses can still be considered reliable.

Table 2. Normality indices related to the final scores obtained for each soft skill.

Skill	Score, mean (SD)	Asymmetry	Kurtosis
Problem solving	21.47 (3.615)	0.133	−0.109
Team working	13.10 (2.269)	−1.271	1.261
Time management	7.09 (2.251)	0.059	−0.165
Decision-making	12.68 (3.673)	−0.250	0.395
Assertive communication	10.63 (2.469)	−0.700	0.523
Passive communication	2.15 (2.050)	0.912	0.751
Aggressive communication	0.82 (1.479)	2.120	4.969

Figure 3. Normal distribution curves. The x-axis represents values, and the y-axis indicates probability in the normal curves.



First Try Out: Feedback Analysis

A trial of the AOC experiment was conducted, and at the end of the simulation, users were asked to complete a questionnaire about their experience. The data analysis showed a strong consistency between the user evaluation produced by AOC and the user's self-awareness. Specifically, 88.3% (121/137) of responses to the question "Do you see yourself in the evaluation?" were at least "partly," 70.1% (96/137) were at least "quite," and 29.2% (40/137) were at least "yes." It was also useful to analyze the users' responses to the question "How would you describe the simulation in 3 adjectives?" The most common adjective used was "interesting," with a frequency of 16.1% (63/392) of all adjectives, followed by "fun" (36/392, 9.2%), "useful" (23/392, 5.9%), "engaging" (22/392, 5.6%), "realistic" (22/392, 5.6%), "stimulating" (17/392, 4.3%), and "innovative" (16/392, 4.1%), only considering adjectives with more than 15 repetitions (Table 3).

Table 3. Top unique repetitions of adjectives given as feedback from the assessed users to the serious game "Among the Office Criticality" after an assessment session.

Adjective	Unique repetitions (N=392), n (%)
Interesting	63 (16.1)
Fun	36 (9.2)
Useful	23 (5.9)
Engaging	22 (5.6)
Realistic	22 (5.6)
Stimulating	17 (4.3)
Innovative	16 (4.1)
Sympathetic	15 (3.8)
Effective	10 (2.6)
Appealing	7 (1.8)
Constructive	7 (1.8)
Efficient	7 (1.8)
Rapid	6 (1.5)

We found it useful to group the adjectives used by users into clusters based on their focus during the simulation. These clusters were arbitrarily defined as "involvement" (cluster 1; 120/392, 30.6%), "pleasure" (cluster 2; 73/392, 18.6%), "functionality" (cluster 3; 71/392, 18.1%), "innovation" (cluster 4; 25/392, 6.4%), "truthfulness" (cluster 5; 23/392, 5.9%), "dynamism" (cluster 6; 15/392, 3.8%), "personal growth" (cluster 7; 14/392, 3.6%), "challenge" (cluster 8; 5/392, 1.3%), and "other" (43/392, 11.7%). In this study, the first, second, and third clusters accounted for 67.3% (264/392) of user responses in the survey administered after they played the serious game. We found that these clusters corresponded to other questionnaires conducted after serious games in the literature. A key factor considered, as reflected in the final feedback from users, was fidelity.

Fidelity, referring to the consistency of the game with the real world, is a crucial attribute for reality-based games as it enhances player immersion. Immersion refers to the player's involvement in the "player's world," which is a crucial factor in motivating players to pursue "serious" goals [90]. However, it is important to balance immersion with entertainment elements, as previous studies have shown [27,91,92]. Fidelity can also contribute to the entertainment value of a game.

The enjoyment of playing a video game can increase motivation and lead players to find pleasure in the activities within the game, regardless of their achievements. This is especially relevant when the objectives of the game are perceived as enjoyable by the player [90].

Previous studies have found that user-perceived determinants after playing a serious game include feedback, ease of use and usability, and learning effectiveness, among others. This is consistent with the findings of this study, in which the analysis of the open-ended questionnaire taken by users at the end of the game revealed factors associated with the functionality cluster, such as ease of use and effectiveness [93]. Additionally, the enjoyment and presence-immersion factors identified in the study by Fokides et al [93] can be linked to the pleasure and involvement clusters.

According to a literature review (54 studies, 59 data sets, and 586 variables) conducted in 2019 by Baptista and Oliveira on gamification, the best predictors of acceptance for gamified technology were attitude, enjoyment, and usefulness on intention. The clusters of adjectives that were found to be most significant (involvement, pleasure, and functionality) in this study aligned with these findings, suggesting that the proposed serious game follows the trend of accepted gamification technology.

The results of the study showed that users were particularly interested in the level of engagement and interest generated by the simulation [94], as well as the entertainment value and overall emotional reactions (such as "interesting," "engaging," and "stimulating"). This aligns with the concept of recrutainment, which emphasizes the role of engagement in the recruitment process [95]. In addition, users were interested in the functionality of the assessment tool, as indicated by adjectives like "useful," "effective," and "efficient." These results highlight the importance of designing the tool with users' needs in mind. Overall, about half (193/392, 49.2%) of the adjectives in the involvement and pleasure clusters [86] supported the theory of user-centered design.

Discussion

Role of Gamification in Assessing Soft Skills for Talent Acquisition

This study proposes an immersive serious game model, called AOC, which aims to evaluate 5 important soft skills sought after in the job market, namely, problem solving, team working, time management, decision-making, and communication. The design of AOC was based on the literature and followed a user-centered design approach to create a user-friendly and intuitive environment. The output provided to the user holds significance as AOC was designed to generate value for both the evaluator and the evaluated subject. Therefore, it is essential to show areas of potential growth and increase the user's self-awareness after the simulation. This study found that the proposed serious game model may be considered in line with existing literature. Nevertheless, it is worth acknowledging that this study is not without limitations. One such limitation is the relatively small sample size, which may have implications for the generalizability of the findings. To build upon and strengthen our findings, future studies with larger and more diverse samples are recommended.

Gamification is a viable solution to improve some aspects of personnel selection [95], particularly the concept of recrutainment, which focuses on the candidate's involvement in the selection process [4,83]. Serious games are useful for both education and assessment, and are increasingly used in business and work contexts, as they help reduce selection time, avoid subjective evaluation [70], and reduce cognitive bias. They also allow for employer branding, which can positively influence the user's opinion of the evaluator [84]. According to Diercks and Kupka [84], the use of self-assessment elements in selection can increase the success rate of achieving objectives to 93%, especially when employer branding and personnel marketing are properly carried out. The term "recrutainment," which combines the words "recruiting" and "entertainment," has gained popularity among Generation Y and refers to gamified, user-oriented, and simulation games that aim to improve the quality of suitable candidates through self-assessment procedures [84]. The use of gamification, combined with cognitive and aptitude assessment methods [57], is increasing in the field of recruitment and human resources in general. It is expected to triple from 2020 to 2025, with a focus on its use in personnel selection [95].

However, as noted by Kirovska et al in 2020 [95], implementing a gamification model in the recruitment process carries risks, including the need for constant monitoring. Therefore, many companies outsource it to third-party organizations to benefit from reduced hiring times and increased interaction levels, as well as to delegate risks. Attracting innovative talent is a goal for many organizations and allows them to consider characteristics and attitudes aligned with their brand's aim. Gamification also encourages the user to do more than what is required [96], which can be a competitive advantage. In 2017, Korn et al [83] identified 42 applications (evaluating 60% of them) proposed by well-known organizations that use recrutainment, with a focus on the correlation between the profile and the hiring subject's needs (job relatedness). They also emphasized that a low score in a single game does not necessarily mean poor user skills and that, in fact, each result could identify areas for improvement.

The human resource industry has come to fully understand and use gamification in the talent acquisition process, including from a strategic perspective. While the evaluation of technical skills is important and can be inferred from a candidate's resume, transversal skills, which are intrinsic, innate, or developed through training and life experiences, are more difficult to objectively evaluate. This requires a significant amount of time and energy from human resource professionals [97]. In this context, gamification becomes important as it allows certain characteristics to emerge indirectly, which can be very complicated to discover otherwise [63]. Soft skills can make a significant difference in the business environment, and serious games are particularly effective at evaluating them because they can be assessed in various contexts and methods [12,13], including through self-assessment.

Conclusions and Future Developments

This research presents AOC, a serious game designed to meet the needs of the job market and place the user at the center. Evaluation techniques consistent with the literature were used to create an interdisciplinary approach for adequately evaluating the user and adding value. Initial analysis suggested that the scores obtained by subjects during the serious game can be generalized to the general population. Additionally, feedback from a postgame questionnaire indicated that the game is engaging, enjoyable, functional, innovative, and realistic, and promotes personal growth. The feedback specifically emphasizes the engagement and interest sparked by the simulation, aligning with the principles of user-centered design and recrutainment theory.

In conclusion, we propose the methodologies used in the development of the serious game AOC as a framework for designing serious games that consider the key aspects of the user journey and their relevance to theory and traditional assessment.

Future work may include analyses of the data generated by the serious game, including skills of the studied sample, skill development over time, cross-analysis with other samples, and comparison with data from other serious games evaluating different work-life skills.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
AOC: Among the Office Criticality
ICT: information and communications technology

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Original Paper

Preference of Virtual Reality Games in Psychological Pressure and Depression Treatment: Discrete Choice Experiment

Shan Jin[1*], BSc, MPhil; Zijian Tan[2*], MPH; Taoran Liu[3], PhD; Sze Ngai Chan[4], MD, MPH; Jie Sheng[3], MSc; Tak-hap Wong[3], MBBS, MMed; Jian Huang[5], BSc, MPH, PhD; Casper J P Zhang[6], MPH, PhD; Wai-Kit Ming[3], MD, PhD, MPH, MMSc

[1]The Thrust of Computer Media and Art, The Hong Kong University of Science and Technology (Guangzhou), Guangzhou, China

[2]Department of Public Health and Preventive Medicine, School of Medicine, Jinan University, Guangzhou, China

[3]Department of Infectious Diseases and Public Health, Jockey Club College of Veterinary Medicine and Life Sciences, City University of Hong Kong, Hong Kong, China (Hong Kong)

[4]Department of Obstetrics and Gynaecology, First Affiliated Hospital of Jinan University, Guangzhou, China

[5]Department of Epidemiology and Biostatistics, School of Public Health, Imperial College London, London, United Kingdom

[6]School of Public Health, The University of Hong Kong, Hong Kong, China (Hong Kong)

[*]these authors contributed equally

Corresponding Author:
Wai-Kit Ming, MD, PhD, MPH, MMSc
Department of Infectious Diseases and Public Health
Jockey Club College of Veterinary Medicine and Life Sciences
City University of Hong Kong
Room 1A-503, 5/F, Block 1, To Yuen Building, 31 To Yuen Street
Hong Kong
China (Hong Kong)
Phone: 852 34426956
Email: wkming2@cityu.edu.hk

Abstract

Background: Virtual reality (VR) can be used to build many different scenes aimed at reducing study-related stress. However, only few academic experiments on university students for preference testing have been performed.

Objective: This study aims to assess the preference of VR games for stress and depression treatment using a discrete choice experiment (DCE).

Methods: A total of 5 different attributes were selected based on the depression therapy parameters and attributes related to VR: (1) treatment modality; (2) therapy duration; (3) perceived remission rate; (4) probability of adverse events; and the (5) monthly cost of adding treatment to a discrete choice experiment. By comparing different attributes and levels, we could draw some conclusions about the depression therapy testing preference for university students; 1 university student was responsible for VR scene development and 1 for participant recruitment.

Results: The utility value of different attributes for “0% Probability of adverse events” was higher than others (99.22), and the utility value of VR treatment as the most popular treatment method compared with counseling and medicine treatment was 80.95. Three parameter aspects (different treatments for depression) were statistically significant (P<.001), including “0%” and “50%” of “Probability of adverse events” and “¥500” (a currency exchange rate of ¥1 [Chinese yuan]=US $0.15 is applicable) of “The monthly cost of treatment.” Most individuals preferred 12 months as the therapy duration, and the odds ratio of “12 months” was 1.095 (95% CI 0.945-1.270) when compared with the reference level (6 months). Meanwhile, the cheapest price (¥500) of depression therapy was the optimum choice for most students.

Conclusions: People placed great preference on VR technology psychological intervention methods, which indicates that VR may have a potential market in the treatment of psychological problems. However, adverse events and treatment costs need to be considered. This study can be used to guide policies that are relevant to the development of the application of VR technology in the field of psychological pressure and depression treatment.

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KEYWORDS
virtual reality; discrete choice experiment; college student; depression therapy

Introduction

According to a report provided by World Health Organization [1], the incidence of depression accounts for about 4.4% of the total world population [2,3]. A detailed report [4] specifically about the prevalence of depression among Chinese individuals was recently published [5]. The China Mental Health Survey estimated that more than 95 million patients have depression in China: 83% of the patients with depression were reported to be older than 35 years old, and 65% of the patients were female [6]. Among Chinese university students, the overall prevalence of depression was 28.4% (n=185,787), and the percentage of depressed individuals was reported to be high [7].

Depression is the emotional expression of a state of ego-helplessness and ego-powerlessness to live up to certain strongly maintained narcissistic aspirations [8]. Individuals with depressive disorders usually feel sad, lonely, or irritable, and in most cases, they are in a bad mood [9]. People with depression usually experience at least five of the following 9 characteristics: (1) people feel sad and unhappy; (2) people have less interest in doing things; (3) individuals do not follow a diet, but their weight losses are obvious; (4) their weights increase, or their appetites change; (5) they suffer insomnia or drowsiness; (6) some people have mental agitation; (7) they feel that life is meaningless, or they feel guilty; (8) they have difficulty concentrating; or (9) they have suicidal thoughts [10,11].

Three categories offer reasons that individuals have this illness: (1) the influence of environmental factors (eg, abuse, criticism, or neglect in childhood); (2) the genetic factors (individuals whose close relatives have been diagnosed with depression are at an increased risk); or (3) the effects of hormones, such as serotonin and norepinephrine [12-14].

At present, the 3 main therapy methods to tackle this issue are drug treatment (antidepressants, antipsychotics), psychotherapy (psychotherapy consultation), and phototherapy (usually suitable for dealing with seasonal depression). Other alternative therapy methods are Chinese herbal medicine, exercise, meditation, self-relaxation, and others. Some antidepressants have side effects, and the cost of psychotherapy is high [15-17].

Virtual reality (VR) technology has *3I* characteristics, namely, immersion, interaction, and imagination [18,19]. In the previous research on VR, as it relates to therapy for depression, a new concept of VR exposure therapy had been used in the treatment of anxiety and depression. The growing body of literature suggests that VR exposure therapy is a successful tool for relieving stress caused by psychological problems [20-22]. For example, the VR gaming experience could be used in conjunction with exercise, using games such as VirZoom, in which a VR exercise bike is compatible with most VR headsets [23,24]. The participant could wear the headset and alleviate stress and depression using the game [25].

According to the literature review, DCE is not widely applied in the field of VR technology. Research on the uses of VR technology has only covered a few areas, such as fire emergency exit testing [26], willingness-to-pay services research [27], and the testing of pedestrian behavior models [28]. By contrast, there are studies on depression and DCE. Lokkerbol et al [29] demonstrated how different components of depression treatment could impact patients' preferences. The study conducted by van Loenen et al [30] showed that DCE could support the preference of genetic testing for the user's willingness-to-pay and help improve depression therapy. Actually, some research suggests that the VR technology is useful in treating depression [22-25]. For example, the result from Schleider et al [31] revealed that using immersive technology, such as a VR headset, may be an efficient strategy for reducing adolescent depressive symptoms. However, to our knowledge, there is no research that investigates the participants' preference regarding using VR technology in treating depression. There is still a big gap in the application of VR technology in DCE, and our experiments could help in this field. The purpose of this experiment is to investigate the preference for VR technology in psychological pressure relief and depression treatment for college students.

Methods

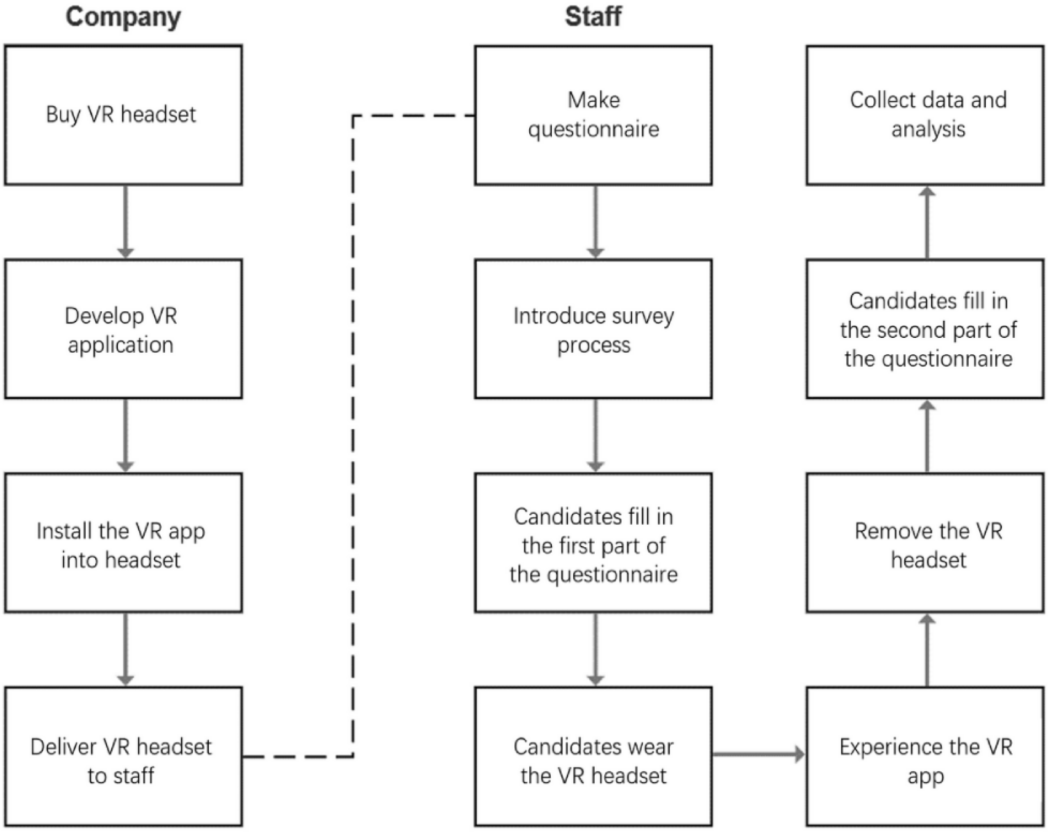
Study Sample

The study was conducted at 2 comprehensive universities in China, Jinan University in Guangzhou and the University of Electronic Science and Technology of China (UESTC) in Chengdu. We recruited our study participants from different majors at the 2 universities. Inclusion criteria included 3 parameters: (1) at least 18 years old; (2) interested in their mental state or with depressive disorders/episodes; and (3) interested in using VR technology to improve mental health problems. Those who did not agree to participate in the study and were suffering from major diseases other than depression and other mental illnesses were excluded.

Process

Figure 1 illustrates our research process. Two groups of students from different areas were enrolled in this study. Students in group 1 came from the UESTC in Chengdu, and students in group 2 came from Jinan University in Guangzhou. The students from the UESTC needed to borrow a VR device as they did not have a VR headset to support app development.

Figure 1. The process of conducting the experiment. VR: virtual reality.



Discrete Choice Experiment

Discrete choice experiment (DCE) is a utility method in the field of economics [32]. The theory is not only applicable to economics but is also widely used in other disciplines, such as in industries, education, software, and medical care [33,34]. Medical applications include prenatal diagnostic testing and myocardial infarction diagnostic testing [35]. We conducted the questionnaire survey and VR game experience and then collected the corresponding statistical data based on the results that were collected [36,37].

VR Platform

Our devices were a Pico Neo 2 (Sichuan Shuyun Technology Co., Ltd) with a head display, earphones, handle, connecting cable, and other accessories. The VR headset also has some disadvantages: when people wear this device for a long time to play games, it may cause dizziness, nausea, eye fatigue, blurred vision, and other problems [38-40]. However, those negative influences will decrease if users just wear the headset for several minutes.

Virtual Reality Applications

Figures 2 and 3 demonstrate the VR device and application panel, respectively. It is obvious that scholars have previously performed some research experiments on static scene VR applications; thus, we selected 2 dynamic and interactive applications in this experiment: (1) VR physical and mental relaxation system and (2) VR music comfort system.

The VR physical and mental relaxation system needs participants to cooperate with the virtual professional psychologist's guidance into scenes to help them correctly and quickly adjust to negative emotions, such as psychological anxiety and tension. First, this system could provide 16 3D realistic natural sceneries (Figures 4 and 5) so that patients can enjoy the beauty of nature without leaving home with the aim of relieving anxiety and maintaining physical and mental health for themselves. Second, based on the logic of relaxation therapy, it can provide a psychotherapist's voice as a relaxation guide to help patients correctly relax their body and mind, and it allows them to become immersed in the atmosphere of nature to quickly eliminate negative emotions and adjust their mentality.

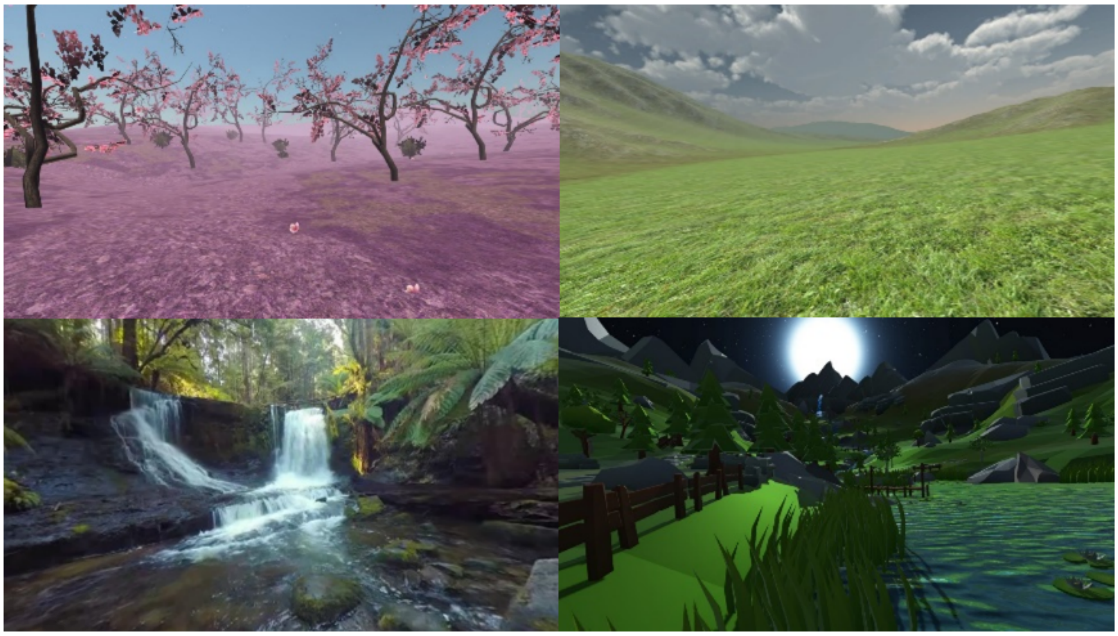
We designed a "VR music comfort system," which included dozens of psychological medical music approaches. Through comfortable music activities, this system could trigger positive experiences in physiology to promote perception, memory, and arousal. This application's key features are as follows: users can choose different scenes according to their preferences and can listen to music to relax. At the same time, users can also turn on the voice guidance function to receive guidance regarding depression and relaxation. The key step here is the user interface design because we must make sure participants could listen to the music from different VR buttons and experience the application without failure. Unity 3D and Visual Studio were used to create the user interface design, and we must make sure participants can wear the headset and click different scenes from the VR buttons correctly. Then, they can listen to music and travel to different environments in VR. At the same time, this system also integrates a positive music interaction system with the aim of promoting people's physical and mental health; thus, music interactive scene training is carried out in the virtual world to relieve emotions [41,42].

Figure 2. Display of handle, headset, and function key in the device.

Figure 3. Application Panel for Pico Neo 2 (Sichuan Shuyun Technology Co., Ltd).

Figure 4. Scene selection interface (includes 16 various scenes, such as historical city, beautiful mountain, waterfall, and peaceful lake).

Figure 5. Scene examples (the first picture illustrates peach blossom, the second scene is a lawn on top of a mountain, the third is a 360° video that we could watch at different angles in the virtual world, and the fourth is a peaceful scene under the moon at night).



Attributes and Levels

In this paper, for the DCE attribute and the level design, we conducted a focus group with the professors in medicine at Jinan University. We came up with 5 attributes and levels. In addition, for details on the setting of the levels, we performed a literature search. There are some studies on the perceived remission rate and the incidence of adverse reactions regarding the selection of depression indicators. Different countries and experts have their own indicator considerations. Possible attributes were identified from a panel of experienced chief physicians from Jinan University. Finally, 5 different attributes were selected: (1) treatment modality, (2) therapy duration, (3) perceived remission rate, (4) probability of adverse events, and (5) the monthly cost of treatment. Based on the academic research experiments for depression therapy, we divided the attributes into several independent parameters concerning therapy duration [43,44], cost [45-48], perceived remission rate [49-55], and probability of adverse events [56-60] with the aim of building different intervals for real life. To eliminate the influence of dimensions between different attributes, the average utility values of all attribute levels were measured using the utility scaling method with zero-centered differences. Attributes and levels are shown in Table 1.

Table 1. Attributes and levels.

Attributes	Levels of attributes
Treatment modality	• kL1 Medication only • L2 Counseling only • L3 VR[a] only
Therapy duration	• L1 6 months • L2 12 months • L3 18 months • L4 Lifetime
Perceived remission rate	• L1 35% • L2 40% • L3 45% • L4 50%
Probability of adverse events	• L1 0% • L2 30% • L3 50%
The monthly cost of treatment	• L1 ¥500[b] • L2 ¥1000 • L3 ¥1500 • L4 ¥2000 • L5 ¥2500

[a]VR: virtual reality.

[b]A currency exchange rate of ¥1 (Chinese yuan)=US $0.15 is applicable.

Questionnaire

This questionnaire is collected from the online questionnaire platform. It includes 4 parts: (1) basic information (5 questions: gender, education level, the impact of depression on health, level of understanding of depression, and level of understanding of VR technology); (2) the first DCE experiment; (3) VR experience evaluation feedback (5 questions: effective treatments for depression, the function of this VR app in therapy, defects of VR in psychotherapy, the best time for VR for psychotherapy, and VR scenes preferred to experience); and (4) the second DCE experiment. In the beginning, the users should complete the basic information collection step; then, they will fill in the first part of the DCE questionnaire. After finishing these sections, they will be asked to wear the VR headset and experience the apps. They will then need to finish the VR experience evaluation feedback part and the second DCE questionnaire sequence. Brief introductions for participants to acquire related knowledge at the beginning of each part, such as VR's introduction, DCE procedure, and the meaning of the probability of adverse events, will be included. The duration of the VR applications will be around 5 minutes. Based on completing the questionnaire prior to VR application and pretesting the VR, participants were allowed 20 minutes to complete the research. An interactive design was devised; when the cursor or fingers touch the nouns (perceived remission rate, probability of adverse events), volunteers will see the introduction around the concepts and gain some useful information about them [35,36].

The first part of the DCE was conducted before the participants viewed the VR scenes, and the second part of the DCE was conducted after the participants had viewed the VR scenes. This research compared the 2 different DCE parts to understand whether VR could produce different effects on different participants. Each DCE contained 6 multiple-choice questions with 3 different options: (1) intervention mode 1, (2) intervention mode 2, and (3) other ways. The example questions of DCE are shown in Table 2. For the DCE part, the same DCE design (ie, a random draw of the set of questionnaires from the pool with the same attributes and levels) was used for the "before-and-after" comparison. In this study, we compared the preference "before-and-after" of the participants. Our discussion about the 2 DCE parts has different questions in the "before-and-after" comparison because we subtracted various parameters from the 5 attributes in every DCE's part to discover the user's preference for depression therapy before and after experiencing the VR applications. Some parts of the DCE design are referred to in Ryan and Gerard's [33] experiment, which provides better guidance on disease prevention and treatment using DCE.

Table 2. An example of discrete choice experiment question.

Attributes	Treatment A	Treatment B	Neither
Treatment modality	VR[a] only	Medication only	
Therapy duration	12 months	18 months	Neither
Perceived remission rate, %	35	40	
Probability of adverse events, %	0	50	
The monthly cost of treatment (¥)[b]	500	2000	

[a]VR: virtual reality.

[b]A currency exchange rate of ¥1 (Chinese yuan)=US $0.15 is applicable.

Statistical Analysis

Latent Class Analysis Model

Latent class analysis was used to interpret the DCE data. The conditional logit regression model was used to quantify the correlation between the participant's choice and the attribute levels of various test profiles for which the choices were used as the dependent variable and the attribute levels of tests as covariates. The levels for the 5 attributes were coded based on effects. The conditional logic model makes statistical inferences based on the weights of the respondents' preferences for various attributes and levels in the questionnaire. The resulting positive and negative coefficients after the regression analysis indicated the direction of the respondent's preference for a given attribute level. Based on the importance and magnitude of the coefficients, the marginal rate of substitution between each attribute and the relative importance of the attributes was calculated, which could measure the willingness to accept a trade-off among different options of respondents. These marginal rate of substitution values allowed for the comparison of different attributes using a common scale [61], and the odds ratios (ORs) of respondents' preferences for different attribute levels were also reported. Sawtooth (Sawtooth Software, Inc.) was used to run the coefficients of all attributes and SEs, and *t* ratios to calculate the P values. For the P value of all levels of attributes, we assumed that if the P value of a level was <.05, this level was then statistically significant; when the P value of a level was <.001, this level was considered highly statistically significant.

Latent Class Model

A latent class analysis was conducted to identify correlations among explicit variables, create the fewest number of classes, and achieve local independence. According to Greene and Hensher [62], this method uses a semiparametric approach to model the correlation structure of the data and identify classes that are more homogeneous in terms of variance structure. This method of analysis can be used to sort individuals into a set of classes with a certain segmented size and scale, and different effects of each class were estimated for different attributes. In addition, this method will help us to measure the differences and similarities of preference across classes of respondents. Akaike information criterion 3 and Bayesian information criteria (AIC3 and BIC, respectively) were used as the main criteria, and after the latent class model was created, the resulting data were classified into the appropriate latent classes.

Software

All statistical analyses were performed using Sawtooth Lighthouse Studio (SSI Web version 9.11.0; Sawtooth Software, Inc.).

Ethics Approval

This study was approved by the Medical Ethics Committee of Jinan University (JNUKY-2021-004).

Results

Survey Participants

A total of 154 people were surveyed, among which 114 completed all the questionnaire contents (response rate 74%). The summary of demographic information and the suggestions and preferences of participants after using VR are shown in Table 3.

Table 3. Summary of demographic information, suggestions, and preferences of participants.

Items	Total (N=114), n (%)	Medical students (n=71), n (%)	Nonmedical students (n=43), n (%)	P value
Gender				.84
Male	65 (57.0)	43 (60.6)	22 (51.2)	
Female	49 (42.9)	28 (39.4)	21 (48.8)	
Education level				.04[a]
College degree	13 (11.4)	6 (8.5)	7 (16.3)	
Bachelor	92 (80.7)	57 (80.3)	35 (81.4)	
Master	8 (7.0)	7 (9.9)	1 (2.3)	
Doctoral	1 (0.9)	1 (1.4)	0 (0.0)	
The impact of depression on health				.62
No effect	6 (5.3)	5 (7.0)	1 (2.3)	
Affects only emotions	22 (19.3)	14 (19.7)	8 (18.6)	
Has a certain impact	29 (25.4)	16 (22.5)	13 (30.2)	
Has a serious impact	57 (50.0)	36 (50.7)	21 (48.8)	
Level of understanding of depression				.18
Not clear	14 (12.3)	8 (11.3)	6 (14.0)	
Slightly heard	56 (49.1)	35 (49.3)	21 (48.8)	
General understanding	38 (33.3)	24 (33.8)	3 (7.0)	
Understand completely	6 (5.3)	4 (5.6)	4 (9.3)	
Level of understanding of virtual reality				.20
Not clear	17 (14.9)	8 (11.3)	9 (20.9)	
Slightly heard	64 (56.1)	43 (60.6)	21 (48.8)	
General understanding	23 (20.2)	12 (16.9)	11 (25.6)	
Understand completely	10 (8.8)	8 (11.3)	2 (4.7)	
Effective treatments for depression				.54
Psychological consultation	74 (64.9)	46 (64.8)	28 (65.1)	
Medicine treatment	83 (72.8)	49 (69.0)	34 (79.1)	
Movement regulation	57 (50.0)	36 (50.7)	21 (48.8)	
Self-regulation	67 (58.8)	38 (53.5)	29 (67.4)	
Virtual reality treatment	44 (38.6)	21 (29.6)	23 (53.5)	
Function of this virtual reality app in therapy				.20
Relieve stress	65 (57.0)	36 (50.7)	29 (67.4)	
Divert attention	71 (62.3)	45 (63.4)	26 (60.5)	
Satisfy vanity	20 (17.5)	12 (16.9)	8 (18.6)	
No function or have other function	14 (12.3)	12 (16.9)	2 (4.7)	
Defects of virtual reality in psychotherapy				.86
Uncomfortable wearing	20 (17.5)	12 (16.9)	8 (18.6)	
Technology is immature	35 (30.7)	22 (31.0)	13 (30.2)	
Expensive	29 (25.4)	17 (23.9)	12 (27.9)	
Not easy to operate	16 (14.0)	8 (11.3)	8 (18.6)	
The best time for virtual reality for psychotherapy				.47
Immediately aware of stress	15 (13.2)	10 (14.1)	5 (11.6)	
When depression is diagnosed	27 (23.7)	14 (19.7)	13 (30.2)	

Items	Total (N=114), n (%)	Medical students (n=71), n (%)	Nonmedical students (n=43), n (%)	P value
During psychotherapy	32 (28.1)	17 (23.9)	15 (34.9)	
Experience at any time in daily life	26 (22.8)	18 (25.4)	8 (18.6)	
Virtual reality scenes preferred to experience				.006[a]
Quiet real virtual environment	64 (56.1)	37 (52.1)	27 (62.8)	
Strange real virtual environment	43 (37.7)	23 (32.4)	20 (46.5)	
Help yourself recall the past	52 (45.6)	26 (36.6)	26 (60.5)	
Experience the good things of the past	53 (46.5)	28 (39.4)	20 (46.5)	
Watching movies and television shows	34 (29.8)	14 (19.7)	16 (37.2)	
Play simple mini-games	31 (27.2)	15 (21.1)	12 (27.9)	
The experience that dreams come true	25 (21.9)	13 (18.3)	29 (67.4)	
Play exciting and fun big games	25 (21.9)	16 (22.5)	12 (27.9)	
Other	14 (12.3)	12 (16.9)	9 (20.9)	

[a]P<.05 indicates statistical significance.

For the VR experience, evaluation feedback results showed that most individuals preferred the choice of VR helmet weight, comfort, and application contents. Students also thought that VR relieves stress and diverts attention. Furthermore, students would choose the immersive scenes, memorable places from their childhood, and beautiful fantasies of the virtual world for the VR depression therapy after the VR experience.

Attributes' Levels and Utility Report

In the study, the utility scaling method with zero-centered differences was used to measure the average utility values of all the attribute levels and the utility gap between different treatment methods; additionally, the probability of adverse events was overt. For example, the utility of VR treatment alone was 80.95, whereas it was −42.66 and –38.30 for the attributes "Medication only" and "Psychological counseling," respectively; for 30% probability of adverse events, the utility value was –13.81%, whereas for 50% adverse reactions, the utility value was –85.41%.

To eliminate the influence of dimensions between different attributes, the average utility values of all attribute levels were measured using the User-based Security Model with zero-centered differences. The highest utility levels of the 5 hypothesized attributes were "VR only" (of "Treatment modality"), "12 months" (of "Therapy duration"), "40%" (of "Perceived remission rate"), "0%" (of "Probability of adverse events"), and "¥500" (of "The monthly cost of treatment"; a currency exchange rate of ¥1 [Chinese yuan]=US $0.15 is applicable). The most important attribute was "Probability of adverse events," indicating that most respondents ranked that attribute the highest (Table 4).

Table 4. The utility report of different attributes.

Attributes and levels	Utility
Treatment modality	
VR[a] only	80.95
Medication only	–42.66
Counseling only	–38.30
Therapy duration	
6 months	6.62
12 months	23.24
18 months	5.72
Lifetime	–35.57
Perceived remission rate	
35%	0.22
40%	10.81
45%	–5.35
50%	0.45
55%	–6.14
Probability of adverse events	
0%	99.22
30%	–13.81
50%	–85.41
The monthly cost of treatment[b]	
¥500	69.44
¥1000	16.18
¥1500	3.64
¥2000	–42.71
¥2500	–46.55
None	
N/A[c]	–336.97

[a]VR: virtual reality.

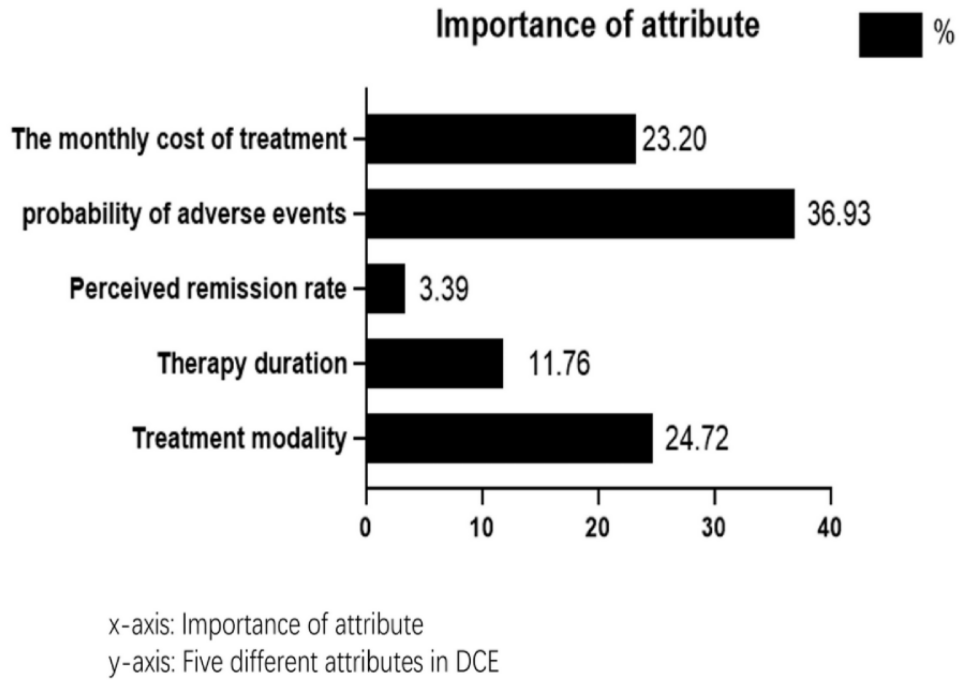
[b]A currency exchange rate of ¥1 (Chinese yuan)=US $0.15 is applicable.

[c]N/A: not applicable.

Logit Result of DCE and Attributes' Percentage Importance

As is presented in Figure 6, the percentage importance of the attribute "Probability of adverse events" was the highest, which shows that people reported being most concerned about the probability of adverse events. The attributes "Treatment modality" and "The monthly cost of treatment" ranked second and third, respectively.

Figure 6. Importance of attributes. DCE: discrete choice experiment.



The results of the logit analysis of all attribute levels are presented in Table 5. For treatment modality, the coefficient of the level "VR only" was positive, which indicated that the level "VR only" was positively correlated with people's preferences and use. In addition, the coefficients of the levels "6 months," "12 months," and "18 months" of "Therapy duration" were positive, and "lifetime" was negative. It is clear that people showed a preference for shorter periods of therapy, but not necessarily for the shortest one. For the attribute "Therapy duration," people were more inclined to choose the level of "12 months." For the levels of other attributes, people preferred the lower probability of adverse events and lower treatment costs. However, for the attribute "Perceived remission rate," people unexpectedly preferred a lower perceived remission rate rather than the "55%" option. A reasonable explanation for this phenomenon is that individuals with various degrees of histories, genders, and other backgrounds would have a different understanding of this concept (perceived remission rate). In addition, some of the participants neglected the tips around this concept in our questionnaire. We found that "VR only," "Medication only," and "Counseling only" for "Diagnosis methods" were highly statistically significant ($P<.001$ for all), "0%" and "50%" of "Probability of adverse events" were extremely statistically significant ($P<.001$), and "¥500" of "The monthly cost of treatment" was also statistically significant ($P<.001$).

Taking the level "VR only" of the "Treatment modality" attribute as the reference, the ORs of "Medication only" and "Counseling only" were 0.509 (95% CI 0.452-0.573) and 0.521 (95% CI 0.462-0.588), respectively. The OR of "12 months" of "Therapy duration" was 1.095 (95% CI 0.945-1.270) with the level "6 months" as the reference. ORs for "30%" and "50%" of the "Probability of adverse events" attribute were 0.539 and 0.364, respectively, with the level "0%" as the reference (95% CI 0.480-0.605 and 0.323-0.412, respectively). All attribute levels for "The monthly cost of treatment" were <1, which indicated that the preference weights declined with increasing medical fees.

Table 5. The result of logit analysis of preference in general (N=114).

Attribute and levels	Coefficient (SE)	P value	Odds ratio (95% CI)
Treatment modality			
VR[a] only	0.44257 (0.06067)	<.001[b]	Reference
Medication only	–0.23321 (0.06124)	<.001[b]	0.509 (0.452-0.573)
Counseling only	–0.20936 (0.06126)	<.001[b]	0.521 (0.462-0.588)
6 months	0.03617 (0.07616)	.64	Reference
12 months	0.12704 (0.07548)	.09	1.095 (0.945-1.270)
18 months	0.03126 (0.07691)	.68	0.995 (0.856-1.157)
Lifetime	–0.19447 (0.07715)	<.05	0.794 (0.683-0.924)
Perceived remission rate			
35%	0.00123 (0.0894)	.99	Reference
40%	0.05912 (0.08968)	.51	1.060 (0.889-1.263)
45%	–0.02924 (0.08919)	.74	0.970 (0.814-1.155)
50%	0.00248 (0.08993)	.98	1.001 (0.839-1.194)
55%	–0.03359 (0.09085)	.71	0.966 (0.808-1.154)
Probability of adverse events			
0%	0.54244 (0.06096)	<.001[b]	Reference
30%	–0.07549 (0.05907)	.20	0.539 (0.480-0.605)
50%	–0.46695 (0.06215)	<.001[b]	0.364 (0.323-0.412)
The monthly cost of treatment			
¥500[c]	0.37962 (0.08936)	<.001[b]	Reference
¥1000	0.08844 (0.08881)	.32	0.747 (0.628-0.889)
¥1500	0.01993 (0.09042)	.83	0.698 (0.585-0.833)
¥2000	–0.2335 (0.09043)	.01[d]	0.542 (0.454-0.647)
¥2500	–0.25448 (0.08962)	.005[d]	0.530 (0.445-0.632)
None			
N/A[e]			

[a]VR: virtual reality.

[b]P<.001 indicates highly statistical significance.

[c]A currency exchange rate of ¥1 (Chinese yuan)=US $0.15 is applicable.

[d]P<.05 indicates statistical significance.

[e]N/A: not applicable.

Latent Class Analysis Result

We compared these potential models, selected the model that maximized the area under the receiver–operating characteristic curve, and minimized the AIC or BIC to compensate for model complexity [63]. According to AIC, 5 classes should have been the best choice for our model. By contrast, BIC favored the 2-class option with the lowest BIC. Under such circumstances, we compared A BIC, that is, sample size–adjusted BIC, which involved sample size values. After comparison, the 2-class option had the lowest value of A BIC. Therefore, the most suitable number of latent classes in our model was 2 (Tables 6 and 7). First, all 114 respondents were divided into 2 classes with segment sizes of 77 (67.5%) and 37 (32.5%), respectively. The average maximum membership probability was around 0.87, and the percent certainty was 26.17, which is relatively low, indicating that a low level of uncertainty according to the respondents is divided into classes.

Table 6. Estimated relative preference weights for the 2 classes.

Attribute and levels	Class 1 (n=77)		Class 2 (n=37)	
	Coefficient (SE)	P value	Coefficient (SE)	P value
Treatment modality				
VR[a] only	0.02171 (0.07483)	.77	1.84767 (0.17233)	<.001[b]
Medication only	–0.00327 (0.07666)	.97	–1.00383 (0.14776)	<.001[b]
Counseling only	–0.01844 (0.07641)	.81	–0.84383 (0.14531)	<.001[b]
Therapy duration				
6 months	0.13392 (0.09565)	.16	–0.14452 (0.17659)	.42
12 months	0.20073 (0.09506)	.04[c]	–0.13237 (0.17046)	.44
18 months	–0.06778 (0.09688)	.49	0.29698 (0.17683)	.09
1 Lifetime	–0.26687 (0.09761)	.008[c]	–0.02009 (0.17657)	.91
Perceived remission rate				
35%	–0.16277 (0.11263)	.15	0.37689 (0.19847)	.06
40%	0.06315 (0.11437)	.58	0.25085 (0.20222)	.22
45%	–0.03595 (0.11223)	.75	–0.13115 (0.20607)	.53
50%	0.05105 (0.11274)	.65	0.01580 (0.20174)	.94
55%	0.08453 (0.11305)	.46	–0.51237 (0.21644)	.02[c]
Probability of adverse events				
0%	0.79611 (0.07858)	<.001[b]	–0.05400 (0.13866)	.70
30%	–0.07486 (0.07208)	.30	–0.01935 (0.14090)	.89
50%	–0.72125 (0.07926)	<.001[b]	0.07336 (0.14025)	.60
The monthly cost of treatment[d]				
¥500	0.29184 (0.11329)	.01[c]	0.99343 (0.20344)	<.001[b]
¥1000	–0.01184 (0.11108)	.91	0.64172 (0.20413)	.002[c]
¥1500	–0.01581 (0.11449)	.89	0.02437 (0.20354)	.90
¥2000	–0.18010 (0.11332)	.12	–0.39729 (0.21176)	.06
¥2500	–0.08408 (0.11113)	.45	–1.26223 (0.23087)	<.001[b]

[a]VR: virtual reality.

[b]P<.001 indicates highly statistical significance.

[c]P<.05 indicates statistical significance.

[d]A currency exchange rate of ¥1 (Chinese yuan)=US $0.15 is applicable.

Table 7. Odds ratios and CIs of attribute levels in the 2 classes.[a]

Attribute and levels	Class 1 (n=77), odds ratio (95% CI)	Class 2 (n=37), odds ratio (95% CI)
Treatment modality		
VR[b] only	Reference	Reference
Medication only	0.975 (0.842-1.129)	0.058 (0.041-0.081)
Counseling only	0.961 (0.827-1.116)	0.068 (0.051-0.090)
Therapy duration		
6 months	Reference	Reference
12 months	1.069 (0.887-1.288)	1.012 (0.725-1.414)
18 months	0.817 (0.676-0.988)	1.555 (1.100-2.199)
Lifetime	0.670 (0.553-0.811)	1.133 (0.801-1.601)
Perceived remission rate		
35%	Reference	Reference
40%	1.253 (1.002-1.568)	0.882 (0.593-1.310)
45%	1.135 (0.911-1.415)	0.602 (0.402-0.901)
50%	1.238 (0.993-1.545)	0.697 (0.469-1.035)
55%	1.281 (1.026-1.598)	0.411 (0.269-0.628)
Probability of adverse events		
0%	Reference	Reference
30%	0.419 (0.363-0.482)	1.035 (0.785-1.365)
50%	0.219 (0.188-0.256)	1.136 (0.863-1.495)
The monthly cost of treatment[c]		
¥500	Reference	Reference
¥1000	0.738 (0.594-0.918)	0.703 (0.472-1.050)
¥1500	0.735 (0.587-0.920)	0.379 (0.255-0.565)
¥2000	0.624 (0.500-0.779)	0.249 (0.164-0.377)
¥2500	0.687 (0.552-0.854)	0.105 (0.067-0.165)

[a]The table presents general results of the multinomial logit model. Data on preferences of respondents from the 2 classes for psychotherapy intervention attributes are reported (N=114).

[b]VR: virtual reality.

[c]A currency exchange rate of ¥1 (Chinese yuan)=US $0.15 is applicable.

For class 1, the attribute “Probability of adverse events” was the most important factor for respondents with a percentage importance value of 55.29%, followed by “The monthly cost of treatment” and “Therapy duration,” with percentage importance values of 17.20% and 17.04%, respectively (Figure 7). Meanwhile, the span of percentage weights of “Probability of adverse events” was obvious (Figure 8), ranging from −0.72 to 0.79. The span of the attribute “The monthly cost of treatment” ranged from 0.29 to −2.33. The preference weight of “The monthly cost of treatment” decreased with increasing expenses. In addition, the OR of “50%” of the attribute “Probability of adverse events” was 0.219 (95% CI 0.188-0.256), indicating that the majority of patients preferred to pay more attention to the safety of treatment modality with respect to all the levels of the attribute “The monthly cost of treatment” when compared with the reference level “¥500” of <1. At the same time, the OR (Table 7) of the levels of the attribute “Therapy duration” decreased with treatment time, indicating that peoples’ preference for this attribute increased as treatment time decreased.

For class 2, the attributes “Treatment modality” and “The monthly cost of treatment” were relatively important; for respondents in this class, the percentage importance values were 43.43% and 34.36%, respectively (Figure 7). For the attribute “Perceived remission rate,” the percentage importance value was 13.54% (Figure 7). The span of the percentage weights of these 2 attributes is presented in Figure 3. The percentage weights for the attributes “Treatment modality” and “The monthly cost of treatment” ranged from −1.003 to 1.847 and −1.26 to 0.073, respectively (Figure 9). In addition, the OR of “Medication only” of the attribute “Treatment modality” was 0.058 (95% CI 0.041-0.081), which was <1, indicating that the VR method appeared to be the best of the 3 methods. The OR of the levels of “Therapy duration” were all >1, and it was different from class 1. Meanwhile, the OR continued to decrease with the increase in the monthly cost of treatment, which was the same condition as that found in the previous class.

For these 2 latent classes, the attribute “Probability of adverse events” was the most preferred factor in class 1, whereas “Treatment modality” was the most preferred factor in class 2. There were 74 and 34 participants in class 1 and class 2, respectively. Class 1 has a similar number of male (39/74, 52.7%) and female participants (35/74, 47.3%), whereas the number of male participants (21/34, 61.8%) is nearly 2 times than that of female participants (13/34, 38.2%) in class 2. In addition, nearly two-thirds of participants in class 1 were medical students (48/74, 64.9%), with nonmedical students comprising only a minority (26/74, 35.1%). By contrast, the numbers of medical and nonmedical students in class 2 were almost even (18/34, 52.9%, and 16/34, 47.1%, respectively).

Figure 7. Percentage importance of attributes in the latent class condition.

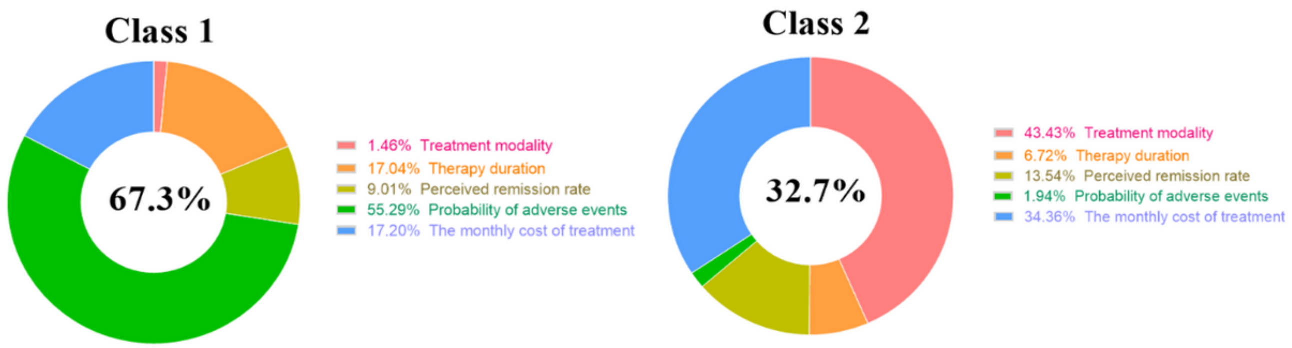


Figure 8. Latent class percentage weights in class 1. VR: virtual reality.

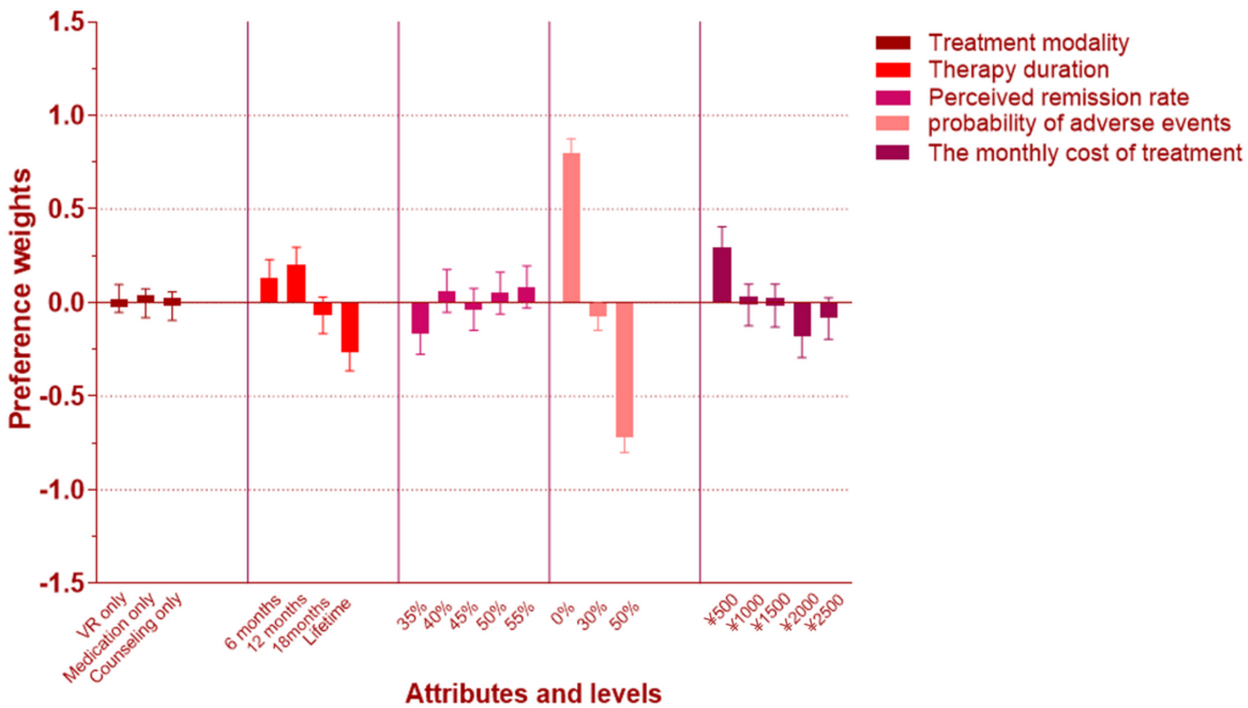


Figure 9. Latent class percentage weights in class 2.

Discussion

Principal Findings

Through the investigation of 5 different attributes and several levels in this survey, our preliminary results indicate that the treatment modality and the probability of adverse events will interfere with people's choice of therapy. Although a host of people are willing to choose VR as the treatment method instead of others, the treatment modality is not the element that most concerns them. However, the influential weight of the treatment modality is second only to the probability of adverse events, especially for college students who have used VR devices. Although the VR headset did not cause severe adverse reactions immediately, such as vomiting and diarrhea, the disadvantages of overweight devices and dizziness during use should not be ignored.

People who have previously used a VR headset and have had uncomfortable reactions after experiencing VR may have different preferences than those reported in this survey. After we finish the DCE experiment for university students, we hope to carry out a clinical VR experiment for the treatment of depression. Although VR has many advantages in the treatment of mental diseases, some problems may occur when VR is actually applied in the treatment of severe psychological depression, such as a lack of willingness to wear VR glasses. We are willing to compare the treatment of VR in clinical patients to better improve the use of VR in stress counseling and depression treatment.

Latent class analysis results showed that most participants in class 2 would consider "Treatment modality" as the most important attribute. As the number of male participants is almost 2 times more than that of female participants in class 2, this result may be due to a more receptive attitude toward VR technology and VR therapy among male participants, compared with female participants. Male students are also more likely to play computer games and VR games in daily life, whereas women might pay more attention to the details of the equipment, such as equipment weight, dizziness, and air permeability. In addition, our results revealed that the majority of participants in class 1 would consider the "Probability of adverse events" as the most important attribute. This result is possibly due to the prominent number of medical students in class 1. Because of the specialty of their major, it is common that participants from clinical medicine and related majors would understand more about the side effects of antidepressants and be more aware of the complications of using VR technology. Thus, it is not surprising that most participants in class 2 chose "Probability of adverse events" as the most important attribute.

The results of the DCE experiment in this study are helpful for doctors and researchers to conduct further analysis, so they can devise better clinical strategies for the treatment of depression. We separated different treatment methods and compared the effects of individual choices, such as just focusing on medical therapy for depression and analyzing the influence from different perspectives (time and cost). At the same time, our experimental results could promote VR technology for the treatment of depression and provide reference and guidance for individuals and hospitals that are willing to use VR treatment.

Our study's results showed that individuals prefer VR technology as a psychological intervention method for treating psychological disorders (such as depression) and easing their anxiety. There are several studies that might support our findings [30,31,64,65]. First, an article suggested that a virtual and peaceful environment with relaxing music could make the participants feel like they are in a realistic soothing environment [64]. Second, the research done by Ioannou et al [65] stated that VR could effectively reduce these symptoms in different contexts and with regard to different diseases, including cancer. Another paper suggested that VR has good clinical potential to reduce the severity of depression [30]. A study conducted by Schleider et al [31] revealed that immersive technology, such as VR headsets, may be an efficient strategy for reducing adolescent depressive symptoms. According to the aforementioned studies, the comfortable feeling that VR technology can provide and its effectiveness in treating depression may explain the participants' preference for using VR technology in treating psychological disorders.

Indeed, most other VR depression experiments are focused on the methodology and VR content making more than the university students' depression therapy. By contrast, participants' preferences in our results, such as "Probability of adverse events" and "Treatment modality" from the DCE, could help doctors adopt some new strategies with VR headsets for depression therapy. Besides, in the university environment, the mental health treatment center and psychological counseling room in the school could use VR applications to prevent depression and anxiety for students. Another similar study used VR to enhance employees' mental health and work performance [66].

Limitation

There are some limitations to this study. First, the new high technocracies that involve VR may influence university students' preferences. In addition, participants with knowledge of drugs (antidepressants), such as selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors, may cause bias in the preferred choice in the questionnaire [67]. All of these factors will cause the experimental process to become more complex. We will continue to perform a variety of mixed treatment experiments in the future to further accurately analyze the effects of different combinations of treatment methods for depression. At the same time, we will also focus on more parameters, such as gender, major, and age, in depression therapy. For example, medical students will have some bias in depression treatment compared with other students.

Conclusion

People placed significant preference on VR technology's psychological intervention methods, which indicates that VR may have a potential market for treating psychological problems, especially for university students. However, most participants were concerned about the side effects and treatment modality of the VR technology, and these 2 attributes need to be considered when designing treatment plans for individuals. This study can guide policies relevant to the development of the application of VR technology in the field of psychological pressure and depression treatment. At the same time, doctors can consider adopting multiple methods, such as VR plus counseling, in clinical applications.

Conflicts of Interest

None declared.

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Abbreviations

AIC3: Akaike information criterion 3
BIC: Bayesian information criteria
DCE: discrete choice experiment
OR: odds ratio
UESTC: University of Electronic Science and Technology of China
VR: virtual reality

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