JMIR Serious Games

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Review

The Effectiveness of Serious Games for Alleviating Depression: Systematic Review and Meta-analysis

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Abstract

Background: Depression is a common mental disorder characterized by disturbances in mood, thoughts, or behaviors. Serious games, which are games that have a purpose other than entertainment, have been used as a nonpharmacological therapeutic intervention for depression. Previous systematic reviews have summarized evidence of effectiveness of serious games in reducing depression symptoms; however, they are limited by design and methodological shortcomings.

Objective: This study aimed to assess the effectiveness of serious games in alleviating depression by summarizing and pooling the results of previous studies.

Methods: A systematic review of randomized controlled trials (RCTs) was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement. The search sources included 6 bibliographic databases (eg, MEDLINE, PsycINFO, IEEE Xplore), the search engine "Google Scholar," and backward and forward reference list checking of the included studies and relevant reviews. Two reviewers independently carried out the study selection, data extraction, risk of bias assessment, and quality of evidence appraisal. Results of the included studies were synthesized narratively and statistically, as appropriate, according to the type of serious games (ie, exergames or computerized cognitive behavioral therapy [CBT] games).

Results: From an initial 966 citations retrieved, 27 studies met the eligibility criteria, and 16 studies were eventually included in meta-analyses. Very low-quality evidence from 7 RCTs showed no statistically significant effect of exergames on the severity of depressive symptoms as compared with conventional exercises (P=.12). Very low-quality evidence from 5 RCTs showed a statistically and clinically significant difference in the severity of depressive symptoms (P=.004) between exergame and control groups, favoring exergames over no intervention. Very low-quality evidence from 7 RCTs showed a statistically and clinically significant effect of computerized CBT games on the severity of depressive symptoms in comparison with no intervention (P=.003).

Conclusions: Serious games have the potential to alleviate depression as other active interventions do. However, we could not draw definitive conclusions regarding the effectiveness of serious games due to the high risk of bias in the individual studies examined and the low quality of meta-analyzed evidence. Therefore, we recommend that health care providers consider offering

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serious games as an adjunct to existing interventions until further, more robust evidence is available. Future studies should assess the effectiveness of serious games that are designed specifically to alleviate depression and deliver other therapeutic modalities, recruit participants with depression, and avoid biases by following recommended guidelines for conducting and reporting RCTs.

Trial Registration: PROSPERO International Prospective Register of Systematic Reviews CRD42021232969; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=232969

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KEYWORDS

serious games; exergames; depression; cognitive behavioral therapy; systematic reviews; meta-analysis

Introduction

Background

An individual's mental health is fundamental to living a healthy and enjoyable lifestyle. Studies estimate that 1 in 3 people may suffer from a mental illness during their lifetime [1]. The World Health Organization (WHO) reports that depression is a "leading cause of disability worldwide and is a major contributor to the overall global burden of disease" affecting more than 264 million people of all ages globally [2]. Depression is a mental health disorder that the Sustainable Development Goals of the United Nations (2015) has listed among its 270 targets and 230 indicators. Depressive disorders account for most of the total disability-adjusted life years globally. Although depressive disorders are global, they particularly affect those living in high and upper-middle-income nations [3]. This heavy toll is exacerbated by the fact that up to one-half (50%) of the people living in high-income countries and 90% of those living in low-resource settings receive no treatment for depressive disorders [4].

Depressive disorders are a family of mental disorders ranging in severity from mild temporary episodes of sadness to more severe and persistent depression [5]. Depressive disorders include disruptive mood dysregulation disorder, premenstrual dysphoric disorder, substance- or medication-induced depressive disorder, and major depressive disorder [6]. Depressive disorders are characterized by disturbances in mood, thoughts, or behaviors. Furthermore, depressive disorders do not affect the mind alone but are reported to impact a person's body [7,8]. Depression is known to be caused by a number of factors that interact in complex mechanisms: social, genetic, pathological, and chemical [9]. Treatments for depressive disorders are generally classified into either pharmacological or psychosocial (ie, nonpharmacological) interventions. Pharmacological treatments involve the use of drugs (eg, antidepressants) while examples of psychosocial treatments include cognitive behavioral therapy (CBT), exposure therapy, and exercise [10].

The use of serious games, defined as games that have a purpose other than entertainment, has seen a rise in recent years [11]. Serious games use elements unique to gaming in order to educate or influence change in experience or behaviors [12]. Several industries have adopted and continue to use serious games including health care, education, and airlines [13]. Among other things, serious games have been effectively utilized for education, prevention, and treatment of chronic conditions (eg, asthma and diabetes) [14], therapeutic rehabilitation [15], and educational resources for health care professionals [16]. Moreover, serious games have been used as a nonpharmacological therapeutic intervention for mental disorders [17]. Serious games have been utilized as a treatment for various mental disorders, including depression [18,19], anxiety [20], posttraumatic stress disorder [21,22], autism spectrum disorder [23,24], dementia [25,26], alcohol use disorder [27], attention deficit hyperactivity disorder [28], and obsessive-compulsive disorder [13,29].

Gaming as a therapeutic tool in mental health can potentially offer several specific advantages that may be missing from traditional forms of delivery. The gaming industry is, as ever, popular globally [30] and arguably easier to access than even basic mental health services [31]. Games by their very nature have the potential to engage the user in game play that can be rewarding through scoring points or following story arcs that can help improve user involvement and lower attrition rates [32,33]. Additionally, as the technology improves, gaming can utilize accessories to provide richer sensory environments and immersive user experiences that allow users to simulate real-life scenarios more safely and help in educating and achieving cognitive and behavioral changes through overlearning and repetition [33,34].

Research Gap and Aim

Many studies have assessed the effectiveness of serious games to alleviate depression. Aggregating the evidence from these studies is very important to draw more definitive conclusions about the effectiveness of serious games as viable therapeutic interventions in depressive disorders. Several published reviews have summarized the evidence about the effectiveness of serious games for depression [18,19,35-37]. However, these reviews are undermined by certain technical shortcomings that limit the generalization of the findings. Specifically, these reviews (1) focused on a certain type of serious games (ie, exergames) [19,37]; (2) focused on a certain age group (older adults) [37]; (3) included non-randomized controlled trials (RCTs) [19,35]; (4) did not search technical databases (such IEEE Xplore and the ACM Digital Library), thereby including only a few studies [35-37]; (5) did not assess the quality of the evidence [18,19,35-37]; and (6) were outdated publications [18,19,35]. Therefore, this study aimed to assess the effectiveness of serious games for alleviating depression by summarizing and pooling the results of previous studies and providing an up-to-date review.

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Methods

We conducted a systematic review in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Multimedia Appendix 1) [38].

Search Strategy

Search Sources

We utilized the following bibliographic databases to retrieve relevant studies: MEDLINE (via Ovid), PsycInfo (via EBSCO), CINAHL (via EBSCO), IEEE Xplore, ACM Digital Library, and Scopus. These databases were searched on March 30, 2021 by the first author. When applicable, we set auto alerts to conduct an automatic search weekly for 12 weeks (ending on June 30, 2021). We also searched the search engine "Google Scholar" to identify grey literature. We checked only the first 10 pages (ie, 100 hits) because Google Scholar retrieved a vast number of studies and it ordered them based on their relevancy. To identify further studies of relevance to the review, we conducted backward reference list checking (ie, screening the reference lists of the included studies and relevant reviews) and forward reference list checking (ie, screening the studies that cited the included studies).

Search Terms

The search query in this review was developed by consulting 2 experts in digital mental health and by checking systematic reviews of relevance to the review. These terms were chosen based on the target intervention (eg, serious games, exergames, and gamification), target outcome (eg, depression and melancholy), and target study design (eg, RCT and clinical trial). Multimedia Appendix 2 shows the detailed search query used to search each of the aforementioned databases.

Study Eligibility Criteria

This review included only RCTs that assessed the effectiveness of serious games for alleviating the severity of depressive symptoms. To be more precise, the intervention of interest in this review was serious games that were delivered on any digital platform such as computers, consoles (eg, Xbox, PlayStation), mobile phones, tablets, handheld devices, or any other computerized devices. The intervention had to utilize elements of gaming as an integral and primary method for therapeutic or prevention purposes. We did not consider nondigital games and those used for other purposes such as monitoring, screening, and diagnosis. We included RCTs whether they were parallel RCTs, cluster RCTs, crossover RCTs, or factorial RCTs but we excluded quasi-experiments, observational studies, and reviews. We focused on studies in which one of the measured outcomes was depression or depressive symptoms regardless of the outcome measures. Only trials in the English language were eligible for inclusion in this review. RCTs published as journal articles, conference proceedings, and dissertations were included, whereas we excluded conference abstracts and posters, commentaries, preprints, proposals, and editorials. We did not apply restrictions related to the population, year of publication, country of publication, comparator, and study settings.

Study Selection

We followed 3 steps to identify the relevant studies. In the first step, we exported the retrieved studies to EndNote to identify and remove duplicates. Then, 2 reviewers (EA and MA) independently screened the titles and abstracts of all retrieved studies. In the last step, the 2 reviewers independently screened the full texts of studies included from the second step. A third reviewer (AA) resolved any disagreements between the 2 reviewers in the second and third steps. Cohen κ in this review indicated a very good level of interrater agreement in the first (0.85) and second (0.90) steps [39].

Data Extraction

Two reviewers (EA and MA) independently extracted data from the included reviews using Microsoft Excel (Microsoft Corporation, Redmond, WA). Multimedia Appendix 3 shows the data extraction form that was used by the 2 reviewers to extract the data precisely and systematically from the included studies. The form was pilot tested using 3 included studies. Any disagreements between the reviewers were resolved by consulting a third reviewer (AA). The interrater agreement between the reviewers was 0.87, indicating a very good level of agreement [39]. Some outcome data (eg, mean, standard deviation, sample size in each group) were missing in 10 studies. Therefore, we contacted their corresponding authors to get them, and 5 corresponding authors did not reply to our emails even after sending 2 reminders.

Risk of Bias Assessment

Two reviewers (EA and MA) independently assessed the risk of bias in the included studies using the Risk-of-Bias 2 (RoB 2) tool, which is recommended by the Cochrane Collaboration [40]. This tool appraises the risk of bias in 5 domains in RCTs: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result [40]. The risk of bias judgments in these domains is used to determine the overall risk of bias for each included study. A third reviewer (AA) resolved any disagreements in judgments between the 2 reviewers. Interrater agreement between the reviewers was very good (Cohen κ=0.93) [39].

Data Synthesis

We utilized narrative and statistical approaches to synthesize the extracted data. Specifically, in narrative synthesis, texts and tables were used to describe the characteristics of the included studies, population, intervention, comparator, and outcome measures. Then, we grouped and summarized the findings of the included studies according to the type of serious games (ie, exergames or computerized CBT games). A meta-analysis was conducted when at least 2 studies of the same type of serious game reported enough data for the analysis (ie, mean, standard deviation, number of participants in each intervention group). When this information was not reported in any included study, we contacted the first and corresponding authors to get the missing information.

Review Manager (RevMan 5.4) was used to conduct the meta-analysis. We measured the effect of each trial and the overall effect using the standardized mean difference (SMD;

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Cohen *d*) because the outcome data (severity of depressive symptoms) were continuous and tools used to measure the outcome were different between the included studies. The random effects model was used in the analysis given the clinical heterogeneity between the meta-analyzed studies in terms of serious game characteristics (eg, types, duration, frequency, and period), population characteristics (eg, sample size, mean age, and health condition), and outcome measures (ie, tools and follow-up period).

When the meta-analysis showed a statistically significant difference between groups, we examined whether this difference was clinically important. A minimal clinically important difference (MCID) is defined as the smallest change in a measured outcome that a patient would consider as worthy and significant and which mandates a change in a patient's treatment. The MCID boundaries for an outcome were calculated as ±0.5 times the SMD of the meta-analyzed studies.

We checked the characteristics of participants, interventions, comparator, and outcomes in studies included in the meta-analysis to assess their clinical heterogeneity. We also examined the statistical heterogeneity of the meta-analyzed studies by calculating a Chi-square *P* value and I^2, which measures the statistical significance of heterogeneity and the degree of heterogeneity, respectively. A Chi-square *P* value ≤.05 indicates heterogeneous meta-analyzed studies [41]. The degree of heterogeneity was considered unimportant, moderate, substantial, or considerable when I^2 was 0%-40%, 30%-60%, 50%-90%, or 75%-100%, respectively [41].

We assessed the overall quality of evidence from the meta-analyses using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, which assesses the quality of evidence based on 5 domains: risk of bias, inconsistency (ie, heterogeneity), indirectness, imprecision, and publication bias [42]. Two reviewers (CT and AA) independently assessed the overall quality of meta-analyzed evidence, and any disagreements were resolved through discussion and consensus. Interrater agreement between the reviewers was very good (Cohen κ=0.88) [39].

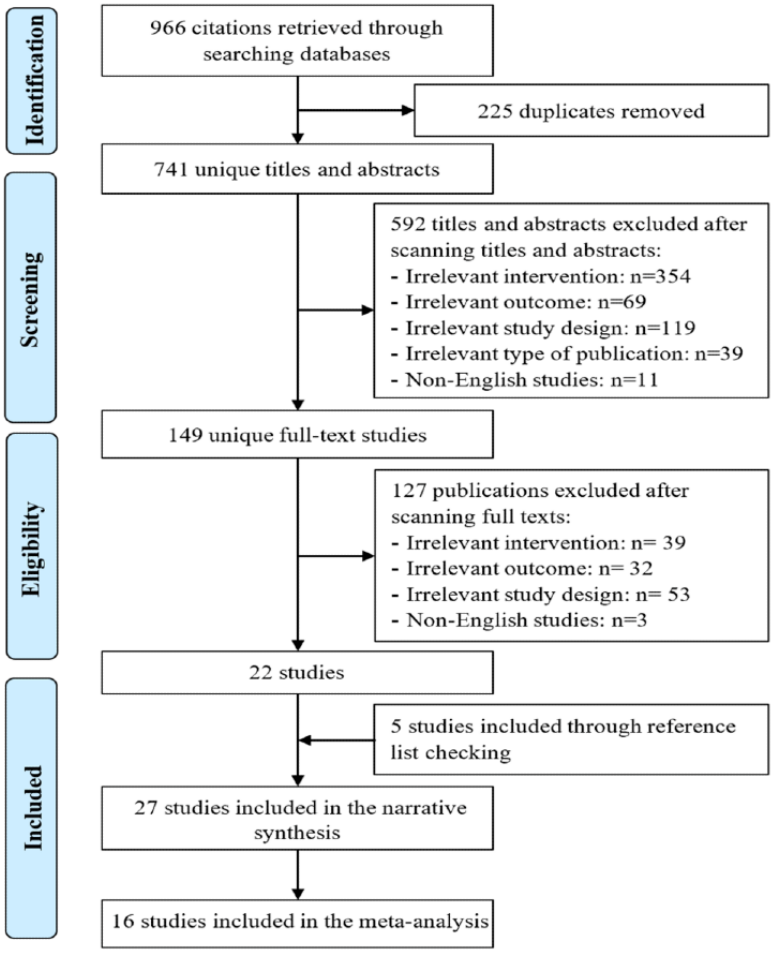
Results

Search Results

As shown in Figure 1, we retrieved 966 citations from searching the 7 electronic databases. Using the software EndNote, we identified and removed 225 duplicates of the retrieved citations. Screening titles and abstracts of the remaining 741 citations led to excluding 592 citations because (1) they did not use serious games (n=354); (2) the severity of depressive symptoms was not a measured outcome (n=69); (3) they were not RCTs (n=119); (4) they were not peer-reviewed articles, theses, nor conference proceedings (n=39); and (5) they were published in non-English languages (n=11). Reading the full text of the remaining 149 publications led to excluding 127 publications because (1) they did not use serious games (n=39), (2) the severity of depressive symptoms was not a measured outcome (n=32), (3) they were not RCTs (n=53), and (4) they were published in non-English languages (n=3). We identified 5 additional RCTs through backward and forward reference list checking. In total, 27 RCTs were included in the current review [43-69]. Of those, 16 RCTs were included in the meta-analyses [45-52,54,59-65].

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Figure 1. Flow chart of the study selection process.



Characteristics of Included Reviews

The included studies were published between 2012 and 2021 (Table 1). The years that witnessed the largest number of included studies were 2018 (n=5) and 2020 (n=5). The included studies were carried out in 15 different countries, as shown in Table 1. The country that published the largest number of the included studies was Germany (n=5). All included papers were papers published in peer-reviewed journals. The trial type used in the most included studies was parallel RCTs (n=24).

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Table 1. Characteristics of studies and population.

Author(s), year	Country	Publication type	RCT[a] type	Sample size, n	Mean age (years)	Sex (male), %	Health condition	Setting
Ruivo et al [43], 2017	Ireland	Journal article	Parallel	32	59.9	81.3	Cardiovascular diseases	Clinical, community, educational
Ferraz et al [44], 2018	Brazil	Journal article	Parallel	62	69	59.7	Parkinson disease	Clinical
Song and Park [45], 2015	South Korea	Journal article	Parallel	40	50.1	55.0	Stroke	Clinical
Schumacher et al [46], 2018	Germany	Journal article	Parallel	42	56.3	59.5	Hematopoietic stem cell transplantation recipients	Clinical
Meldrum et al [47], 2015	Ireland	Journal article	Parallel	71	54.1	38.0	Unilateral peripheral vestibular loss	Clinical
Zhou et al [48], 2020	Qatar	Journal article	Parallel	73	64.6	45.2	Diabetes and end-stage renal disease	Clinical
Vieira et al [49], 2017	Portugal	Journal article	Parallel	46	57.7	_[b]	Coronary artery disease	Clinical
Tollár et al [50], 2018	Hungary	Journal article	Parallel	74	69.4	48.6	Parkinson disease	Clinical
Ozdogar et al [51], 2020	Turkey	Journal article	Parallel	60	40.1	27.1	Multiple sclerosis	Clinical
Kempf and Martin [52], 2013	Germany	Journal article	Parallel	220	61.1	45.9	Type 2 diabetes	Clinical, community
Rendon et al [53], 2012	United States	Journal article	Parallel	40	84.5	35.0	Older adults	Clinical
Jahouh et al [54], 2021	Spain	Journal article	Parallel	80	84.2	44.0	Older adults	Clinical
Rica et al [55], 2019	Brazil	Journal article	Parallel	50	-	0.0	Older adults	Clinical, community
Andrade et al [56], 2020	Brazil	Journal article	Cluster	140	9.41	42.1	Elementary students	Educational
Shin et al [57], 2015	South Korea	Journal article	Parallel	35	54	75	Stroke	Clinical
Adomavičienė et al [58], 2019	Lithuania	Journal article	Parallel	60	64.6	66.7	Stroke	Clinical
Fleming et al [59], 2012	New Zealand	Journal article	Crossover	32	14.9	56	Depression	Educational
Merry et al [60], 2012	New Zealand	Journal article	Parallel	187	15.6	34.2	Depression	Clinical, educational
Donker et al [61], 2019	Netherlands	Journal article	Parallel	193	41.3	33.2	Acrophobia	Community
Perry et al [62], 2017	Australia	Journal article	Cluster	540	16.7	36.9	Secondary students	Educational
Cooney et al [63], 2017	Ireland	Journal article	Parallel	52	40.6	38.8	Anxiety, depression, and/or intellectual disability	Clinical
Poppelaars et al [64], 2016	Netherlands	Journal article	Parallel	208	13.4	0.0	Depression	Educational
Välimäki et al [65], 2018	Finland	Journal article	Parallel	90	41	50.0	Traumatic brain injury	Clinical
Wijnhoven et al [66], 2020	Netherlands	Journal article	Parallel	109	11.1	77.1	Anxiety and autism spectrum disorder	Clinical, educational
Haberkamp et al [67], 2021	Germany	Journal article	Parallel	68	22.8	13.0	Arachnophobia	Educational

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Author(s), year	Country	Publication type	RCT[a] type	Sample size, n	Mean age (years)	Sex (male), %	Health condition	Setting
Butler et al [68], 2020	Germany	Journal article	Parallel	40	33.4	100	Posttraumatic stress disorder	Clinical
David et al [69], 2018	Germany	Journal article	Parallel	165	12.9	35.9	Stroke	Educational

[a]RCT: randomized controlled trial.

[b]Not reported.

The sample size in the included studies varied from 32 to 540, with an average of 104. The mean age of participants in the included studies ranged between 9.41 years and 84.5 years, with an average of 43.9 years. The percentage of the sample who were men reported in 26 studies ranged from 0% to 100%, with an average of 46.1%. Participants' health conditions were varied between studies, and depression and stroke were the most common (n=4 each). Participants in most studies were recruited from clinical settings (n=20).

The intervention in the included studies was only serious games in 19 studies, serious games plus occupational therapy in 2 studies, and serious games plus psychotherapy in 1 study (Table 2). The most common games used in the included studies were SPARX (n=4) and Wii Fit (n=4). There were 5 types of serious games based on the therapeutic modality that they deliver: exergames (n=16), computerized CBT games (n=8), exposure therapy games (n=1), brain training games (n=1), rational emotive behavioral therapy (REBT) and rational emotive behavioral therapy education (REBE)–based game (n=1). Although games were designed with a "serious" purpose from the beginning (designed serious games) in 14 studies, they were not designed as serious games but were being used for a serious purpose (purpose-shifted games) in the remaining 13 studies. The most common platforms used for playing the games were computers (n=12) and video game consoles and their accessories (eg, balance board; n=12). The duration of the games in the included studies ranged between 5 minutes and 85 minutes, but it ranged between 20 minutes and 45 minutes in most studies (n=14). The frequency of playing the games varied between once a week and once a day, but it ranged between once a week and 3 times a week in 20 studies. The period of the intervention varied between 1 week and 24 weeks, but it ranged from 4 to 8 weeks in 19 studies.

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Table 2. Characteristics of interventions.

Author(s)	Intervention	Serious game name	Serious game type	Serious game genre	Platform	Duration (minutes)	Frequency (times/week)	Period (weeks)
Ruivo et al [43]	Serious game	Wii-Sports	Exergame	Purpose-shifted	Wii console and Kinect	60	2	6
Ferraz et al [44]	Serious game	Kinect Adventures	Exergame	Purpose-shifted	Xbox console and Kinect	50	3	8
Song and Park [45]	Serious game	Kinect Sport, Kinect Sport Season 2, Kinect Adventure, and Kinect Gunstringer	Exergame	Purpose-shifted	Computer and Xbox Kinect	30	5	8
Schumacher et al [46]	Serious game	Wii Fit and Wii-Sports	Exergame	Purpose-shifted	Wii console and balance board	30	5	2
Meldrum et al [47]	Serious game	Wii Fit Plus	Exergame	Purpose-shifted	Wii console and balance board and Frii Board	15	5	6
Zhou et al [48]	Serious game	N/R[a]	Exergame	Designed	Computer and wearables (sensors)	30	3	4
Vieira et al [49]	Serious game	Kinect-Rehab-Play	Exergame	Designed	Computer and Xbox Kinect	70-85	3	24
Tollár et al [50]	Serious game	Reflex Ridge, Space Pop, Just Dance	Exergame	Purpose-shifted	Xbox console and Kinect	60	5	5
Ozdogar et al [51]	Serious game	Kinect Sports Rivals	Exergame	Purpose-shifted	Xbox console and Kinect	45	1	8
Kempf and Martin [52]	Serious game	Wii Fit Plus	Exergame	Purpose-shifted	Wii console and balance board	≥30	1	12
Rendon et al [53]	Serious game	Wii Fit	Exergame	Purpose-shifted	Wii console and balance board	35-45	3	6
Jahouh et al [54]	Serious game	Step, Nodding	Exergame	Purpose-shifted	Wii console	40-45	2-3	8
Rica et al [55]	Serious game	Kinect Sports Ultimate Collection, Your Shape Fitness Evolved, Dance Central, and Kinect Training	Exergame	Purpose-shifted	Xbox console and Kinect	60	3	12
Andrade et al [56]	Serious game	Just Dance 2015	Exergame	Purpose-shifted	Xbox console and Kinect	40	2	1
Shin et al [57]	Serious game + occupational therapy	RehabMaster	Exergame	Designed	Computer, sensors, and infrared projector	60	5	4
Adomavičienė et al [58]	Serious game	N/R	Exergame	Designed	Computer and Kinect	45	Once a day	2
Fleming et al [59]	Serious game	SPARX	Computerized CBT[b] game	Designed	Computer	30	1-2	5
Merry et al [60]	Serious game	SPARX	Computerized CBT game	Designed	Computer	20-40	1-2	4-7

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Author(s)	Intervention	Serious game name	Serious game type	Serious game genre	Platform	Duration (minutes)	Frequency (times/week)	Period (weeks)
Donker et al [61]	Serious game	ZeroPhobia	Computerized CBT game	Designed	Smartphone and wearables (VR[c] goggles)	5-40	2	3
Perry et al [62]	Serious game	SPARX-R	Computerized CBT game	Designed	Computer	20-30	1-2	5-7
Cooney et al [63]	Serious game	Pesky Gnats: The Feel Good Island	Computerized CBT game	Designed	Computer	60	1	7
Poppelaars et al [64]	Serious game	SPARX	Computerized CBT game	Designed	Computer	20-40	1	7
Välimäki et al [65]	Serious game	CogniFit	Computerized CBT game	Designed	Computer	≥30	Once a day	8
Wijnhoven et al [66]	Serious game	MindLight	Computerized CBT game	Designed	Computer and wearable (headset)	60	1	6
Haberkamp et al [67]	Serious game	Spider App	Exposure therapy game	Designed	Smartphone	12	2	1
Butler et al [68]	Serious game + psychotherapy	Tetris	Brain-training game	Purpose-shifted	Nintendo DS XL console	60	2	6
David et al [69]	Serious game	REThink	REBT[d]- and REBE[e]-based game	Designed	Tablet	50	3	4

[a]N/R: not reported.

[b]CBT: cognitive behavioral theory.

[c]VR: virtual reality.

[d]REBT: rational emotive behavioral therapy.

[e]REBE: rational emotive behavioral education.

As shown in Table 3, the comparison groups received inactive interventions in 15 studies, while they received active interventions in 18 studies (eg, conventional exercises, CBT programs, video games, and psychotherapy). Note that the numbers do not add up because 6 studies delivered both active and inactive interventions as comparators. The duration of the active comparators ranged between 12 minutes and 100 minutes. The frequency of playing the active comparators varied between once a week and once a day. The period of the active comparators varied between 1 week and 24 weeks. The outcome of interest (eg, severity of depressive symptoms) was measured using 18 different tools, but the most common tool used by the included studies was the Beck Depression Inventory (BDI; n=6), followed by the Hospital Anxiety and Depression Scale (HADS; n=4). The outcome of interest was measured immediately after the intervention in all included studies, and the most common follow-up period was 3 months (n=6). Participant attrition was reported in 24 studies and ranged from 0 to 134.

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Table 3. Characteristics of comparators and outcomes.

Author(s)	Comparator	Duration (minutes)	Frequency (times/week)	Period (weeks)	Outcome measures	Follow up	Attrition, n
Ruivo et al [43]	Conventional exercises (functional training), conventional exercises (bicycle exercise)	50	3	8	GDS[a]	Postintervention	10
Ferraz et al [44]	Robot-assisted trainings	45	Once a day	2	HADS[b]	Postintervention	18
Song and Park [45]	Conventional exercises	30	5	8	BDI[c]	Postintervention	N/R[d]
Schumacher et al [46]	Conventional exercises	30	5	2	HADS-D[e]	Postintervention, 30-day follow-up, 100-day follow-up	11
Meldrum et al [47]	Conventional exercises	15	5	6	HADS-D	Postintervention	9
Zhou et al [48]	Conventional exercises	30	3	4	CES-D[f]	Postintervention	0
Vieira et al [49]	Conventional exercises, control	70-85	3	24	DASS-21[g]	Postintervention, mid-intervention (3 months)	13
Tollár et al [50]	Conventional exercises	60	2	6	HADS	Postintervention, 2-month follow-up	4
Ozdogar et al [51]	Conventional exercises, control	45	1	8	BDI	Postintervention	3
Kempf and Martin [52]	Control	N/A[h]	N/A	N/A	WHO-5[i], PAID[j], ADS-L[k]	Postintervention	44
Rendon et al [53]	Control	N/A	N/A	N/A	GDS	Postintervention	6
Jahouh et al [54]	Control	N/A	N/A	N/A	GDS, GADS[l]	Postintervention	N/R
Rica et al [55]	Conventional exercises, control	60	5	5	BDI	Postintervention	0
Andrade et al [56]	Physical education	40	2	1	BMS[m]	Postintervention	0
Shin et al [57]	Occupational therapy	60	5	4	HAMD[n]	Postintervention	3
Adomavičienė et al [58]	Conventional exercises, control	60	5	5	BDI	Postintervention	0
Fleming et al [59]	Control	N/A	N/A	N/A	CDRS-R[o], RADS-2[p]	Postintervention	5
Merry et al [60]	Control	N/A	N/A	N/A	CDRS-R, RADS-2	Postintervention, 3-month follow-up	17
Donker et al [61]	Control	N/A	N/A	N/A	PHQ-9[q]	Postintervention, 3-month follow-up	59
Perry et al [62]	Interactive online program	20-30	1-2	5-7	MDI[r]	Postintervention, 6-month follow-up, 18-month follow-up	134
Cooney et al [63]	Control	N/A	N/A	N/A	GAS-LD[s]	Postintervention, 3-month follow-up	3
Poppelaars et al [64]	CBT[t] program + serious game, CBT program, control	CBT program + serious game (80-100), CBT program (60)	1	7	RADS-2	Postintervention, 3-month follow-up, 6-month follow-up, 12-month follow-up	10
Välimäki et al [65]	Video game, control	≥30	Once a day	8	PHQ-9	Postintervention, 3-month follow-up	20
Wijnhoven et al [66]	Video game	60	1	6	CDI-2[u]	Postintervention, 3-month follow-up	35

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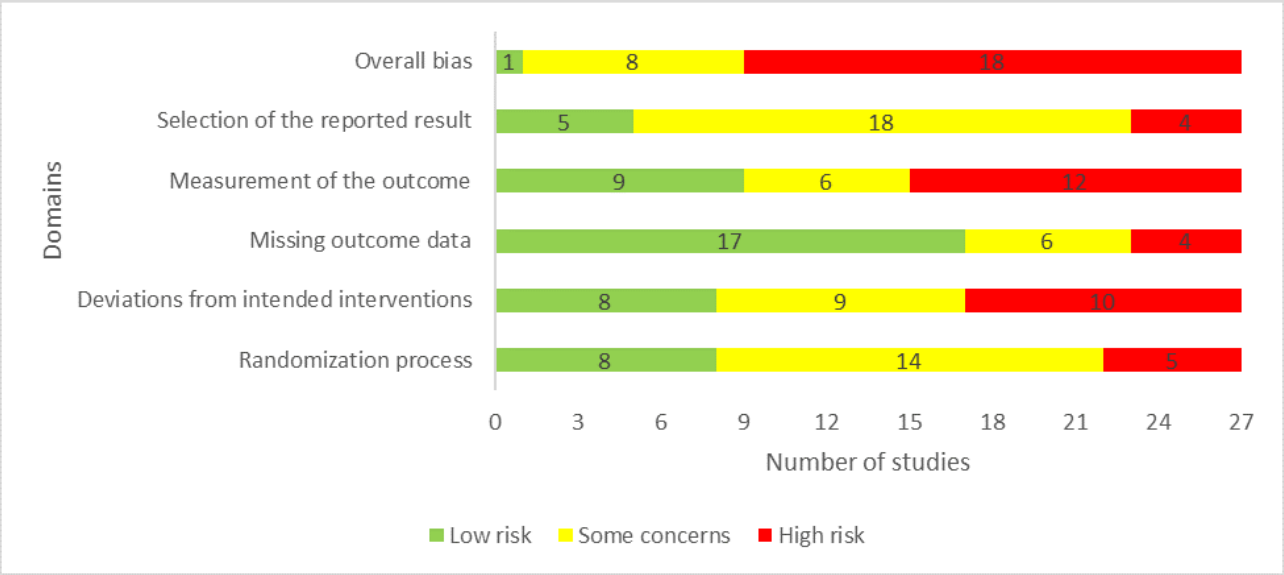
Author(s)	Comparator	Duration (minutes)	Frequency (times/week)	Period (weeks)	Outcome measures	Follow up	Attrition, n
Haberkamp et al [67]	Video game	12	2	1	BDI-II	Postintervention, 2-week follow-up	6
Butler et al [68]	Psychotherapy	60	2	6	BDI-II	Postintervention, 6-month follow-up	0
David et al [69]	Rational emotive behavioral therapy and education, control	50	3	4	EATQ-R[v]	Postintervention	23

[a]GDS: Geriatric Depression Scale.
[b]HADS: Hospital Anxiety and Depression Scale.
[c]BDI: Beck Depression Inventory.
[d]N/R: not reported.
[e]HADS-D: depression subscale of the HADS.
[f]CES-D: Center for Epidemiologic Studies Depression Scale.
[g]DASS-21: Depression, Anxiety and Stress Scale 21.
[h]N/A: not applicable.
[i]WHO-5: WHO 5-item Well-Being Index.
[j]PAID: Problem Areas in Diabetes.
[k]ADS-L: Allgemeine Depressionsskala.
[l]GADS: Goldberg Anxiety and Depression Scale.
[m]BMS: Brunel's Mood Scale.
[n]HAMD: Hamilton Depression Rating Scale.
[o]CDRS-R: Children's Depression Rating Scale-Revised.
[p]RADS-2: Reynolds Adolescent Depression Scale.
[q]PHQ-9: Patient Health Questionnaire-9.
[r]MDI: Major Depression Inventory.
[s]GAS-LD: Glasgow Depression Scale for people with a learning disability.
[t]CBT: cognitive behavioral therapy.
[u]CDI-2: Child Depression Inventory 2.
[v]EATQ-R: Early Adolescent Temperament Questionnaire-Revised.

Results of Risk of Bias Appraisal

The random allocation sequence for the randomization process was appropriate in 23 included studies. However, only 10 studies concealed the allocation sequence until participants were enrolled and assigned to interventions, and groups were not comparable in 4 studies. Accordingly, the risk of bias due to the randomization process was rated as low for only 8 studies (Figure 2).

Figure 2. Review authors' judgments about each "risk of bias" domain.



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Participants and individuals delivering the interventions were aware of assigned interventions during the experiment in 22 and 20 studies, respectively. Deviation from the intended intervention occurred in 2 studies due to the experimental contexts. Only 14 studies used an appropriate analysis (intention-to-treat or modified intention-to-treat analyses) to estimate the effect of assignment to intervention. Therefore, the risk of bias due to the deviations from the intended interventions was judged as low in only 8 studies (Figure 2).

Outcome data were not available for all or nearly all participants in 21 studies, and there was evidence that the findings were not biased by missing outcome data in only 5 studies. The reasons for missing outcome data could not be related to the true value of the outcome in 18 studies. As a result, 17 studies were judged as having a low risk of bias in the "missing outcome data" domain.

All included studies assessed the outcome of interest (ie, depression level) using appropriate measures and used measurement methods comparable across intervention groups. However, the assessor of the outcome was blinded in only 9 studies. For this reason, only these studies were rated as low risk of bias in the "measuring the outcome" domain (Figure 2).

In 17 studies, a prespecified analysis plan (ie, protocol) was not published. Only 4 studies reported outcome measurements different from those specified in the analysis plan. There is no evidence that all included studies selected their results from many results produced from multiple eligible analyses of the data. Accordingly, the risk of bias due to the selection of the reported results was considered low in 4 studies (Figure 2).

In the last domain "overall bias," the risk of bias was considered high in 20 studies as they were judged as having a high risk of bias in at least one domain; 6 studies were judged to have some concerns in the domain of overall bias as they had some concerns in at least one of the domains and were not at high risk for any domain. The remaining study was judged to be at low risk of bias for the domain of overall bias given that it was rated to be at low risk of bias for all domains. Reviewers' judgments about each "risk of bias" domain for each included study are presented in Multimedia Appendix 4.

Results of Studies

Types of Serious Games

As mentioned earlier, we identified 5 types of serious games based on the therapeutic modality that they deliver in the included studies. The first type is exergames, which refer to video games that require physical exercises (eg, fitness and balance exercises) in order to be played. The second type is computerized CBT games, which are video games that provide CBT for the users. The third type is exposure therapy games, which are video games that apply exposure principles to reduce anxiety in users with phobias. The fourth type is brain training games, which are video games that are based on cognitive interference tasks to reconsolidate traumatic memories. The last type is REBT- and REBE-based games, which are video games that enable users to replace irrational beliefs (eg, demandingness, intolerance, and frustration) with rational beliefs (eg, unconditional acceptance and tolerance). Results of the included studies were grouped into 3 categories based on the types of serious games.

Exergames

Exergames were the intervention in 16 studies [43-58]. Exergames were compared with conventional exercises, no intervention, physical education, and occupational therapy. The results of these comparisons are summarized in the following sections.

Exergames Versus Conventional Exercises

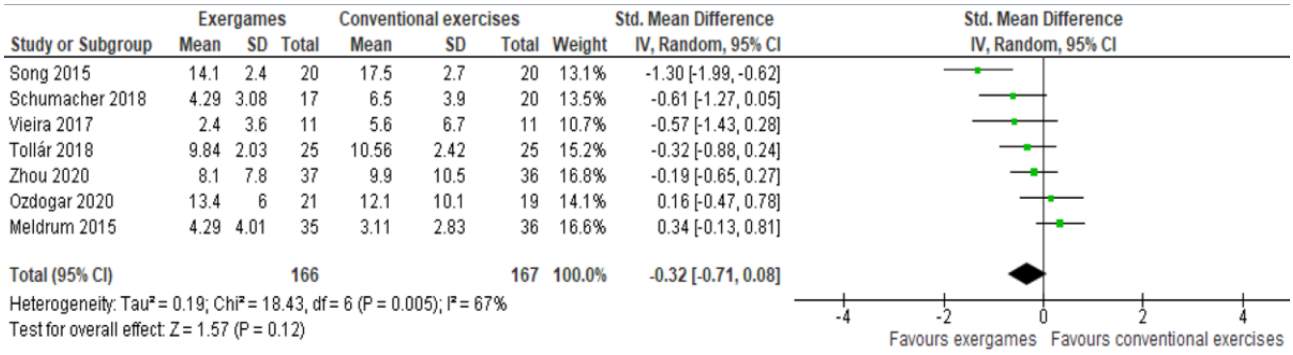
In 9 studies, the effect of exergames was compared with that of conventional exercises on the severity of depressive symptoms [43-51]. Although 1 study did find a statistically significant difference in the severity of depressive symptoms between the groups [45], the remaining 8 studies did not [43,44,46-51]. Specifically, Song and Park [45] compared the effect of exergames (Kinect Sport, Kinect Sport Season 2, Kinect Adventure, and Kinect Gunstringer) with that of conventional exercises (ergometer bicycle training) on the severity of depressive symptoms (measured using the BDI) among patients with stroke. The study found a statistically significant difference (P<.05) in depressive symptoms between the groups, favoring exergames over ergometer training. Another study assessed the effect of exergames (Wii Fit Plus) on the severity of depressive symptoms (measured using the HADS-D) among patients with unilateral peripheral vestibular loss [47]. The study did not find any statistically significant difference (P=.49) in the severity of depressive symptoms between the exergame group and conventional exercise group [47]. Schumacher et al [46] assessed the effects of exergames (Wii Fit and Wii-Sports) and conventional exercises on depression symptoms (measured using the HADS-D) among hematopoietic stem cell transplantation recipients and found no significant difference (P=.07) between both groups in the severity of depressive symptoms. A study by Ozdogar et al [51] examined the effects of exergames (Kinect Sports Rivals) and conventional exercises on the severity of depressive symptoms among patients with multiple sclerosis, and there was no significant difference (P>.05) in the severity of depressive symptoms between the 2 groups. A study examining the effect of exergames (Kinect-RehabPlay) on the severity of depressive symptoms (measured using the BDI) among patients with coronary artery disease in comparison with conventional exercises found no significant difference in the severity of depressive symptoms between the 2 groups [49]. In another study [48], no significant difference in the severity of depressive symptoms (measured using the Center for Epidemiologic Studies Depression Scale in patients with diabetes and end-stage renal disease) was detected between the exergame group and conventional exercise group. Tollár et al [50] compared the effect of exergames (Reflex Ridge, Space Pop, Just Dance) with that of conventional exercises (ergometer bicycle training) on the severity of depressive symptoms (measured using the BDI) among patients with Parkinson disease. The study showed no statistically significant difference (P=.27) in the severity of depressive symptoms between the 2 groups. A study assessed the effects of exergames (Wii-Sports) and conventional exercises on the severity of depressive symptoms (measured by HADS) among

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patients with a high risk of cardiovascular diseases [43]. No statistically significant difference between the groups was reported in the study [43]. In the last study, no significant difference in the severity of depressive symptoms (measured using the Geriatric Depression Scale [GDS] in patients with Parkinson disease) was detected between the exergame group (Kinect Adventures) and 2 conventional exercise groups (functional training and bicycle exercises) [44].

Results of 7 studies were meta-analyzed as shown in Figure 3 [45-49,51]. No statistically significant difference (P=.12) in the severity of depressive symptoms was found between the exergame group and conventional exercise group (SMD –0.32, 95% CI –0.71 to 0.08). There was substantial heterogeneity in the evidence (P=.005; I^2=67%). The quality of the evidence was very low, as it was downgraded by 5 levels due to a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

Figure 3. Forest plot of 7 studies comparing the effect of exergames with that of conventional exercises on the severity of depressive symptoms.



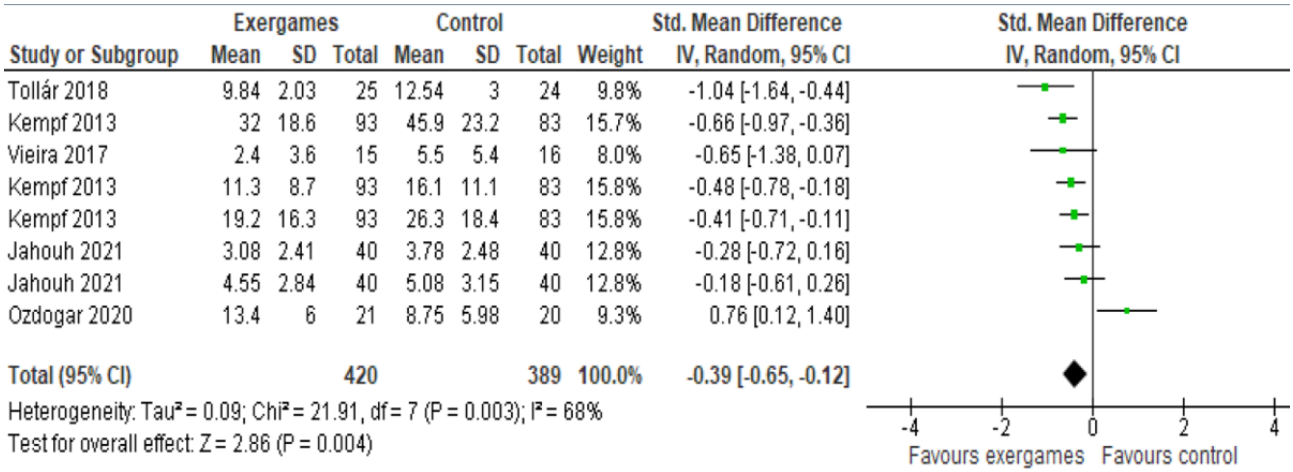
Exergames Versus No Intervention

In 7 studies, the effect of exergames was compared with that of no intervention on the severity of depressive symptoms [49-55]. Although 4 studies showed a statistically significant difference in the severity of depressive symptoms between the groups [50-52,55], 3 studies did not [49,53,54]. Specifically, Kempf and Martin [52] compared the effect of exergames (Wii Fit Plus) with that of no intervention on the severity of depressive symptoms (measured using the WHO 5-item Well-Being Index [WHO-5], Problem Areas in Diabetes [PAID], and Allgemeine Depressionsskala [ADS-L]) in patients with type 2 diabetes. The study found a statistically significant effect of exergames over no intervention on the severity of depressive symptoms as measured using the WHO-5 (P<.001), PAID (P=.007), and ADS-L (P=.002) [52]. A study conducted by Ozdogar et al [51] examined the effects of exergames (Kinect Sports Rivals) and no intervention on the severity of depressive symptoms (measured using the BDI) among patients with multiple sclerosis. Interestingly, the study demonstrated a statistically significant difference (P<.05) between the groups, favoring no intervention over exergames [51]. In another study [55], the influence of exergames (Kinect Sports Ultimate Collection, Your Shape Fitness Evolved, Dance Central, Kinect Training) and no intervention on the severity of depressive symptoms (measured using the BDI) among older women was investigated, and a statistically significant difference in the severity of depressive symptoms between groups was detected, favoring exergames over no intervention. Tollár et al [50] compared the effect of exergames (Reflex Ridge, Space Pop, Just Dance) with that of no intervention on the severity of depressive symptoms (measured using the BDI) among patients with Parkinson disease. The study showed a statistically significant difference (P<.001) in the severity of depressive symptoms between the 2 groups, favoring exergames over no intervention. Jahouh et al [54] assessed the effect of exergames (Wii Fit game) on the severity of depressive symptoms (measured using the GDS and Goldberg Anxiety and Depression Scale [GADS]) among older adults. No significant difference in the severity of depressive symptoms as measured using the GDS (P=.43) and GADS (P=.21) was detected between the exergame group and the control group [54]. Another study examining the effect of exergames (Kinect-RehabPlay) on the severity of depressive symptoms (measured using the BDI) among patients with coronary artery disease in comparison with no intervention found no significant difference (P>.05) in the severity of depressive symptoms between the 2 groups [49]. The effects of exergames and no intervention on the severity of depressive symptoms (measured by GDS) among older adults were compared in another study [53], and no significant difference (P=.09) was found in the severity of depressive symptoms between the 2 groups [53].

We meta-analyzed results of 5 studies, as they reported enough and appropriate data for the analysis [49-52,54]. Of the 5 studies, 2 assessed the severity of depressive symptoms using more than one measure (ie, WHO-5, PAID, and ADS-L [52]; GDS and GADS [54]); therefore, we included the results of all these measures in the meta-analysis. The meta-analysis showed a statistically significant difference in the severity of depressive symptoms (P=.004) between exergame and control groups, favoring exergames over no intervention (SMD –0.39, 95% CI –0.65 to –0.12; Figure 4). This difference was also clinically important as the overall effect was outside the MCID boundaries (–0.195 to 0.195) and its CI did not cross the “no effect” line (zero effect) and both MCID boundaries. The statistical heterogeneity of the evidence was substantial (P=.003; I^2=68%). The quality of the evidence was very low, as it was downgraded by 6 levels due to a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

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Figure 4. Forest plot of 5 studies (8 comparisons) comparing the effect of exergames with that of no intervention on the severity of depressive symptoms.



Exergames Versus Other Active Interventions

In 3 studies, the effect of exergames was compared with that of active interventions on the severity of depressive symptoms, and no statistically significant difference was found between the groups [56-58]. To be more precise, the first study examined the effects of an exergame (Just Dance 2015) and physical education on the severity of depressive symptoms (measured with the Brunel Mood Scale) among elementary students and demonstrated no statistically significant difference (*P*=.13) in the severity of depressive symptoms between the exergame group and physical education group [56]. The second study compared the effect of exergames (RehabMaster) with that of occupational therapy on the severity of depressive symptoms (measured using the Hamilton Depression Rating Scale) among patients with stroke. The study found no statistically significant difference (*P*=.56) in the severity of depressive symptoms between the exergame group and occupational therapy group [57]. The third study compared the effect of exergames with that of robot-assisted training on the severity of depressive symptoms (measured using the HADS) among patients with stroke and did not find any statistically significant difference between the groups [58].

Computerized CBT Games

Computerized CBT games were the intervention in 8 studies [59-66]. Computerized CBT games were compared with no intervention, video games, and conventional CBT. The results of these comparisons are summarized in the following sections.

Computerized CBT Games Versus No Intervention

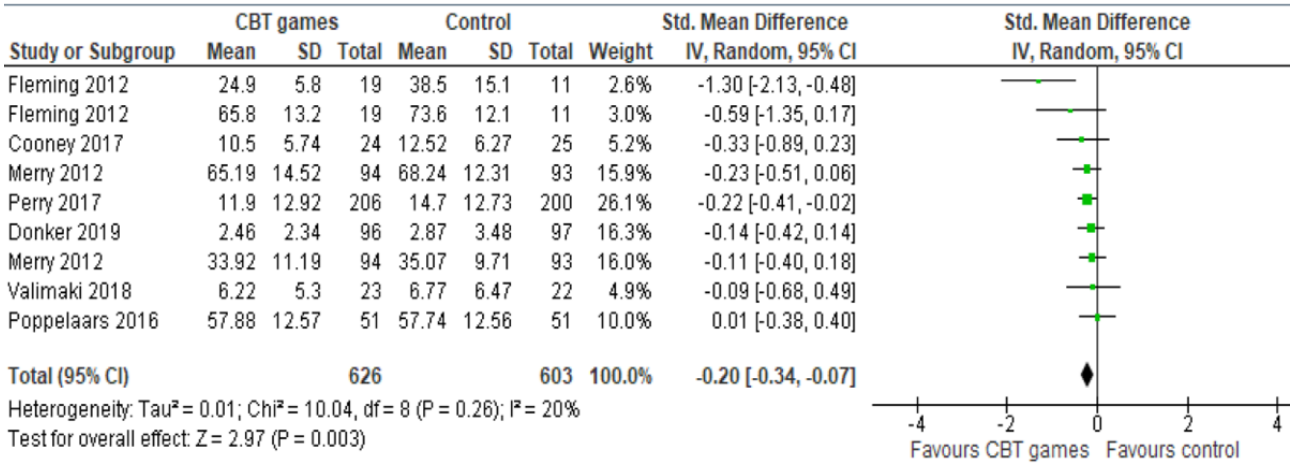
In 7 studies, the effect of computerized CBT games was compared with that of no intervention on the severity of depressive symptoms [59-65], and 4 of these studies assessed the effect of a computerized CBT game (SPARX) on the severity of depressive symptoms among patients with depression [59,60,64]. The first study found a statistically significant effect of the computerized CBT game over no intervention on the severity of depressive symptoms as measured using the Children's Depression Rating Scale-Revised (CDRS-R; *P*=.001) but not the Reynolds Adolescent Depression Scale (RADS-2; *P*=.08) [59]. In the second study [62], the effect of a computerized CBT game (SPARX-R) on the severity of depressive symptoms (measured using the Major Depression Inventory) among secondary students was compared with placebo, an interactive online program (LIFESTYLE) that provides information about several topics unrelated to mental health. The study found a statistically significant difference in the severity of depressive symptoms (as measured postintervention, *P*<.001, and at a 6-month follow-up, *P*=0.01) between the groups, favoring SPARX-R over LIFESTYLE [62]. In contrast, the third study found no statistically significant difference between the 2 groups in the severity of depressive symptoms as measured with the CDRS-R (*P*=.26) and RADS-2 (*P*=.16) [60]. Similarly, the fourth study did not show any statistically significant difference (*P*=.96) in the severity of depressive symptoms between the SPARX group and the control group [64]. Another study examined the effects of a computerized CBT game (Pesky Gnats: The Feel Good Island) and no intervention on the severity of depressive symptoms (measured using the Glasgow Depression Scale for people with a learning disability) among patients with anxiety, depression, or intellectual disability [63]. No statistically significant difference (*P*=.25) in the severity of depressive symptoms was detected between the groups [63]. Välimäki et al [65] compared the effect of a computerized CBT game (CogniFit) with that of no intervention on the severity of depressive symptoms (measured using the Patient Health Questionnaire-9 [PHQ-9]) among patients with traumatic brain injury and found no statistically significant difference (*P*=.76) between the groups. In the last study in this comparison, the effects of a computerized CBT game (ZeroPhobia) and no intervention on the severity of depressive symptoms (measured using the PHQ-9) among patients with acrophobia were investigated [61]. No statistically significant difference (*P*=.12) in the severity of depressive symptoms was found between the 2 groups [61].

Results of these 7 studies were meta-analyzed, as shown in Figure 5. Because 2 of these studies assessed the severity of depressive symptoms using 2 different measures (CDRS-R and RADS-2), we included the results of both measures of each study in the meta-analysis. The overall effect was statistically significant (*P*=.003) indicating that computerized CBT games are more effective than no intervention in alleviating depressive symptoms: (SMD –0.20, 95% CI –0.34 to –0.07). This difference was also clinically important as the overall effect

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was outside the MCID boundaries (–0.10 to 0.10) and its CI did not cross the "no effect" line (zero effect) and both MCID boundaries. For this outcome, MCID boundaries were calculated as ±0.5 times the SMD value (–.20). The heterogeneity of the evidence was not a concern (P=.26; I^2= 20%). The quality of the evidence was very low, as it was downgraded by 3 levels due to the high risk of bias and impression (Multimedia Appendix 5).

Figure 5. Forest plot of 7 studies (9 comparisons) comparing the effect of CBT games with that of no intervention on depression.



Computerized CBT Games Versus Active Interventions

Välimäki et al [65] compared the effect of a computerized CBT game (CogniFit) with that of entertainment video games on the severity of depressive symptoms (measured using the PHQ-9) among patients with traumatic brain injury and found no statistically significant difference (P=.36) between the groups. Another study compared the effect of a computerized CBT game (MindLight) with that of an entertainment video game (Triple Town) on the severity of depressive symptoms (Child Depression Inventory 2) among patients with autism spectrum disorder and anxiety [66]. No statistically significant difference (P>.05) in the severity of depressive symptoms was detected between the groups [66]. A study carried out by Poppelaars et al [64] assessed the effects of a computerized CBT game (SPARX) and a conventional CBT program on the severity of depressive symptoms (measured using the RADS-2) among patients with depression. The study did not detect a statistically significant difference (P=.58) in the severity of depressive symptoms between the groups.

Other Types of Serious Games

One study compared the effect of an exposure therapy game (Spider App) with that of an entertainment video game (Bubble Shooter) on the severity of depressive symptoms (measured using the BDI-II) among patients with arachnophobia [67]. No statistically significant difference (P=.95) in the severity of depressive symptoms was detected between the groups [67]. Butler et al [68] examined the effects of brain training games and psychotherapy on the severity of depressive symptoms (measured using the BDI) among patients with posttraumatic stress disorder. No statistically significant difference (P=.95) in the severity of depressive symptoms between the 2 groups was detected [68]. In another study, the effect of REBT- and REBE-based games on the severity of depressive symptoms (measured using the Early Adolescent Temperament Questionnaire-Revised) among patients with stroke was compared with conventional REBE and no intervention [69]. The study found a statistically significant difference in the severity of depressive symptoms between the groups, favoring REBT- and REBE-based games over conventional REBE (P=.03) and no intervention (P<.001).

Discussion

Principal Findings

This review assessed the effectiveness of serious games on the severity of depressive symptoms as reported by RCTs. Although 27 RCTs were included in the current review, 16 studies were included in the meta-analysis. Very low-quality evidence from 7 RCTs showed no statistically significant effect of exergames on the severity of depressive symptoms as compared with conventional exercises. Furthermore, 3 studies that compared the effect of exergames with that of other active interventions (eg, occupational therapy and robot-assisted training) on the severity of depressive symptoms and were not included in the meta-analyses found no statistically significant difference between the groups. These findings indicate that exergames are as effective as active interventions, which are usually delivered and supervised by health care providers (eg, physiotherapists, occupational therapists, and psychologists).

Very low-quality evidence from 5 RCTs showed a statistically and clinically significant effect of exergames on the severity of depressive symptoms when compared with no intervention.

Findings in this review are comparable to other reviews. Specifically, a recently published meta-analysis of 5 RCTs conducted by Yen and Chiu [37] showed an overall statistically significant effect (P<.001) of exergames on depression. Additionally, another recent meta-analysis of 8 RCTs conducted by Li et al [19] showed a significant effect of exergames on depression. However, both reviews [19,37] compared the effect of exergames with the effects of different active and inactive interventions through one meta-analysis, while our review conducted 2 separate meta-analyses to compare exergames with conventional exercises and no intervention respecting the uniqueness of these 2 interventions. Further, in contrast to our

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review, 5 of the 8 studies included in the review by Li et al were not RCTs (quasi-experimental or pre-post one-group trials) [19].

Very low-quality evidence from 6 RCTs showed a statistically and clinically significant effect of computerized CBT games on the severity of depressive symptoms when compared with no intervention. In contrast, 3 studies that compared the effect of computerized CBT games with those of active interventions (eg, video games and conventional CBT) on depressive symptoms and were not included in the meta-analyses found no statistically significant difference between the groups. This insignificant effect can be attributed to the fact that conventional CBT is comparable to the active interventions, thereby comparing the effect of 2 comparable interventions usually produces no significant difference, which indicates that computerized CBT games are at least as effective as these active interventions. None of the previous reviews [18,19,35-37] assessed the effect of computerized CBT games on depression.

Strengths and Limitations

Strengths

This review bridged the gaps of previous reviews by focusing on all types of serious games, including only RCTs, targeting all age groups, searching technical databases, assessing the quality of evidence, and synthesizing the data statistically. Therefore, it is more comprehensive than previous reviews [18,19,35-37]. As we followed highly recommended guidelines (ie, PRISMA) to conduct this review, it can be considered a robust and high-quality review.

The risk of publication bias in this review is minimal, as we searched the most popular databases in information technology and health fields; conducted backward and forward reference list checking; used a comprehensive search query; searched grey literature databases; and did not restrict our search to a certain country, year, setting, population, and comparator.

The risk of selection bias in this review is minimal because 2 reviewers independently performed the study selection, data extraction, risk of bias assessment, and quality of evidence evaluation with a very good interrater agreement for all processes. The quality of the evidence was appraised to enable the reader to draw more accurate conclusions. When possible, we synthesized data statistically, and this improved the power of studies and increased the estimates of the likely size of the effect of serious games on depression.

Limitations

The intervention of interest in this review was restricted to serious games delivered on any digital platform and used as a therapeutic intervention. Thus, this review cannot comment on the effectiveness of nondigital serious games and those used for other purposes such as monitoring, screening, or diagnosis. The outcome of interest in this review was depression; therefore, we cannot comment on the effectiveness of serious games on other mental health outcomes.

The review was restricted to RCTs written in the English language; therefore, many studies were excluded because they were quasi-experiments or written in other languages. This restriction was necessary because RCTs have higher internal validity than any other study design [70] and owing to practical constraints, it was not feasible to translate all non-English studies.

Most included studies recruited patients without depression; thereby, the effect of serious games on the severity of depression symptoms was not significant. Further, the overall risk of bias was high in most included studies, and the quality of evidence for the meta-analyses was very low. Accordingly, findings in this review must be interpreted with caution.

Research and Practical Implications

Research Implications

Although the severity of depression was one of the measured outcomes in all included studies, only 5 studies recruited patients with depression. This might lead to underestimating the effect of serious games. Therefore, future studies need to recruit participants with depression to assess the effectiveness of serious games on depression.

The therapeutic modalities provided by serious games in most included studies were either exercises or CBT. Further, serious games were not designed specifically to alleviate depression in about half of the studies. Thus, there is a pressing need to assess the effectiveness of serious games that are designed specifically to alleviate depression and deliver other therapeutic modalities such as art therapy, psychotherapy, relaxation-based exercises, psychoeducation, rational emotive behavioral therapy, and exposure therapy, and the list goes on.

Most included studies were carried out in high-income countries; thereby, our findings may not be generalizable to low-income countries. Researchers should conduct more studies to assess the effectiveness of serious games in low-income countries. We excluded many studies that assessed the effectiveness of serious games on other mental disorders such as anxiety and dementia. Further systematic reviews need to be carried out to investigate the effectiveness of serious in alleviating other mental disorders.

The overall risk of bias was high in most included studies mainly due to issues in the randomization process, deviations from the intended outcomes, and selection of the reported result. Further, several studies were not included in the meta-analysis due to missing outcome data. For this reason, we encourage researchers to follow recommended guidelines or tools (eg, RoB 2 [40]) when conducting and reporting RCTs to avoid such biases.

This review hopefully augurs the possible potential of serious games in mental health disorders, but it also underlines that this field, albeit full of potential, is still in its infancy. More studies are needed to prove the significant role of serious games in alleviating depression.

Practical Implications

Overall, this study showed that serious games can be effective in alleviating depression in comparison with no intervention, and they can be comparable to other traditional therapeutic interventions for alleviating depressive symptoms. However, findings in this review must be interpreted with caution because the overall risk of bias was high in most included studies, the quality of evidence in the meta-analyses was very low, few

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studies recruited patients with depression, and serious games in half of the studies were purpose-shifted. Therefore, we can only recommend health care providers consider offering serious games as an adjunct to existing interventions until further, more robust evidence is available.

As mentioned before, serious games in more than half of the studies were not designed to specifically alleviate depression and did not deliver other therapeutic modalities such as art therapy, REBT, and psychoeducation. This may be attributed to the lack of such serious games in real life. Accordingly, there is a need to develop more serious games that are designed to specifically alleviate depression and deliver other therapeutic modalities.

The most common platforms used for playing the games were computers and video game consoles and their accessories, which are relatively more expensive and less accessible than smartphones that were the platform for serious games in only 1 study. The number of smartphone users in the world exceeded 6.4 billion in 2021 [71], which forms about 82% of the global population (7.8 billion) [72]. We encourage developers to develop serious games that can be played through smartphones.

Most studies were carried out in high-income countries, and this may indicate the lack of serious games in low-income countries. People in low-income countries may be more in need of serious games than those in high-income countries because low-income countries have a greater shortage of mental health professionals than high-income countries (0.1 per 1,000,000 people vs 90 per 1,000,000 people) [73,74]. Serious games should be exploited to alleviate depression in low-income countries.

Gaming and mental health have traditionally been two distinctly separate fields and come with their own unique pedagogy and praxis. The potential of utilizing the advantages inherent to gaming, as described earlier, from its reach to its transformative potential in mental health holds a lot of promise in theory. However, to achieve this potential, experts from the two disciplines need to work together in order to understand the unique strengths and limitations of each field when designing serious games.

Conclusion

Overall, serious games can be better than no intervention in alleviating depression and as effective in alleviating depression as other active interventions (eg, conventional CBT, exposure therapy, conventional exercise). However, definitive conclusions regarding the effectiveness of serious games could not be drawn in this review because the overall risk of bias was high in most included studies, the quality of the meta-analyzed evidence was very low, and few studies recruited patients with depression. Therefore, we can only recommend health care providers consider offering serious games as an adjunct to existing interventions until further, more robust evidence is available. To have sufficient evidence, future studies should assess the effectiveness of serious games that are designed specifically to alleviate depression and deliver other therapeutic modalities, recruit participants with depression, and avoid biases by following recommended guidelines for conducting and reporting RCTs (eg, RoB 2).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.
[DOCX File , 33 KB - games_v10i1e32331_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 31 KB - games_v10i1e32331_app2.docx]

Multimedia Appendix 3
Data extraction form.
[DOCX File , 26 KB - games_v10i1e32331_app3.docx]

Multimedia Appendix 4
Reviewers' judgements about each "risk of bias" domain for each included study.
[DOCX File , 45 KB - games_v10i1e32331_app4.docx]

Multimedia Appendix 5
Grading of Recommendations Assessment, Development and Evaluation (GRADE) Profile for comparison of serious games to control or conventional exercises for depression.
[DOCX File , 19 KB - games_v10i1e32331_app5.docx]

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Abbreviations

ADS-L: Allgemeine Depressionsskala
BDI: Beck Depression Inventory
CBT: Cognitive behavioral therapy
CDRS-R: Children's Depression Rating Scale-Revised
GADS: Goldberg Anxiety and Depression Scale
GDS: Geriatric Depression Scale
GRADE: Grading of Recommendations Assessment, Development and Evaluation
HADS: Hospital Anxiety and Depression Scale
MCID: minimal clinically important difference
PAID: Problem Areas in Diabetes
PHQ-9: Patient Health Questionnaire-9
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RADS-2: Reynolds Adolescent Depression Scale
RCT: randomized controlled trial
REBE: rational emotive behavioral education
REBT: rational emotive behavioral therapy
RoB 2: Risk-of-Bias 2
SMD: standardized mean difference
WHO: World Health Organization
WHO-5: WHO 5-item Well-Being Index

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Original Paper

Exploring Middle School Students' Perspectives on Using Serious Games for Cancer Prevention Education: Focus Group Study

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Abstract

Background: Cancer in the United States is a leading cause of mortality. Educating adolescents about cancer risks can improve awareness and introduce healthy lifestyle habits. Public health efforts have made significant progress in easing the burden of cancer through the promotion of early screening and healthy lifestyle advocacy. However, there are limited interventions that educate the adolescent population about cancer prevention. Previous studies have demonstrated the effectiveness of serious games (SGs) to teach adolescents about healthy lifestyle choices, but few research efforts have examined the utility of using SGs to educate youth specifically on cancer prevention.

Objective: This study aimed to investigate middle school students' preferences for the use of SGs for cancer prevention education. The study also characterized the students' perceptions of desired game design features for a cancer prevention SG.

Methods: Focus groups were held to allow adolescents to review a game playbook and discuss gaming behaviors and preferences for an SG for cancer education. The game playbook was developed based on "Cancer, Clear & Simple," a curriculum intended to educate individuals about cancer, prevention, self-care, screening, and detection. In the game, the player learns that they have cancer and is given the opportunity to go back in time to reduce their cancer risk. A focus group discussion guide was developed and consisted of questions about aspects of the playbook and the participants' gaming experience. The participants were eligible if they were 12 to 14 years old, could speak and understand English, and had parents who could read English or Spanish. Each focus group consisted of 5 to 10 persons. The focus groups were audio recorded and professionally transcribed; they were then analyzed content-wise and thematically by 2 study team members. Intercoder reliability (kappa coefficient) among the coders was reported as 0.97. The prevalent codes were identified and categorized into themes and subthemes.

Results: A total of 18 focus groups were held with 139 participants from a Wisconsin middle school. Most participants had at least "some" gaming experience. Three major themes were identified, which were educational video games, game content, and purpose of game. The participants preferred customizable characters and realistic story lines that allowed players to make choices that affect the characters' outcomes. Middle school students also preferred SGs over other educational methods such as lectures, books, videos, and websites. The participants desired SGs to be available across multiple platforms and suggested the use of SGs for cancer education in their school.

Conclusions: Older children and adolescents consider SGs to be an entertaining tool to learn about cancer prevention and risk factors. Their design preferences should be considered to create a cancer education SG that is acceptable and engaging for youth.

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KEYWORDS

adolescents; adolescent education; adolescent health; older children; middle school students; cancer awareness; cancer education; cancer prevention; health education; serious games

Introduction

Cancer is a serious disease that affects the health, well-being, and overall quality of life for the diagnosed person as well as their loved ones. Despite progress in medical and scientific technology, cancer remains the second leading cause of mortality in the United States [1]. The American Cancer Society estimates that 1.9 million new cancer cases will be diagnosed in the United States in 2021 [1]. In addition to the personal health and emotional costs of cancer, it is also a leading American health care expenditure, projected to cost $245 billion by the year 2030 [2]. While the type of cancer, stage, and diagnosed individual's age can affect prognosis and outcomes, cancer is a severe illness that significantly affects people's lives across the United States.

Although the adolescent population is not the most at risk for cancer mortality, adolescence is an important stage for cancer prevention [3]. Adolescents are in a crucial developmental phase where they can be influenced to develop healthy habits, such as eating a healthy diet and exercising or avoiding hazardous habits, such as smoking and vaping [4]. Behaviors developed in adolescence can reduce cancer risk or predispose adolescents to cancers at later stages in life. In 2014, approximately 42% of diagnosed cancers (excluding nonmelanoma skin cancers) and 45.1% of cancer deaths were attributed to modifiable risk factors including cigarette smoking, excess body weight, alcohol intake, poor diet, physical inactivity, ultraviolet light exposure, and cancer-associated infections [5]. Targeting youth for early cancer education related to modifiable cancer risk factors can promote healthy lifestyle patterns that remain throughout the rest of their adult lives.

In recent years, researchers have explored serious games (SGs) as an educational public health tool due to the popularity of gaming among teenagers and young adults. The Pew Research Center reports that 80% of teenagers have access to gaming devices, and 90% play video games [6]. SGs, also known as educational games, are video games designed not only for entertainment, but to educate or create awareness of a certain issue [7]. Between 2003 and 2014, 16 SGs were developed to promote vaccinations and demonstrated the potential to influence health behaviors [8]. SGs have also been used to educate students about healthy eating habits. In 2010, a meta-analysis analyzed the role of 11 video games designed to support children with type 1 diabetes mellitus in managing their disease state [9]. These games presented education in a comfortable, exciting, and understandable manner and demonstrated the potential to educate students. Additionally, SGs have been used to educate adolescents on medication use [10]. These studies suggest that SGs can improve health literacy in adolescents and indicate the potential for positive impact on improving adolescent awareness regarding cancer prevention.

While studies regarding SG cancer medication education in diagnosed adolescents have been conducted in the United States, there are few studies that examine the role of SGs for cancer prevention strategies and associated cancer risk factors for adolescents [11]. In a recent study, researchers conducted a randomized controlled trial to study the educational impact of a web-based game intervention (Re-Mission [Hopelab]) on cancer risk perception in college students and the relationship between risky behaviors and carcinogenic susceptibility. The results indicated that SGs can have an impact on information-seeking behaviors and perceptions of cancer among young adults [12]. This strategy could be implemented in SGs targeted toward adolescents to reduce their risk of cancer.

Public health efforts have significantly improved cancer awareness, preventative screening, and lifestyle modification among adults [13,14]. However, there are few SGs specifically developed to educate the adolescent population about the importance of cancer prevention [15]. Exploration of this emerging field can provide insights on the impact of SGs and game features preferred by older children and adolescents. Investigating the use of SGs in cancer education is crucial, as education can instill healthy habits to prevent future cancer risk behaviors. Thus, this study aimed to investigate middle school students' preferences for the use of SGs to provide cancer prevention education and their desired game design features for a cancer prevention SG.

Methods

Study Design

Focus groups were chosen to capture group interactions, discussions of participants' gaming behaviors, and preferences for a cancer education game [16]. This qualitative data collection method allowed the participants to expand on their responses and opinions and offered the moderators an opportunity to ask follow-up questions as needed. A focus group discussion guide was created by the study team based on a questionnaire from the principal investigator's previous research (Multimedia Appendix 1). The study team reviewed and revised the discussion guide prior to data collection. The guide consisted of mostly open-ended questions about aspects of a cancer education SG playbook. Questions were designed to explore the participants' perspectives on characters, story line and scenarios, and the purpose of the game, as well as their experience with video games. The participants' demographic information was collected, including age, gender, race and ethnicity, zip code, and number of persons under 18 years living in their household.

Game Playbook

The game playbook used in the focus group discussions was created based on "Cancer, Clear & Simple," a curriculum designed by the Cancer Health Disparities Initiative to educate individuals about cancer [17,18]. The curriculum covers "Cancer Basics," "Cancer Prevention & Self-Care," and "Cancer Screening & Detection" and has been adapted for rural, Black, and Latino communities [17,18].

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The game playbook was presented to older children and adolescents in paper format and included images, a brief game overview, and descriptions of game levels. The participants reviewed the game playbook before answering focus group questions about the overall game and individual aspects of the game. The playbook introduced a scenario in which the player is a 57-year-old patient who learns of a stage 4 colorectal cancer diagnosis. The player is then transported back in time and given the opportunity to make different life choices. If the player makes healthier choices regarding diet, tobacco use, and cancer screening, they are transported back to the present day, where they find they now have stage 2 colorectal cancer and an increased chance of survival.

The game playbook presented to the participants included 4 levels with corresponding images and level descriptions. In Level 1, the player is introduced to the game, and their doctor informs them that they have stage 4 colorectal cancer (Figure 1).

The purpose of Level 1 was to explain genetic and lifestyle reasons for cancer to the player and emphasize the importance of early detection and screening. Level 2 introduced basic cancer knowledge by demonstrating what was happening inside the patient's body during stage 4 cancer (Figure 2).

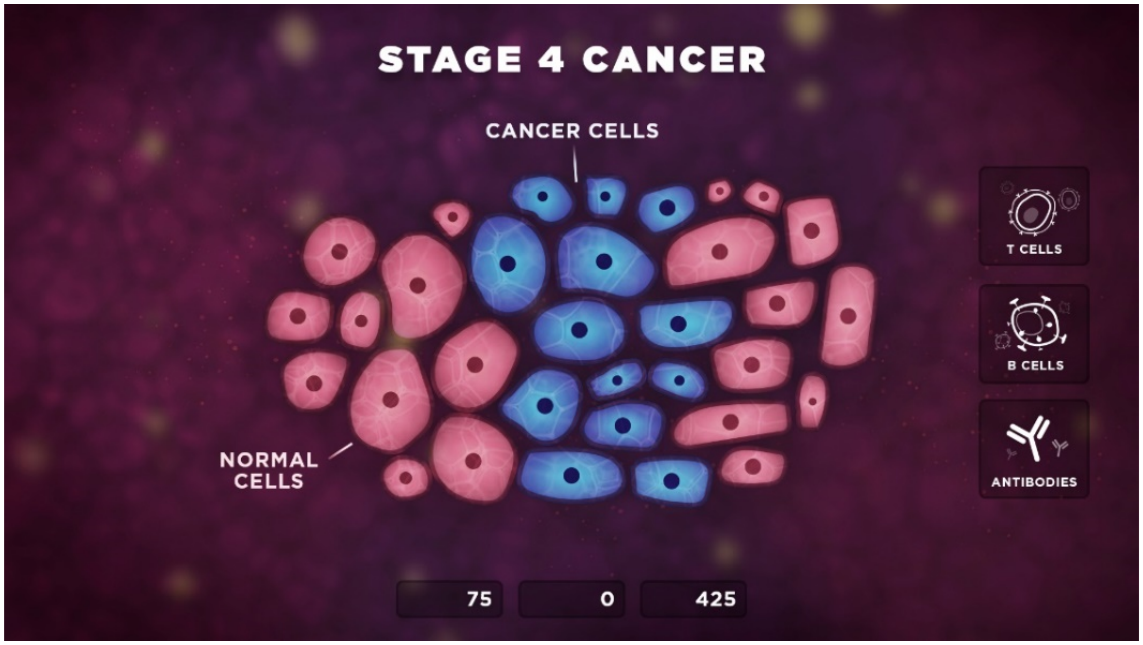
In Level 3, the player is given the opportunity to learn about cancer risk and prevention through time travel (Figure 3). The goal was to identify what the player could do differently to reduce their risk of cancer.

In the final level, the player is transported back to the present (Figure 4). The player is presented with a view inside the patient's body again, this time demonstrating stage 2 cancer and an opportunity to play as the immune system, combating cancer. The player learns that, due to early detection, they can survive their cancer diagnosis.

Figure 1. Level 1 of the game playbook.



Figure 2. Level 2 of the game playbook.

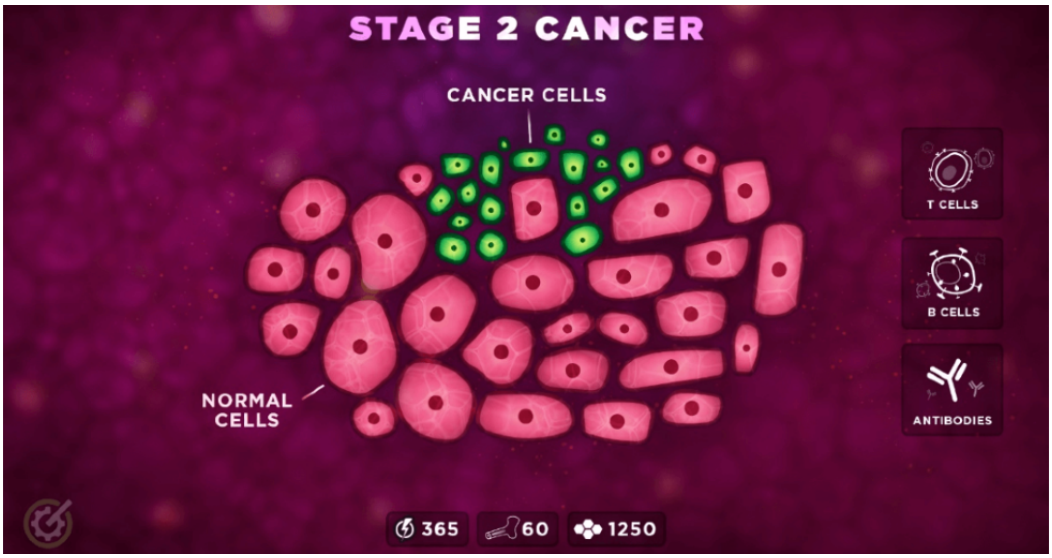


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Figure 3. Level 3 of the game playbook.



Figure 4. Level 4 of the game playbook.



Sampling and Recruitment

The participants were recruited from a US Midwest middle school in March 2020. Students were eligible if they were 12 to 14 years old, could speak and understand English, and if their parents could read English or Spanish. The study team members worked with school staff to develop a recruitment and data collection plan that met the needs of the school setting. The school staff distributed packets containing a letter of introduction to the study and consent forms to all students in a required 8th grade health class. All consent documents were available in English and Spanish. Parent or guardian consent was required for participants under the age of 18 years. This study was approved by the University's Institutional Review Board. The participants were each given $10 in cash after participation in the focus groups.

Data Collection

Each focus group consisted of 5 to 10 participants and was facilitated by 1 to 3 members of the study team. Of the 343 eligible students, 148 (43%) consented to participate in the study. A total of 139 students who consented were present for data collection. Schools provided separate rooms for each focus group to ensure privacy for the participants. One study team member led the focus group discussion, while the others took observation notes and asked additional follow-up questions as needed. The focus groups lasted approximately 35 to 50 minutes each, were audio-recorded, and were professionally transcribed verbatim. The facilitators and moderators completed reflection notes at the end of each focus group.

Data Analysis

Transcripts were independently verified for accuracy and quality of transcription by 2 members of the study team before beginning data analysis. The transcripts were analyzed content-wise and thematically by 2 study team members using the NVivo 12 (QSR International) qualitative software [19-22]. Codes were developed using an inductive and deductive approach. Each team member independently reviewed and coded transcripts to develop relevant codes, which were combined to create a master codebook. Two team members then completed coding using the master codebook and code definitions and held weekly meetings to review coding and address discrepancies.

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The intercoder reliability (kappa coefficient) among the 2 coders was reported as 0.97. The prevalent codes were identified by the research team and categorized into major themes and subthemes.

Results

Participant Demographic Characteristics

A total of 18 focus groups were held with 139 participants. The reasons for nonparticipation include absence on the day of study activities, participants forgetting to provide their parents with the recruitment packets or to bring back signed forms, lack of signed parental consent, or unknown factors such as time constraint or research burden. All participants were 8th grade students at a Wisconsin middle school. Table 1 summarizes participant characteristics.

The study participant demographics were similar to past years' student demographics at the school [23]. More than half of the participants were male (54% [n=75]), White (89.9% [n=125]), and 14 years of age (54% [n=75]). Moreover, 39% (n=54) of the participants had 2 other people under the age of 18 living at home with them, while nearly one-third (28% [n=39]) had 3 other people under the age of 18 living at home with them. Three major themes were identified in the focus groups, which were (1) educational video games, (2) game content, and (3) purpose of game (Table 2).

Table 1. Participant demographics (N=139).

Characteristics	Values, n (%)
Gender[a]	
Male	75 (54.0)
Female	63 (45.3)
Age[b] **(years)**	
12	1 (0.7)
13	60 (43.2)
14	75 (54.0)
Number of youths living at home	
1	19 (13.7)
2	54 (38.8)
3	39 (28.1)
4	18 (12.9)
5	5 (3.6)
6	4 (2.9)
Race or ethnicity[c]	
American Indian or Native American	2 (1.4)
Asian	6 (4.3)
Black or African American	5 (3.6)
Hispanic or Latino	8 (5.8)
Native Hawaiian or Other Pacific Islander	1 (0.7)
White	125 (89.9)

[a]Gender was missing for 1 participant. An option for "Other" was provided but not selected by any participant.

[b]Age was missing for 3 participants.

[c]Race or ethnicity was missing for 1 participant. Race was not a mutually exclusive choice for 8 participants. An option for "Other" was provided but not selected by any participant.

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Table 2. Themes, subthemes, and verbatim quotes.

Theme and subtheme	Verbatim quotes
Educational video games	
Overall perceptions	*I think it's a good idea because it really gives you an understanding of what you're learning about, and it's fun at the same time. So it really makes kids want to go back to it*. [Male participant, focus group J]
Recommended settings	*I also think it could be a good study tool, you know. If it were to be, if we were to have a test on cancer and cancer prevention and all that stuff, I think a game like this could be super helpful in that because then you could still have fun and learn*. [Female participant, focus group N]
Recommended platforms	*Computers, definitely, because we have them supplied at our school.* [Male participant, focus group S]
Game content	
Story lines	*Maybe you get a few choices at the beginning that are kind of in between. They're not really about cancer or anything like that. But depending on how you answer those first few, they could change what you can answer later. Maybe let's say you choose, at one point, to have a certain group of friends. And then later in life, when you go back later, I don't know, it could have where you don't have the choice to not smoke. You have to because of your friend group you chose*. [Male participant, focus group M]
Characters	*I think if you could have different options, like different hairstyles or something, and you could just customize it like that, like different things, that would be cool because then you could make it relatable because they could make it more personalized*. [Female participant, focus group K]
Educational components	*You could have like the doctor talk about the cancer cells, and like they can describe it instead of just clicking all over*. [Female participant, focus group G]
Purpose of game	
Cancer education	*I think it's like, the game is a fun way to educate people who don't really know about cancer*. [Female participant, focus group O]
Cancer prevention	*[The purpose is] to educate school-aged children on the choices they can make now that can help prevent cancer in the future*. [Female participant, focus group K]

Participant Gaming Experience and Preferences

The study participants had varying levels of gaming experience, ranging from “a little” to “a great deal.” Approximately 17% (n=23) had “a little,” 46% (n=63) had “some,” 26% (n=36) had “a lot,” and 15% (n=20) had “a great deal” of experience. The reasons for not playing games included participation in other activities, not having enough time, and use of social media such as Snapchat and TikTok.

Combat was most often reported as the participants’ favorite video game genre, followed by sports, adventure, racing, and strategy. The participants preferred the combat genre due to its competitive, adventurous, and challenging nature. They stated that they played video games such as Call of Duty, Madden, Fortnite, NBA 2K, and Rainbow Six Siege, and mobile games, including Clash of Clans, Clash Royale, and Slope. The participants reported using video game platforms such as Xbox, Wii, Nintendo Switch, and PlayStation. Most participants identified mobile phones as their preferred platform for gaming. The participants also mentioned playing card or tabletop games. The most frequently mentioned tabletop games included Monopoly, Life, and Sorry, and the most reported card games were Uno, Cards Against Humanity, and Poker.

Theme 1: Educational Video Games

Overall Perceptions

The study participants stated that SGs could be used to teach players about cancer through active engagement. Games can offer an entertaining way to visually learn information, thereby making it easier to remember. SGs were preferred over lectures, books, videos, and websites for educational purposes.

> *School is really stressful, and you get this time to have a little bit of fun while still learning the stuff you need to learn. And I think that if we are able to learn that way, I don't know why the teachers don't let us. It will stick with you.* [Female participant, focus group B]

Recommended Settings

The participants reported that SGs about cancer would be useful in school and for individuals who know someone with cancer. They suggested the use of video games in school, such as in health class, guidance counseling, and test preparation.

> *As opposed to making us sit through a 30-minute video or read a bunch of websites, I think this [educational video game] would be much more appreciated to learn from at school.* [Female participant, focus group D]

Recommended Platforms

The participants expressed a desire for SGs to be compatible for use on multiple devices or platforms, such as mobile phones and computers.

> *I feel like in school, computer would be better. But then outside of school, a phone would be a lot more accessible.* [Male participant, focus group D]

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Theme 2: Game Content

Story Lines

The participants preferred an SG that enables players to make choices for their characters. They suggested that in-game decision-making should carry consequences and affect the characters' outcome. Options could include making healthier dietary choices, resisting peer pressure to smoke, and having regular exercise. The study participants also desired more details provided in the story for context and to create a more immersive experience.

> *It would be able to help you really get immersed in the game and all the experiences you could feel and all the choices you'd make would have their own consequences, whether good or bad.* [Male participant, focus group A]

The participants suggested using a story line that included a fight scene between cancer cells and the body's own immune cells to make the game more interactive. However, some participants indicated that this may only be appealing to a younger audience. The inclusion of some lifestyle choices was recommended.

> *I think that we should make an actual fighting level for the cancer so kids would be more interacting with the game, so they don't just watch what happens. They can choose, I don't know, to actually fight the cancer cells with the normal cells.* [Male participant, focus group F]

Characters

The ability to customize the main character was discussed in all focus groups. The participants stated that the ability to design a character that looks like them makes a game more engaging. This includes customizing various features such as the character's age, gender, hair, and clothes.

> *I think if you had a character customization thing, so at the beginning, you can choose the gender and then all the attributes about him, the age and stuff, so that it could be as much as you or your family member or whoever.* [Male participant, focus group H]

Secondary characters discussed in the focus group included a doctor, family, and friends. The doctor was the most frequently discussed secondary character. The participants explained that a doctor could serve as an informational resource for the player and could teach players about cancer. Family and friends were similarly considered pertinent to the story and could be used to illustrate the effects a cancer diagnosis may have on loved ones or create peer pressure to make decisions more complex.

> *I think it's a good idea to have the character of a doctor explaining it [information about cancer] rather than just a normal person.* [Male participant, focus group H]

Educational Components

The participants expressed their desire to learn about different types of cancers (eg, colorectal, lung, skin, and breast) through video games. They expressed interest in having different types and stages of cancers incorporated into different levels in the game. They also suggested including information about the various types of cells involved, cancer stages, and other facts about cancer.

> *I think different characters could have different types of cancers in different stages.* [Female participant, focus group O]

Theme 3: Purpose of the Game

Cancer Education

Cancer education was identified as the main purpose of the game prototype. The participants thought the game could be used as an educational tool to help the player learn about cancer because it allowed the player to visualize different aspects of the disease, including its causes, pathophysiology, and the emotional repercussions on friends and family.

> *Cancer is not fun, but it [the educational video game] gives you a fun way to actually learn about it. It's not just, oh, all this happens. It gives you visuals, and you actually get to make the choices and see the effects of it.* [Female participant, focus group B]

Cancer Prevention

The participants also identified cancer prevention as a main purpose of the game prototype. They stated that the game could be used to highlight modifiable cancer risk factors so players could minimize these risk factors in their own lives. Additionally, the participants recognized the importance of forming healthy habits at a younger age and affirmed that the game could equip them to do so as well.

> *It will teach about cancer and cancer prevention because it's showing you things that you can do to prevent cancer, and it's also kind of showing you some more specific things about the cancer cells itself.* [Female participant, focus group N]

Discussion

Principal Findings

An SG for cancer-related education was well received by most participants across the focus groups in this study. The participants desired the ability to customize the main character to look like themselves. Customizing a game character is a popular feature in video games because it increases the player's engagement, thereby creating a more immersive experience, which may make the game more enjoyable [24-26]. Secondary characters, such as a doctor, family, and friends, were favored to teach the players about cancer. Secondary characters may also contribute to the educational experience by evoking an emotional response when the players observe the effects of their choices. The participants reported that SGs provide an entertaining method for cancer education, thus improving the likelihood of retaining what they learned. Additionally, the participants desired the SG to be used as a supplemental learning material during classes in school.

The participants preferred settings and story lines that mirror real life situations, which could also increase engagement and

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attachment to the gaming experience. Additionally, they suggested that SGs would be useful in the school setting and preferred SGs over other educational materials, such as lectures, books, and websites. Engaging with the material presented in the game by evaluating choices and decision-making promotes active learning and can be a more effective tool than passively reading text or listening to a lecture. Active learning provides opportunities for discussion and critical thinking that can be meaningful for both students and teachers [27]. In addition to the promotion of active learning, the ability to make choices for characters in the games can encourage students to explore their own perceptions and beliefs about the decisions they might make in the future or under peer pressure [28-30]. Realistic scenarios can bring to life the nuances and complexities that go into the decisions people make in their daily lives and encourage behavior change [28-30].

Overall, 87% of the participants stated they had at least "some" to "a great deal" of gaming experience. This is similar to national trends, which found that approximately 90% of adolescents play video games and 80% of teenagers have access to gaming devices [6]. Although the participants described their favorite video game genre as combat, they preferred an SG for cancer education to follow a more realistic story line that offers decision-making opportunities. Additionally, many participants stated they want an SG to be accessible across multiple platforms, such as computers, mobile phones, and video game consoles. Games accessible by computer would be beneficial for use in schools, while mobile games would allow older children and adolescents to engage in gameplay at home as well.

Our study provides middle school students' support for the use of an SG as an educational tool for cancer prevention education. An SG can simulate real-life situations in which making healthier decisions may be difficult due to social pressures or other barriers. An SG can provide players with a visual tool for learning about cancer and cancer prevention through the illustration of modifiable risk factors set in realistic scenarios the players may encounter in their own lives. Therefore, the SG could provide youth with the tools needed to make healthy behavior choices in real life. Future research should examine the effect an SG has on adolescents' cancer awareness, knowledge, and mindfulness of lifestyle choices.

Limitations

This study was conducted at a single Midwestern middle school. While the demographics of the study participants mirror the demographics of this school, the responses gathered from this sample may not be representative of the general United States older children and adolescent population. Future studies should explore preferences of a larger and more representative sample of middle school students for an SG on cancer education and incorporate their feedback into the design of a game prototype.

Conclusions

This study suggests that children and adolescents consider SGs an entertaining tool for education about cancer prevention and associated healthy lifestyle habits, particularly in the school setting. The study participants stated that SGs can offer a "real-life" virtual immersion experience with rewards and consequences of health-based lifestyle choices. Many participants reported customizing the main characters would enable them to partake in the gaming experience and emotionally connect with the outcomes. Additionally, the participants favored an SG that incorporated realistic settings and story lines, customizable characters, and information about various cancer types. Older children and adolescent preferences should be considered in the process of designing an SG for cancer education to create a game that is engaging and acceptable for youth.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group guide.
[DOCX File , 20 KB - games_v10i1e31172_app1.docx]

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Abbreviations

SG: serious game

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Original Paper

Evaluation of an AIDS Educational Mobile Game (AIDS Fighter · Health Defense) for Young Students to Improve AIDS-Related Knowledge, Stigma, and Attitude Linked to High-Risk Behaviors in China: Randomized Controlled Trial

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Abstract

Background: The AIDS epidemic among young students is serious, and effective preventive interventions are urgently needed. Game-based intervention has become an innovative way to change healthy behaviors, and we have developed an AIDS educational game called AIDS Fighter · Health Defense.

Objective: In this study, we tested the effect of AIDS Fighter · Health Defense on young students in improving AIDS-related knowledge, stigma, and attitude related to high-risk behaviors in Southwest China.

Methods: A randomized controlled trial was conducted from September 14 to 27, 2020. In total, 96 students from 2 classes in a middle school were selected by stratified cluster sampling in Luzhou City, Southwest China. The students were randomly divided into the intervention group (n=50, 52%) and the control group (n=46, 48%). The intervention group played the AIDS educational game AIDS Fighter · Health Defense; the control group learned AIDS-related knowledge through independent learning on the QQ chat group. An AIDS-related knowledge questionnaire, a stigma scale, and an attitude questionnaire on AIDS-related high-risk behaviors were used to measure the effect of the AIDS educational game via face-to-face interviews. The user experience of the game was assessed using the Educational Game User Experience Evaluation Scale. The difference was statistically significant at $P \leq .05$.

Results: After the intervention, the AIDS knowledge awareness rate (X [SD], %) of the intervention and control groups were 70.09 (SD 11.58) and 57.49 (SD 16.58), with $t=4.282$ and $P<.001$. The stigma scores of the 2 groups were 2.44 (SD 0.57) and 2.48 (SD 0.47), with $t=0.373$ and $P=0.71$. The positive rate (X [SD], %) of attitudes of high-risk AIDS behaviors of the 2 groups were 82.00 (SD 23.44) and 79.62 (SD 17.94), with $t=0.555$ and $P=0.58$. The mean percentage of the game evaluation was 54.73% as excellent, 31.45% as good, 13.09% as medium, and 0.73% as poor.

Conclusions: AIDS Fighter · Health Defense could increase AIDS-related knowledge among young students, but the effect of the game in reducing AIDS-related stigma and improving the attitudes of high-risk AIDS behaviors was not seen. Long-term effects and large-scale studies are needed to assess the efficacy of game-based intervention.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2000038230; https://trialsearch.who.int/Trial2.aspx?TrialID=ChiCTR2000038230

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(JMIR Serious Games 2022;10(1):e32400) doi:10.2196/32400

KEYWORDS

young students; AIDS education; educational game; game-based intervention; serious games; public health; HIV; AIDS epidemic; stigma; health defense; health knowledge; digital health; digital health intervention

Introduction

Importance of AIDS Prevention Education for Young Students

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) data, there were approximately 3.4 million HIV infections among young people aged 15-24 years worldwide and approximately 460,000 new HIV infections among young people in 2019 [1], most of them being students, and we are far away from reaching UNAIDS testing and condom use targets of 95% coverage by 2030 [2].

Therefore, it is necessary to take effective measures to control the prevalence of AIDS among young students [3]. Studies have shown that AIDS health education for young students can improve their ability to prevent AIDS [4-6], but traditional education methods are not attractive to them, and the effect is poor [7,8]. Therefore, it is urgent to innovate the AIDS education model to improve the education effect and curb the spread of AIDS among young students.

Importance of AIDS Educational Games for AIDS Prevention

With the development of science and technology, AIDS prevention education has changed from using traditional methods to using modern ones [9,10]. Among them, game-based intervention has become an innovative way to change healthy behaviors [11-13]. Educational games contain mechanisms such as tasks, rules, feedback, challenges, and components such as points, badges, and leaderboards [14], which may influence people's motivation and behavior by stimulating their immersion, satisfaction, and experience [15].

Research on AIDS health education games started late, mainly aimed at adolescents, including HIV-infected adolescents, gay men and other high-risk groups, and healthy adolescents. The targets of education are to increase adolescents' adherence to antiviral therapy and pre-exposure prophylaxis (PrEP) [16-18], promote HIV screening [19], reduce adolescent risky sex and multiple sexual partners, avoid drug and alcohol abuse, and thus reduce the infection of AIDS and sexually transmitted diseases among adolescents [20-22]. The main types of games are role-playing, online interaction, knowledge contest, hero combat, etc, and the main game mechanisms are challenge, task, upgrade, interaction, virtual, etc. [23-26].

AIDS Educational Games in China

AIDS health educational games in China are in their infancy, and with few existing studies, single game elements, incomplete game mechanisms, and a lack of effect evaluation studies, the actual educational effect is not clear. To solve these problems, we developed an AIDS educational game, mainly targeting education for HIV/AIDS knowledge, attitude, and behavior, and refusal of drug and alcohol abuse. The game has a variety of elements and mechanisms that are suitable for AIDS prevention education of adolescents in China.

In this study, we tested the effectiveness of the AIDS educational game on preventing HIV among young students in Luzhou City, Southwest China. Here we report results from this study.

Methods

Game Design

The AIDS educational game is called AIDS Fighter · Health Defense. The story line is that HIV launches an attack on the human body and players need to control heroes to eliminate HIV. During the battle, players are repeatedly trained to take condoms and refuse dangerous sexual behaviors, avoid drugs to refuse intravenous drug use, avoid alcohol to refuse dangerous sex when drunk, obtain antiviral drugs for PrEP and postexposure prophylaxis (PEP) [27].

The human body system is used as the level in the game. There are 7 levels in total. The difficulty of the game increases from low to high. The sequence of levels is (1) immune system, (2) blood system, (3) skin and mucosal system, (4) central nervous system, (5) respiratory system, (6) digestive system, and (7) genitourinary system.

The game copywriting of each level corresponds to the human body system of the level, describing that the system is infected with HIV. The success or failure of the game has corresponding text prompts. If the game fails, it prompts HIV to invade the human body and shows what the result will be; if it succeeds, encouraging text appears to remind the player that they have successfully avoided HIV infection.

AIDS Fighter · Health Defense has the following mechanisms and components: (1) a virus combat game, (2) goal setting to eliminate HIV, (3) questions to be answered to be resurrect in the game, (4) point ranking, and (5) recognition and rewards. The game includes 5 functional modules:

- Game module: There are 7 levels involving 7 systems of the human body affected by AIDS.
- Quiz-and-Answer module: It provides a chance to the player to resurrect by answering questions on AIDS-related knowledge.
- Knowledge Corner module: It contains educational articles and videos on AIDS.
- Point-ranking module: Points are awarded according to the behavior and clearance situation during the game and the learning in the Knowledge Corner module, and the points are ranked.
- Data Management module: The educational information in the Knowledge Corner module can be edited, and in-game data collection, integration, classification, and application can be realized.

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The gameplay and screenshots are shown in Figure 1.

Figure 1. Gameplay and screenshots of AIDS Fighter · Health Defense. Interface 1 is the gameplay. Interface 2 is the screenshot of game failure. Interface 3 is the Quiz-and-Answer module. Interface 4 is the Knowledge Corner module.



Study Design

A randomized controlled trial was conducted, in which 2 classes were selected from a middle school in Luzhou City using stratified cluster sampling. Third-party staff randomly allocated the 2 classes to the intervention group and the control group by tossing a coin.

We had the following hypotheses (H):

- H1: AIDS Fighter · Health Defense can increase the awareness of AIDS-related knowledge among young students.
- H2: AIDS Fighter · Health Defense can reduce AIDS-related stigma among young students.
- H3: AIDS Fighter · Health Defense can improve the attitude of AIDS-related high-risk behaviors among young students.

The study was approved by the ethics committee of the Affiliated Hospital of Southwest Medical University, China.

Participants

The participants of the study were first-grade students of a secondary vocational school, and the location was Luzhou City, Southwest China. The eligibility criteria for participation were as follows: young students aged 15-24 years, informed consent and voluntary participation in this study (<16 years old required the consent of the guardian), and ability to access the internet. The exclusion criteria were as follows: The participant or guardian refused to provide consent to participate in the study, the participant did not complete the questionnaire survey, and the participant had used similar games before.

Intervention

The intervention and control groups received the corresponding intervention from September 14 to 27, 2020.

The intervention group played AIDS Fighter · Health Defense through WeChat (social software that can also provide some games). Participants were asked to play the game and study the AIDS-related knowledge in the Knowledge Corner module and were required to earn at least 20 points per day. The details of the participants' use of the game can be checked through the game's data management system.

Participants in the control group were added to the QQ chat group (QQ software is one of the most popular social software programs in China, which supports online chat, video chat, and voice chat; file sharing; network hard disk; remote control; email; online teaching; and other functions; Shenzhen Tencent Computer Systems Company Limited). The same educational resources as the Knowledge Corner module in AIDS Fighter · Health Defense were uploaded to the QQ group. Participants were asked to learn the knowledge by themselves.

Outcomes and Measurements

The primary outcomes were AIDS-related knowledge, stigma, and attitude before and 14 days after intervention.

AIDS-related knowledge was assessed through a self-made questionnaire with a total of 45 items, including the following 6 dimensions: basic knowledge of AIDS, knowledge of AIDS prevention, knowledge of AIDS testing, knowledge of AIDS treatment, knowledge of AIDS PrEP, and knowledge of AIDS-related laws and regulations.

AIDS-related stigma was assessed through the Chinese version of the Zelaya HIV/AIDS Stigma Scale [28] with 24 items, including 6 positive items, 18 negative items. The positive items have a score of 1 for totally agree to 5 for totally disagree, and the negative items have a score of 1 for totally disagree to 5 for totally agree. The items are divided into the following 4 dimensions: fear of transmission and disease; association with

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shame, blame, and judgment; personal support of discriminatory actions or policies; and perceived community support of discriminatory actions or policies. Each dimension contains 6 items with a score of 1 for totally agree to 5 for totally disagree. The higher the score, the more the participant's stigma of AIDS.

AIDS-related attitude was assessed through a questionnaire with 8 items with the choice of "Yes" or "No" in Chinese. Five experts were invited to verify the content validity of these questionnaires, and the item-level content validity index (I-CVI) and scale-level CVI (S-CVI) were both 1.00.

The secondary outcome was the user's experience of the game in the intervention group. It was assessed through the Educational Game User Experience Evaluation Scale with 22 items in Chinese. After playing the game, the user selects one of 4 options (excellent, good, medium, and poor) to evaluate each indicator according to their actual experience.

Data Analysis

The classification data were statistically described by percentage, the qualitative data were compared using the chi-square test, the statistical description of the quantitative data was given using by $\bar{X}$ (SD), the two-tailed *t* test was performed to compare the groups, and difference-in-difference analysis was used to accurately evaluate the change in the intervention group. The difference was statistically significant when $P \leq .05$. The data analysts were blinded to the allocation.

Results

Description of Study Sample

The 96 students included were aged from 16 to 19 years. There were no significant demographic differences between the 2 groups (Table 1).

Table 1. Participant demographics (N=96).

Characteristics	Intervention group (n=50), n (%)	Control group (n=46), n (%)	t/χ^2 (*df*=94)	*P* value
Age (years), mean (SD)	16.68 (0.74)	16.76 (0.71)	0.547	0.59
Gender				
Male	21 (42)	21(45.65)	0.130	0.72
Female	29 (58)	25(54.35)	0.130	0.72
Ethnicity				
Han	49 (98)	43(93.48)	0.356	0.55
Other ethnic groups	1 (2)	3 (6.52)	0.356	0.55
Place of residence				
Rural area	29 (58)	32 (69.57)	1.383	0.24
Urban areas	21 (42)	14 (30.43)	1.383	0.24
Growth environment				
Living with parents	22 (44)	29 (63.04)	6.873	0.15
Living with mother	7 (14)	8 (17.39)	6.873	0.15
Living with father	6 (12)	1 (2.17)	6.873	0.15
Living with grandparents	11 (22)	5 (10.87)	6.873	0.15
Other	4 (8)	3 (6.52)	6.873	0.15
Access to AIDS information[a]				
TV	37 (74)	38 (82.61)	1.712	0.19
Newspaper	11 (22)	12 (26.09)	0.250	0.62
Internet	44 (88)	39 (84.78)	0.373	0.54
WeChat	19 (38)	17 (36.96)	0.014	0.91
WeiBo	18 (36)	16 (28.26)	0.019	0.89
School education	38 (76)	31 (67.39)	1.369	0.24
Medical staff	25 (50)	18 (39.13)	1.473	0.23
Relatives, friends	20 (40)	11 (23.91)	3.376	0.07
Other	1 (2)	3 (6.52)	0.896	0.34

[a]Multiple choices available.

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Comparison of AIDS-Related Knowledge, Stigma, and Attitude Between the 2 Groups Before the Intervention

Before the intervention, there was no statistically significant difference in the AIDS knowledge awareness rate, stigma scores, and positive rates of attitude of high-risk IDS behaviors between the 2 groups (Table 2).

Table 2. Comparison of indicators between the 2 groups before intervention (N=96).

Items	Intervention group (n=50), mean (SD)	Control group (n=46), mean (SD)	*t* (*df*=94)	*P* value
AIDS knowledge awareness rate				
Overall	58.04 (17.55)	57.87 (11.80)	0.056	0.96
Basic knowledge of AIDS	64.77 (17.10)	65.55 (15.19)	0.236	0.81
Knowledge of AIDS prevention	55.20 (25.97)	51.74 (16.37)	0.787	0.43
Knowledge of AIDS testing	48.80 (24.96)	47.83 (22.50)	0.200	0.84
Knowledge of AIDS treatment	68.00 (31.15)	65.76 (27.06)	0.377	0.71
Knowledge of AIDS PrEP[a]	35.20 (18.76)	32.17 (19.54)	0.774	0.44
Knowledge of AIDS-related laws and regulations	65.75 (27.87)	71.47 (21.03)	1.141	0.26
Stigma score				
Overall	2.58 (0.61)	2.51 (0.49)	0.622	0.54
Fear of transmission and disease	2.93 (1.13)	2.97 (0.96)	0.187	0.85
Association with shame, blame, and judgment	2.47 (0.82)	2.31 (0.70)	1.031	0.31
Personal support of discriminatory actions or policies	2.72 (0.74)	2.58 (0.68)	0.966	0.34
Perceived community support of discriminatory actions or policies	2.20 (0.82)	2.16 (0.65)	0.266	0.79
Positive rate of attitude of high-risk AIDS behaviors				
Overall	77.50 (22.73)	85.05 (19.30)	1.747	0.08
Do you support premarital sex?	72.00 (45.40)	80.00 (40.10)	0.917	0.36
Do you support premature love?	52.00 (50.50)	57.00 (50.10)	0.487	0.63
Do you support a 1-night stand?	88.00 (32.80)	96.00 (20.60)	1.443	0.15
Will you have premarital sex with your boyfriend/girlfriend?	74.00 (44.30)	80.00 (40.10)	0.697	0.49
Will you have sex with someone other than your lover?	82.00 (38.80)	87.00 (34.10)	0.650	0.52
Will you have sex with the same gender?	88.00 (32.80)	89.00 (31.50)	0.152	0.88
Will you use condoms when you have sex with your lover?	80.00 (40.40)	93.00 (25.00)	1.912	0.06
Will you use condoms when you have sex with other people of the same/opposite sex?	74.00 (44.30)	80.00 (40.00)	0.697	0.49

[a]PrEP: pre-exposure prophylaxis.

Comparison of AIDS-Related Knowledge, Stigma, and Attitude Between the 2 Groups After the Intervention

After the intervention, the awareness rate of AIDS-related knowledge in the intervention group was higher than that in the control group (t=4.282, P<.001). The stigma scores of the 2 groups were not statistically significant (t=0.373, P=.71). The positive rates of attitude of high-risk AIDS behaviors in the 2 groups were not statistically significant (t=0.555, P=.58); see Table 3.

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Table 3. Comparison of indicators between the 2 groups after intervention (N=96).

Items	Intervention group (n=50), mean (SD)	Control group (n=46), mean (SD)	*t* (*df*=94)	*P* value
AIDS knowledge awareness rate				
Overall	70.09 (11.58)	57.49 (16.58)	4.282	<0.001
Basic knowledge of AIDS	74.62 (13.84)	64.38 (17.04)	3.243	0.002
Knowledge of AIDS prevention	66.20 (18.83)	52.61 (22.15)	3.247	0.002
Knowledge of AIDS testing	62.00 (25.64)	42.61 (25.86)	3.685	<0.001
Knowledge of AIDS treatment	83.00 (21.09)	72.28 (30.84)	2.002	0.05
Knowledge of AIDS PrEP[a]	44.40 (17.75)	26.52 (20.25)	4.609	<0.001
Knowledge of AIDS-related laws and regulations	82.25 (15.79)	73.64 (20.79)	2.296	0.02
Stigma score				
Overall	2.44 (0.57)	2.48 (0.47)	0.373	0.71
Fear of transmission and disease	2.59 (0.86)	2.85 (0.95)	1.407	0.16
Association with shame, blame, and judgment	2.55 (0.83)	2.34 (0.51)	1.478	0.14
Personal support of discriminatory actions or policies	2.45 (0.67)	2.54 (0.61)	0.686	0.49
Perceived community support of discriminatory actions or policies	2.15 (0.73)	2.17 (0.63)	0.143	0.89
Positive rate of attitude of high-risk AIDS behaviors				
Overall	82.00 (23.44)	79.62 (17.94)	0.555	0.58
Do you support premarital sex?	84.00 (37.00)	76.00 (43.10)	0.978	0.33
Do you support premature love?	64.00 (48.50)	59.00 (49.80)	0.498	0.62
Do you support a 1-night stand?	92.00 (27.40)	98.00 (14.70)	1.320	0.19
Will you have premarital sex with your boyfriend/girlfriend?	82.00 (38.80)	74.00 (44.40)	0.942	0.35
Will you have sex with someone other than your lover?	86.00 (35.10)	89.00 (31.50)	0.439	0.66
Will you have sex with the same gender?	94.00 (24.00)	98.00 (14.70)	0.974	0.33
Will you use condoms when you have sex with your lover?	84.00 (37.00)	70.00 (46.50)	1.639	0.11
Will you use condoms when you have sex with other people of the same/opposite sex?	80.00 (40.00)	74.00 (44.40)	0.697	0.49

[a]PrEP: pre-exposure prophylaxis.

Comparison of AIDS-Related Knowledge, Stigma, and Attitude Before and After Intervention in the 2 Groups

After the intervention, the AIDS knowledge awareness rate of the intervention group was higher than that before the intervention (t=4.052, P<.001). The difference in the AIDS stigma score was not statistically significant (t=1.186, P=.24) after the intervention. The difference in the positive rate of attitude of high-risk AIDS behaviors was also not statistically significant (t=0.975, P=.33) after the intervention. After the intervention in the control group, the AIDS knowledge awareness rate, the stigma score, and the positive rate of attitude of high-risk AIDS behaviors were not statistically significant, but the positive rate of "Will you use condoms when you have sex with your lover?" dropped from 93.00 (SD 25.00) to 70.00 (SD 46.50), with t=2.955 and P=.004; see Table 4.

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Table 4. Comparison of indicators before and after intervention in the 2 groups (N=96).

Items	Intervention group (n=50)				Control group (n=46)			
	Before intervention, mean (SD)	After intervention, mean (SD)	*t* (*df*=49)	*P* value	Before intervention, mean (SD)	After intervention, mean (SD)	*t* (*df*=45)	*P* value
AIDS knowledge awareness rate								
Overall	58.04 (17.55)	70.09 (11.58)	4.052	<0.001	57.87 (11.80)	57.49 (16.58)	0.127	0.90
Basic knowledge of AIDS	64.77 (17.10)	74.62 (13.84)	3.166	0.002	65.55 (15.19)	64.38 (17.04)	0.348	0.73
Knowledge of AIDS prevention	55.20 (25.97)	66.20 (18.83)	2.425	0.017	51.74 (16.37)	52.61 (22.15)	0.214	0.83
Knowledge of AIDS testing	48.80 (24.96)	62.00 (25.64)	2.608	0.011	47.83 (22.50)	42.61 (25.86)	1.033	0.30
Knowledge of AIDS treatment	68.00 (31.15)	83.00 (21.09)	2.820	0.006	65.76 (27.06)	72.28 (30.84)	1.078	0.28
Knowledge of AIDS PrEP[a]	35.20 (18.76)	44.40 (17.75)	2.519	0.013	32.17 (19.54)	26.52 (20.25)	1.362	0.18
Knowledge of AIDS-related laws and regulations	65.75 (27.87)	82.25 (15.79)	3.642	<0.001	71.47 (21.03)	73.64 (20.79)	0.498	0.6280
Stigma score								
Overall	2.58 (0.61)	2.44 (0.57)	1.186	0.239	2.51 (0.49)	2.48 (0.47)	0.300	0.77
Fear of transmission and disease	2.93 (1.13)	2.59 (0.86)	1.693	0.094	2.97 (0.96)	2.85 (0.95)	0.603	0.55
Association with shame, blame, and judgment	2.47 (0.82)	2.55 (0.83)	0.485	0.629	2.31 (0.70)	2.34 (0.51)	0.235	0.82
Personal support of discriminatory actions or policies	2.72 (0.74)	2.45 (0.67)	1.913	0.059	2.58 (0.68)	2.54 (0.61)	0.297	0.77
Perceived community support of discriminatory actions or policies	2.20 (0.82)	2.15 (0.73)	0.22	0.748	2.16 (0.65)	2.17 (0.63)	0.075	0.94
Positive attitude rate of high-risk AIDS behaviors								
Overall	77.50 (22.73)	82.00 (23.44)	0.975	0.332	85.05 (19.30)	79.62 (17.94)	1.398	0.17
Do you support premarital sex?	72.00 (45.40)	84.00 (37.00)	1.449	0.151	80.00 (40.10)	76.00 (43.10)	0.461	0.65
Do you support premature love?	52.00 (50.50)	64.00 (48.50)	1.212	0.228	57.00 (50.10)	59.00 (49.80)	0.192	0.85
Do you support a 1-night stand?	88.00 (32.80)	92.00 (27.40)	0.662	0.510	96.00 (20.60)	98.00 (14.70)	0.536	0.59
Will you have premarital sex with your boyfriend/girlfriend?	74.00 (44.30)	82.00 (38.80)	0.961	0.339	80.00 (40.10)	74.00 (44.40)	0.680	0.49
Will you have sex with someone other than your lover?	82.00 (38.80)	86.00 (35.10)	0.541	0.590	87.00 (34.10)	89.00 (31.50)	0.292	0.77
Will you have sex with the same gender?	88.00 (32.80)	94.00 (24.00)	1.044	0.299	89.00 (31.50)	98.00 (14.70)	1.756	0.08
Will you use condoms when you have sex with your lover?	80.00 (40.40)	84.00 (37.00)	0.516	0.607	93.00 (25.00)	70.00 (46.50)	2.955	0.004
Will you use condoms when you have sex with other people of the same/opposite sex?	74.00 (44.30)	80.00 (40.00)	0.711	0.479	80.00 (40.00)	74.00 (44.40)	0.681	0.49

[a]PrEP: pre-exposure prophylaxis.

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Mean Change in AIDS-Related Knowledge, Stigma, and Attitude Before and After Intervention in the 2 groups

The mean differences between the intervention and control groups before the intervention (baseline differences) were not statistically significant. After the intervention, the AIDS knowledge awareness rate of the intervention group was higher than that of the control group, and the difference-in-difference of the two groups was significant (P=.004), but the difference in the knowledge of AIDS testing and AIDS treatment was not significant. The mean differences in stigma scores and positive rates of attitude of high-risk AIDS behaviors were not statistically significant (Table 5).

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Table 5. Mean change in indicators before and after intervention in the 2 groups (N=96).

Items	Intervention group (n=50)		Control group (n=46)				
	Before intervention, mean (SD)	After intervention, mean (SD)	Before intervention, mean (SD)	After intervention, mean (SD)	Baseline difference[a] *P* value	Difference-in-difference,[b] mean (SD)	*P* value
AIDS knowledge awareness rate							
Overall	58.04 (17.55)	70.09 (11.58)	57.87 (11.80)	57.49 (16.58)	0.96	12.40 (4.23)	0.004
Basic knowledge of AIDS	64.77 (17.10)	74.62 (13.84)	65.55 (15.19)	64.38 (17.04)	0.81	11.02 (4.58)	0.02
Knowledge of AIDS prevention	55.20 (25.97)	66.20 (18.83)	51.74 (16.37)	52.61 (22.15)	0.43	10.13 (6.13)	0.100
Knowledge of AIDS testing	48.80 (24.96)	62.00 (25.64)	47.83 (22.50)	42.61 (25.86)	0.85	18.42 (7.16)	0.01
Knowledge of AIDS treatment	68.00 (31.15)	83.00 (21.09)	65.76 (27.06)	72.28 (30.84)	0.69	8.48 (8.03)	0.29
Knowledge of AIDS PrEP[c]	35.20 (18.76)	44.40 (17.75)	32.17 (19.54)	26.52 (20.25)	0.44	17.88 (3.89)	<0.001
Knowledge of AIDS-related laws and regulations	65.75 (27.87)	82.25 (15.79)	71.47 (21.03)	73.64 (20.79)	0.20	14.33 (6.31)	0.02
Stigma score							
Overall	2.58 (0.61)	2.44 (0.57)	2.51 (0.49)	2.48 (0.47)	0.50	–0.11 (0.16)	0.48
Fear of transmission and disease	2.93 (1.13)	2.59 (0.86)	2.97 (0.96)	2.85 (0.95)	0.84	–0.34 (0.29)	0.23
Association with shame, blame, and judgment	2.47 (0.82)	2.55 (0.83)	2.31 (0.70)	2.34 (0.51)	0.29	0.05 (0.21)	0.81
Personal support of discriminatory actions or policies	2.72 (0.74)	2.45 (0.67)	2.58 (0.68)	2.54 (0.61)	0.33	–0.23 (0.20)	0.25
Perceived community support of discriminatory actions or policies	2.20 (0.82)	2.15 (0.73)	2.16 (0.65)	2.17 (0.63)	0.78	–0.05 (0.21)	0.79
Positive rate of attitude of high-risk AIDS behaviors							
Overall	77.50 (22.73)	82.00 (23.44)	85.05 (19.30)	79.62 (17.94)	0.08	9.93 (6.09)	0.10
Do you support premarital sex?	72.00 (45.40)	84.00 (37.00)	80.00 (40.10)	76.00 (43.10)	0.32	16.33 (11.99)	0.18
Do you support premature love?	52.00 (50.50)	64.00 (48.50)	57.00 (50.10)	59.00 (49.80)	0.66	9.83 (14.36)	0.49
Do you support a 1-night stand?	88.00 (32.80)	92.00 (27.40)	96.00 (20.60)	98.00 (14.70)	0.14	1.83 (7.25)	0.80
Will you have premarital sex with your boyfriend/girlfriend?	74.00 (44.30)	82.00 (38.80)	80.00 (40.10)	74.00 (44.40)	0.45	14.52 (12.13)	0.23
Will you have sex with someone other than your lover?	82.00 (38.80)	86.00 (35.10)	87.00 (34.10)	89.00 (31.50)	0.49	1.83 (10.13)	0.86
Will you have sex with the same gender?	88.00 (32.80)	94.00 (24.00)	89.00 (31.50)	98.00 (14.70)	0.38	–14.70 (7.75)	0.06
Will you use condoms when you have sex with your lover?	80.00 (40.40)	84.00 (37.00)	93.00 (25.00)	70.00 (46.50)	0.23	19.91 (11.00)	0.07
Will you use condoms when you have sex with other people of the same/opposite sex?	74.00 (44.30)	80.00 (40.00)	80.00 (40.00)	74.00 (44.40)	0.46	12.52 (12.24)	0.31

[a]*P* value for the mean difference between intervention and control groups before the intervention (baseline differences).

[b]Difference-in-difference. It shows whether the expected mean change in indicators from before to after the intervention was different between control and intervention groups.

[c]PrEP: pre-exposure prophylaxis.

Game Experience Evaluation of the Intervention Group

The user's evaluation of the game was divided into 4 options: excellent, good, medium, and poor. The mean percentage of the game evaluation was 54.73% as excellent, 31.45% as good, 13.09% as medium, and 0.73% as poor (Table 6).

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Table 6. Game evaluation details.

Second-level index	Excellent, %	Good, %	Medium, %	Poor, %
Perceived beauty first-level index, mean (SD)				
Clear interface design	34 (68)	12 (24)	4 (8)	0
Reasonable interface menu	29 (58)	17 (34)	4 (8)	0
New and interesting interface	28 (56)	13 (26)	8 (16)	1 (2)
Beautifully crafted interface	26 (52)	16 (32)	7 (14)	1 (2)
Pleasant interface	22 (44)	18 (36)	9 (18)	1 (2)
Availability first-level index, mean (SD)				
Easy to remember	28 (56)	11 (22)	11 (22)	0
Easy to play	29 (58)	14 (28)	7 (14)	0
Easy to learn	35 (70)	10 (20)	5 (10)	0
The game runs stably without faults	24 (48)	10 (20)	13 (26)	3 (6)
System feedback is obviously timely and appropriate	28 (56)	16 (32)	6 (12)	0
Educational first-level index, mean (SD)				
Knowledge feedback is clear and timely	32 (64)	15 (30)	3 (6)	0
Levels conform to the regular pattern of learning	28 (56)	16 (32)	6 (12)	0
Reliable content, flexible and diverse forms	34 (68)	12 (24)	4 (8)	0
Clear learning goals	30 (60)	14 (28)	5 (10)	1 (2)
Balance of skill and challenge	29 (58)	16 (32)	5 (10)	0
Gameplay first-level index, mean (SD)				
Suitable challenge	21 (42)	17 (34)	12 (22)	0
Reasonable incentives	25 (50)	17 (34)	8 (16)	0
Optional	20 (40)	25 (50)	5 (10)	0
Attractive plot	17 (34)	20 (40)	12 (24)	1 (2)
Clear rules of the game	29 (58)	19 (38)	2 (4)	0
Learning needs				
The learning content of the game meets or exceeds the needs of learners	31 (62)	15 (30)	4 (8)	0
The function of the game meets or exceeds the needs of learners	23 (46)	23 (46)	4 (8)	0

Discussion

Effect on AIDS-Related Knowledge of AIDS Fighter · Health Defense Game

After the intervention with the AIDS educational game, the awareness rate of AIDS knowledge of the intervention group was higher than that of the control group, and the differences were statistically significant, which implies AIDS Fighter · Health Defense can improve AIDS-related knowledge of young students and has the potential to improve their AIDS prevention capabilities. However, the difference-in-difference analysis of the knowledge of AIDS testing and treatment was not statistically significant, which was different from the results of the *t* test. The possible reason is that the AIDS-related knowledge received during the intervention period led to the same trend of change in the 2 groups, while the effect of the game intervention was not significant on the knowledge of AIDS testing and treatment. This may also be due to the short intervention time and small sample size, leading to an insignificant intervention effect. Future studies should carry out continuous, large-sample intervention investigations to improve the knowledge of HIV testing and treatment of young students, especially the knowledge of HIV treatment, which is not only important for young students to take PrEP and PEP but also important for people with HIV, especially in low- and middle-income countries, to improve their antiviral treatment adherence [29].

After the intervention group played the AIDS Fighter · Health Defense game, the awareness rate of AIDS knowledge in all dimensions was higher than that before the intervention. Of these dimensions, the awareness rate of AIDS-related laws and regulations increased the most (t=3.642, P<.001). Due to the low awareness of AIDS-related laws and regulations in the public [30], patients with HIV infection are still being unfairly treated in terms of equal employment, privacy protection, and social discrimination. They not only need to endure the discomfort caused by HIV but also need to face social

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disapproval and exclusion [31]. We found that AIDS Fighter · Health Defense has a good effect on improving the knowledge of AIDS-related laws and regulations in young students. Further studies could try to apply the game to other groups for AIDS health education and provide educational tools for improving the public's knowledge of AIDS-related laws and regulations.

There was no significant difference in the awareness rate of AIDS knowledge in the control group after the intervention, which implies that the effect of self-learning via the internet to improve AIDS-related knowledge of young students is poor. Under the background of exam-oriented education represented by China, young students have a strong learning ability to master the key points of learning quickly and effectively before the exam. Therefore, if an examination or assessment to test the learning effect could be added to the self-learning of AIDS health education for young students, it may increase the self-learning effect for them and improve their AIDS-related knowledge.

Effect on AIDS-Related Stigma of AIDS Fighter · Health Defense

This study found that after the intervention with AIDS Fighter · Health Defense, the AIDS-related stigma of young students showed a downward trend, although the results were not statistically significant. This may be because the formation and change of an individual's cognition of or attitude toward something is a complex process that takes a long time [32], while the intervention time of this study was 2 weeks, so the results obtained may only have found a trend of decreasing AIDS-related stigma. If long-term intervention can be carried out, the AIDS-related stigma reduction may be more obvious. In addition, the sample size of this study was small, which may also have caused the difference to be not significant enough. AIDS Fighter · Health Defense has shown some effects in reducing AIDS-related stigma among young students. Therefore, it may have the potential to become an effective educational tool to reduce AIDS-related stigma in the public.

Effect of AIDS Fighter · Health Defense on Attitude of High-Risk AIDS Behaviors

Reducing high-risk AIDS behaviors is one of the effective ways to prevent AIDS [33], and one of our goals of AIDS education is to improve the attitudes of drug injection–related risk behaviors and sexual risk behaviors. Unexpectedly, after 2 weeks of self-learning of AIDS knowledge in the control group, the positive rate of attitudes of high-risk AIDS behaviors decreased, and the most obvious option for the decline in the positive rate was "Will you use condoms when you have sex with your lover?", which dropped from 93.00 (SD 25.00) to 70.00 (SD 46.50), with t=2.955 and P=.004. This result suggests that acquiring AIDS-related knowledge through online self-learning is not only less effective in education but may also make young students more open to sexual attitudes and more likely to indulge in risky sexual behaviors. We found that after the intervention with AIDS Fighter · Health Defense, the positive rate of attitudes of high-risk AIDS behaviors of young students increased. Therefore, game-based AIDS education has the potential to become an intervention method to improve the attitudes of high-risk AIDS behaviors and AIDS Fighter · Health Defense could become an effective and large-scale intervention tool.

Game Experience Evaluation of the Intervention Group

The results of game experience suggest that young students have positive feedback for AIDS Fighter · Health Defense, believing that the game probably has high aesthetics and usability and is educational and playful, which can achieve or exceed the needs of learners. However, there are problems, such as insufficient stability of the game, insufficient novelty of the game elements, and insufficient appeal of the game plot. This reminds us that we should strengthen the combination of education and entertainment in AIDS game education and increase the appeal of educational games on the premise of ensuring the effect of AIDS education.

Conclusion

This study found that AIDS Fighter · Health Defense can improve the AIDS-related knowledge among young students, but the effect of the game in reducing AIDS-related stigma and improving the attitudes of high-risk AIDS behaviors was not observed. This might be due to the small sample size and short intervention time; the results of AIDS-related stigma and attitudes of high-risk behaviors were not statistically significant. Therefore, large-scale, continuous, and multicenter research is needed to assess the efficacy of game-based intervention.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V. 1.6.1).
[PDF File (Adobe PDF File), 20319 KB - games_v10i1e32400_app1.pdf]

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Abbreviations

CVI: content validity index
I-CVI: item-level content validity index
PEP: postexposure prophylaxis
PrEP: pre-exposure prophylaxis
S-CVI: scale-level content validity index
UNAIDS: Joint United Nations Programme on HIV/AIDS

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Review

An Evidence Map on Serious Games in Preventing Sexually Transmitted Infections Among Adolescents: Systematic Review About Outcome Categories Investigated in Primary Studies

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Abstract

Background: Sexually transmitted infections (STIs) represent a global health risk. Adolescents are at increased risk of infection for several reasons such as lack of knowledge, risky sexual behaviors, and lack of behavioral sills (eg, to negotiate safer sex). Given the fact that adolescents often use digital media and that serious games are considered to have the potential to change knowledge, attitudes and behavior, serious games represent an opportunity for the prevention of STIs.

Objective: The aim of this systematic review was to identify and systematically summarize the dimensions that have been investigated in primary studies on serious games targeting STI prevention among adolescents.

Methods: A systematic review was conducted in PubMed and Web of Science. Studies published from 2009 to 2021 were included that assessed the effectiveness of serious games on adolescent sexual health. A total of 18 studies met the inclusion criteria and were categorized according to dimensions of effectiveness and user experience.

Results: Various dimensions of effectiveness and aspects of user experience were investigated in the primary studies. In total, 9 dimensions of effectiveness were observed: sexual behavior, behavioral intentions, knowledge, attitudes and beliefs, self-efficacy and personal limitations, character traits and future orientation, environmental and individual risk factors, risk perception and risk assessment, as well as normative beliefs and (social) norms. Furthermore, several dimensions related to user experience were investigated in primary studies, that is, motivation, acceptability, trustworthiness, comprehensibility, handling and control, perceived effectiveness, as well as satisfaction.

Conclusions: This review provides an overview of serious games interventions that are vastly different in approach, content, and even platform. In previous studies, knowledge has already been comprehensively assessed, and a positive influence of serious games on knowledge about sexual topics is evident. The results clearly show that adolescents' sexual knowledge has been increased by the serious games interventions. However, methodological and content differences in the surveys make it difficult to draw conclusions about the effectiveness related to changes in attitudes and behavior.

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KEYWORDS

serious games; entertainment education; STI; STD; sexual health; effect; impact; sexually transmitted infections; adolescents; adolescent sexual health

Introduction

From a global perspective, the relevance of sexually transmitted infections (STIs) is reflected in continued high numbers of HIV infections, particularly in African countries [1,2] and the fact that approximately 1 million people worldwide become infected with a curable STI every day [3,4]. In addition to specific risk groups such as men who have sex with men, sex workers, and intravenous drug users [5-9], adolescents are an important target group in STI prevention approaches. For example, increasing rates of infections among adolescents have been found for chlamydia in recent years [10,11]. Although studies indicate that knowledge of HIV has increased, knowledge of other STIs is significantly lower, even despite their widespread [12,13]. Misinformation as well as knowledge gaps related to STIs frequently occur among adolescents from poor to middle class backgrounds [14]. Lack of knowledge and low awareness of STIs as well as shame and fear inhibit adolescents from talking about STIs and contacting health care providers when problems arise [15]. These conditions may increase risky sexual behaviors and, thereby, the risk of acquiring an STI [16].

As a result of the high prevalence of STIs among adolescents and frequent use of digital media in this group, there is increasing consideration of using digital approaches as part of sexuality education and STI prevention in educational settings [17,18]. One of the instruments being discussed are digital games. Popularity and interest in these serious games have been growing in research and practice in recent years [19]. Serious games are an instrument of entertainment education, which include “any attempt to make learning [more] enjoyable, no matter if media-based, mediated or within a classroom setting” [20]. Various definitions for serious games exist, but all definition have, in common, to focus on the serious use of games to achieve goals, such as learning and education, by combining serious topics with entertaining and, in recent times frequently, multimedia aspects [21]. These serious games are challenging and engaging and supply the users with competencies useful in reality [22]. Therefore, serious games are characterized particularly by the use of a competency-based approach by integrating the game principle into the learning process and thus becoming part of this process [23]. Overall, digital game applications are applied with the aim of increasing attention and knowledge as well as changing attitudes and behavior [21]. Areas of disease prevention and health promotion for the application of serious games are comprehensive sexuality education (CSE), STI prevention, and promotion of sexual health [19,24]. The potential of serious games to positively influence knowledge, attitudes, and behaviors and to promote attention are goals that are also pursued in CSE [17]. Serious games, with their innovative character, thus form a new way to educate adolescents about sexual health and, thereby, contribute to STI prevention.

The characteristics of serious games offer manifold possibilities for STI prevention, which make their use reasonable. First, the entertaining nature of serious games offers the opportunity to facilitate communication about sensitive topics such as sexuality and sexual health [19,25]. Second, serious games allow to keep content anonymous and confidential, making it easier to deal with these sensitive topics [24]. Third, through the digital, fictional, and playful environment, serious games offer a low-threshold access and usage as well as the possibility to have different experiences without being exposed to real risk [26]. Fourth, the content of serious games can be adapted to the demands and requirements of the target group as a whole and even at an individual level through tailored approaches [24]. Owing to gender-, origin-, and culturally-specific differences as well as various sexual experiences and orientations, serious games offer great potential in STI prevention [24,26,27]. However, criticism related to serious games is expressed in that the content, target groups, as well as the quality of the games greatly differ, and existing evaluation studies are inconclusive. In studies on the effectiveness of serious games, the focus is on the measurement of so-called “soft facts,” which are collected, for example, through self-reported competence beliefs. Therefore, the results need to be evaluated with caution [21].

In order to implement serious games in practical work with adolescents, it is important to investigate whether and how serious games influence adolescents and impact STI prevention. This evidence map [28] based on a systematic review focusses on the outcomes, which have been investigated in previous primary studies related to serious games targeting STI prevention. The aim is not to summarize the direct effects of respective serious games, which are also quite heterogeneous in terms of approach and content, but to provide a systematic overview about the outcomes (effectiveness/impact and perceptions/user experience) that have been investigated to date.

Methods

We conducted a systematic literature review in 2 databases, namely, MEDLINE (via PubMed) and Web of Science to identify studies investigating serious games in the context of STI prevention, which have been published until March 2021. The search in PubMed was conducted in May 2019 and an update was performed in March 2021. The search in Web of Science was conducted in March 2021. The search strategy consisted of a combination of terms related to the type of the game with the field of action. For both databases, we used the following complete search algorithm:

(game* OR video game* OR interactive multimedia OR serious game*) AND (sexual health OR sexual transmitted infections OR sexual transmitted disease OR sexuality education OR hiv OR sti OR sexuality*)

In PubMed, we applied the filters to include only those studies published since 2009 because the aim was to identify only recent literature (published in the past decade) owing to the fast progress in the development of serious games. Furthermore, a filter was applied to restrict the search to studies published in

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English or German language. In addition, we used a backward snowballing technique by searching the reference list of studies included in the full-text screening.

To identify appropriate studies, 2 reviewers screened the studies with regard to their (1) title and abstract and (2) appraised the full-texts if inclusion criteria were fulfilled. The basic criteria for the combined screening of title and abstract was whether the information provided seemed to be related to serious games related to preventing STIs. Overall, 1559 manuscripts were identified after removal of duplicates. To ensure systematic management of the information, references located through the search were downloaded to a bibliographical software package (Citavi 6, Swiss Academic Software), which automatically identifies and removes duplicates.

Two authors (KI and KJW) carried out the title and abstract screening. Subsequently, KI and KJW independently reviewed the full texts (n=76) to determine whether the inclusion criteria were met. We defined inclusion and exclusion criteria (Table 1), which were used for the screening of full texts. According to this, studies that did not comply with serious games (n=10) or the target group of adolescents (n=15) were excluded. Furthermore, we excluded studies that did not describe an intervention study (n=7), did not comply with the evaluation of an intervention (n=15), or for further reasons (n=13) such as a focus on individuals who tested positive for an STI. There were no divergent appraisals between the 2 reviewers. From a total of 76 relevant studies (and 2 additional studies identified through the snowballing technique), 18 were identified for inclusion in this overview (Figure 1). Overall, the search algorithm used in PubMed proved to be very reliable, because the supplementary search in Web of Science led to only 1 additional record included in the synthesis.

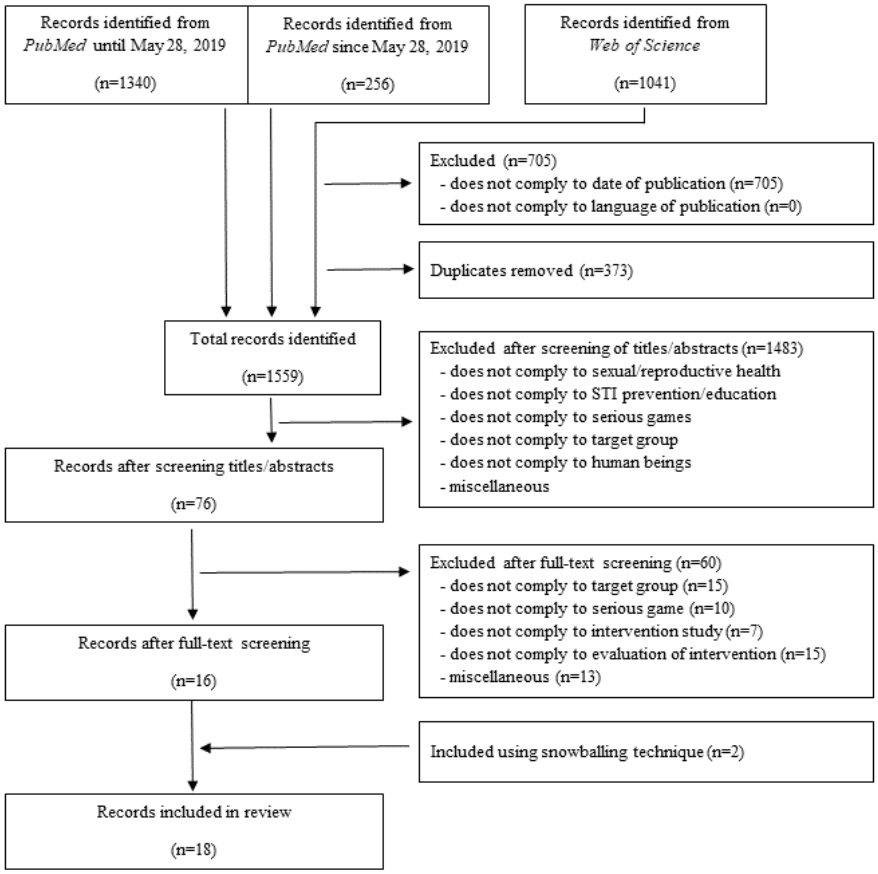
We analyzed whether serious games have been used for STI prevention and CSE and mapped the results according to the levels of effectiveness/impact and perceptions/user experiences of users. The results are described in form of a qualitative overview, allowing for a systematization of the outcomes, which have been addressed in previous studies so far. We did not perform a quality appraisal of primary studies because various study designs (eg, randomized controlled trial [RCT], quasi-experimental study, pilot test) have been included and no meta-analysis was performed. The procedures and reporting of the systematic review follow the recommendations published in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [29].

Table 1. Inclusion and exclusion criteria for screening of full texts.

Criterion	Inclusion	Exclusion
Population	Adolescents (9-21 years)	Adults; particular risk groups (eg, men who have sex with men, drug users, sex workers); sexually transmitted infection/HIV-positive persons
Study design	Empirical study including an evaluation of a serious game	Studies of theoretical nature only with no empirical data
Type of study	All published studies, identifiable via PubMed or Web of Science Abstract must be available	Books; all forms of grey literature, including conference abstracts, commentaries, presentations, proceedings, regulatory data, unpublished trial data, government publications, dissertations/theses, journalistic interviews, policy reports as well as any other nonscientific material No abstract available
Focus of study	Sexually transmitted infections Comprehensive sex education or HIV/ sexually transmitted infection prevention	Nonsexually transmitted Noncomprehensive sexuality education or HIV/sexually transmitted infection prevention Other aspects in a broader sense of sexual health (eg, sexual violence, sexual dysfunction, use of antiviral therapy or HIV pre-exposure prophylaxis) not related to sexually transmitted infection prevention in the general population using digital technologies
Role of digital serious game	Digital serious games (including all digital games for learning purposes)	No use of digital serious games Analogous serious games or gamification approaches
Language of publication	English and German	All other languages other than English or German
Date of publication	January 2009 to March 2021	Before 2009

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Figure 1. Flowchart for study selection. STI: sexually transmitted infection.



Results

Characteristics of the Studies

A total of 18 studies identified within the systematic review were included in the synthesis on effectiveness and user experiences investigated in primary studies related to serious games in STI prevention (Table 2). Three of the studies are usability tests that focus on usability, user experience, and cultural adaptation or adaptation, among other factors [30-32]. One of these studies only reported perceived efficacy [31]. Another study included a usability and a feasibility study, in which adapted computer-based components of an existing intervention are tested, and subsequently, a computer-only intervention developed based on these findings is deployed [33]. The aforementioned studies do not focus on efficacy, but they do provide evidence of effectiveness and insights into the play experience. For that reason, they were included in this systematic review. In total, 10 completely different serious games interventions have been focused upon in primary studies. The intervention that was used most frequently in the studies was "It's Your Game"—it was used in 10 out of 18 studies. In each of the other studies, different interventions were used. Overall, 8 studies have been conducted as RCTs. Interventional studies used either a conventional health training or video games as controls. The target group consisted entirely of schoolchildren and teenagers between the ages of 12 and 19 years. Various study designs and methods have been used. The sample size ranges from 19 to 4562 participants. Table 2 presents the main information about the primary studies. Further details about the characteristics of the interventions are described in Multimedia Appendix 1.

Various dimensions of effectiveness and aspects of user experience were investigated in the primary studies. At least one dimension of effectiveness has been addressed in 16 of the 18 studies. In total, the following 9 dimensions of effectiveness were observed: (1) sexual behavior, (2) behavioral intentions, (3) knowledge, (4) attitudes and beliefs, (5) self-efficacy and personal limitations, (6) character traits and future orientation, (7) environmental and individual risk factors, (8) risk perception and risk assessment, and (9) normative beliefs and (social) norms.

Furthermore, 7 aspects related to user/gaming experience were investigated in overall 11 studies: (1) motivation, (2) acceptability, (3) trustworthiness, (4) comprehensibility, (5) handling and control, (6) perceived effectiveness, and (7) satisfaction. A full overview of the categorizations can be found in Table 3 and Table 4.

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Table 2. Characteristics of the primary studies.

Authors, year of publication, country	Intervention	Study participants (n)	Age (years; range)	Study design	Control group	Methods	Follow-Up
Bertozzi et al [34], 2018, India	My future family	393	15-19	Pilot study		Questionnaire (paper-and-pencil based, postgame) In-game data	
Chib [35], 2011, Peru	Planeta Riesgo X	102	15-18	Quasi-experimental panel design		Questionnaire (self-administered)	
Chu et al [36], 2015, Hong Kong	Making Smart Choices	1176	12-16	Pilot experiment with pretest and posttest		Knowledge: Questionnaire Feedback: Questionnaire and focus group interviews	
Escobar-Chaves et al [30], 2011, Puerto Rico	It's Your Game: Keep It Real	73	12-14	Pilot study		Questionnaire (paper-and-pencil based) Class discussion Reactions and opinions from 2 teachers, a librarian and a social worker	
Fiellin et al [37], 2017, USA	Play Forward: Elm City Stories	333	11-14	Randomized controlled trial	✓	Questionnaire (face-to-face assessments) In-game data	✓
Gariepy et al [38], 2018, USA	Mobile videogame intervention	26	15-17	Pilot study		Questionnaire (self-administered) Focus group discussions	✓
Haruna et al [39], 2018, Tanzania	Game-Based Learning	120	11-15	Randomized controlled trial	✓	Questionnaire based Focus group interview	
Markham et al [40], 2012, USA	It's Your Game: Keep It Real	1258	mean 12.6	Randomized controlled trial	✓	Audio-computer-assisted self-interview	✓
Oliveira et al [41], 2016, Brazil	Papo Reto	23	15-18	Qualitative study (descriptive and exploratory)		Recorded workshops and speeches analyzed by content analysis	
Peskin et al [42], 2015, USA	It's Your Game: Keep It Real	1374	mean 14.3	Randomized controlled trial	✓	Audio-computer-assisted self-interview	✓
Peskin et al [43], 2019, USA	It's Your Game: Keep It Real	1543	mean 13	Randomized controlled trial	✓	Audio-enhanced, computer-assisted surveys	✓
Potter et al [44], 2016, USA	It's Your Game-Tech	3143	mean 12.7	Randomized controlled trial	✓	Audio-enhanced, computer-assisted surveys	✓
Rohrbach et al [45], 2019, USA	It's Your Game: Keep It Real	4562	mean 15	Quasi-experimental cohort study		Audio-enhanced, computer-assisted surveys	✓
Shegog et al [33], 2014, USA	It's Your Game-Tech	33, 22	12-14 13-15	Single-group, pre/postusability test		Computer-based questionnaire	

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Authors, year of publication, country	Intervention	Study participants (n)	Age (years; range)	Study design	Control group	Methods	Follow-Up
Shegog et al [31], 2017, USA	Native It's Your Game	45	11-15	Usability test (preadaption, adaption, postadaption)		Questionnaire (paper-and-pencil based) Focus group discussions Community advisory meetings	
Shegog et al [32], 2021, USA	Secret of Seven Stones	19	mean 12	Usability test		Questionnaire Qualitative interviews	✓
Tortolero et al [46], 2010, USA	It's Your Game: Keep It Real	981	mean 13	Randomized controlled trial	✓	Audio-computer-assisted self-interview	✓
Winskell et al [47], 2018, Kenya	Tumaini	60	11-14	Randomized controlled trial	✓	Audio-computer-assisted self-interview For intervention arm: Postintervention survey Postintervention focus group discussions	✓

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Table 3. Dimensions of effectiveness.

Study	Sexual behavior	Behavioral intentions	Knowledge	Attitudes and beliefs	Self-efficacy and personal limitations	Character traits and future orientation	Environmental and individual risk factors	Risk perception and risk assessment	Normative beliefs and (social) norms
Bertozzi et al (2018) [34]			✓	✓					
Chib (2011) [35]			✓	✓	✓				
Chu et al (2015) [36]			✓	✓					
Escobar-Chaves et al (2011) [30]			✓						✓
Fiellin et al (2017) [37]	✓	✓	✓	✓					
Gariepy et al (2018) [38]		✓	✓		✓		✓	✓	
Haruna et al (2018) [39]			✓						
Markham et al (2012) [40]	✓	✓	✓	✓	✓	✓	✓		✓
Oliveira et al (2016) [41]			✓				✓		
Peskin et al (2015) [42]	✓	✓	✓	✓	✓	✓	✓		✓
Peskin et al (2019) [43]	✓	✓	✓	✓	✓		✓		✓
Potter et al (2016) [44]	✓	✓	✓	✓	✓		✓		✓
Rohrbach et al (2019) [45]	✓		✓	✓	✓	✓	✓		✓
Shegog et al (2014) [33]		✓	✓	✓	✓				✓
Shegog et al (2017) [31]									
Shegog et al (2021) [32]									
Tortolero et al (2010) [46]	✓	✓	✓	✓	✓		✓		✓
Winskell et al (2018) [47]		✓	✓	✓	✓	✓	✓	✓	✓

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Table 4. Dimensions of aspects of user/gaming experience.

Study	Motivation	Acceptability	Trustworthiness	Comprehensibility	Handling and control	Perceived effectiveness	Satisfaction
Bertozzi et al (2018) [34]	✓					✓	✓
Chib (2011) [35]	✓		✓		✓	✓	✓
Chu et al (2015) [36]		✓				✓	✓
Escobar-Chaves et al (2011) [30]	✓	✓	✓	✓	✓	✓	✓
Fiellin et al (2017) [37]							
Gariepy et al (2018) [38]	✓	✓				✓	✓
Haruna et al (2018) [39]	✓			✓		✓	✓
Markham et al (2012) [40]							
Oliveira et al (2016) [41]	✓			✓			✓
Peskin et al (2015) [42]							
Peskin et al (2019) [43]							
Potter et al (2016) [44]							
Rohrbach et al (2019) [45]							
Shegog et al (2014) [33]	✓	✓	✓	✓	✓	✓	✓
Shegog et al (2017) [31]	✓	✓	✓	✓	✓	✓	✓
Shegog et al (2021) [32]	✓	✓	✓	✓	✓	✓	✓
Tortolero et al (2010) [46]							
Winskell et al (2018) [47]	✓					✓	✓

Dimensions of Effectiveness

Sexual Behavior

The dimension of participants' sexual behavior has been reported in 7 of the 18 studies. Here, all 7 studies consider the influence of serious games on the delay of first sexual intercourse. Three studies found an impact on delay of the first sexual intercourse in the intervention group. These results refer to anal, oral, and vaginal intercourse [40,45,46]. Six of the 7 studies refer to sexual behavior in the past 3 months, with the following aspects: sexual intercourse in general and its frequency, condom use or contraception, alcohol and drug use, number of lifetime sexual partners, and frequency of unprotected intercourse [40,42-46]. Three studies have observed influences of serious games on individual aspects [40,45,46]. Overall, these studies were able to observe positive effects of the respective serious games on participants' sexual behavior, although no study showed a positive result for all aspects. Four studies failed to find any effect of the serious game investigated on behavior, although positive trends were found in 1 study [43].

Behavioral Intentions

Nine studies focused on the impact of serious games on adolescents' behavioral intentions. Of these 9 studies, 6 looked at abstinence intention until marriage or school completion [33,40,42-44,46]. Among these, 3 studies observed a positive effect of serious games, although this was found only for abstinence until marriage in 1 study [33] and only for abstinence for high school graduation in 1 study [46]. One study detected a positive effect for both aspects [40]. Three studies found no effect [42-44]. Seven of the 9 studies assessed the intentions to have sexual intercourse [33,37,40,42-44,46]. In this regard, 3 studies found a positive effect of the respective serious games in that participants in the intervention had fewer intentions to have sexual intercourse in the next year [40,43,46].

Knowledge

The impact of serious games on sexual knowledge as a key dimension to promote sexual health was investigated in 16 of the 18 studies. In 13 studies, the effectiveness was tested on the dimension of knowledge by using questions on a variety of sexual and reproductive health topics [33,35-40,42-47]. In summary, 12 of the 16 studies found positive effects of the investigated serious games on knowledge related to sexual and reproductive health as well as related topic areas. In 4 studies, the results were related to overall sexual and reproductive health, with all 4 studies finding a positive effect of serious games on participants' knowledge [37-39,47]. Nine studies related to knowledge dimension regarding specific sexual and reproductive health topics [33,35,36,40,42-46]. Eight of these studies considered the effects of a serious game on participants' contraceptive knowledge [33,35,40,42-46], of which 7 studies

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found a positive impact of the respective serious game [33,40,42-46]. Throughout 4 studies, the majority of participants perceived knowledge acquisition following the use of a serious game, providing evidence for a positive effect of the intervention on sexual knowledge [30,34,39,47].

Attitudes and Beliefs

Twelve studies examined attitudes and beliefs on sexual behavior and other sexual topics. Seven of these studies investigated reasons for or against performing sexual intercourse [33,40,42-46]. Five of the 7 studies found a positive effect of serious games [33,40,44-46]. Six of the 7 studies assessed attitudes toward condom use, for which none showed a significant positive effect of serious games [33,40,42-45]. Overall, 3 studies investigated attitudes toward sexual health and sexual behavior in a summary variable [35,37,47], but only Chib's study [35] observed a positive impact of serious games on participants' attitudes. Six studies showed positive effects only on specific aspects and 1 study found improved attitudes only for 2 subgroups. Two studies did not demonstrate positive effects on attitudes, but trends indicating a positive impact of serious games emerged. One study provided evidence of positive attitudinal change based on qualitative surveys.

Self-efficacy and Personal Limitations

Out of 18 studies, 10 assessed self-efficacy as a dimension of effectiveness. One study reported the self-efficacy dimension in a summary variable, consisting of pubertal support, condom use, contraceptive discussions with partner, and rejection of risky situations [47]. This study found positive effects of serious games on self-efficacy and positive evidence of change in the qualitative surveys and the gaming experience survey [47]. Seven studies analyzed the effects on self-efficacy of condom use and other contraceptive methods in a stand-alone variable [33,40,42-46]. In 6 studies, improvements in self-efficacy related to condom use and contraception were found within the intervention group [33,40,42-44,46]. Another aspect of self-efficacy considered by 7 of the 10 studies was the self-confidence to refuse sexual intercourse in a pressure situation when there is no consent for it [33,40,42-46]. Four of the 7 studies demonstrated positive effects of serious games on self-efficacy to refuse unwanted sex [40,43,45,46]. All 10 studies found a positive effect of serious games on the dimension of self-efficacy, although 5 studies did not show a positive influence of serious games in every aspect of self-efficacy. One study was not able to confirm the positive effects in all cultural subgroups. Related to personal boundaries, 4 studies observed positive effects of serious games and 1 of these studies added positive evidence from a feasibility study.

Character Traits and Future Orientation

Two out of the 18 studies examined the effects of serious games on participants' character traits, such as character qualities (eg, responsibility) and future orientation (eg, having plans for one's future) [40,42]. One study found positive effects [40], whereas the second study did not demonstrate any effect on participants' character after using the serious game [42]. Four studies investigated the impact of serious games on future orientations [40,42,45,47]. None of the 4 studies found a significant effect after using the investigated serious game. However, the qualitative study conducted by Winskell et al [47] recorded positive expressions of participants and their parents on the topic of future orientation.

Environmental and Individual Risk Factors

The impact of serious games on selected environmental and individual risk factors (eg, exposure to risky situations) has been addressed in 9 studies. Six out of these 9 studies looked at the impact of the serious game on confronting risky situations [40,42-46]. Four studies did not observe a positive effect on this aspect [40,42-44]. Seven of the 9 studies made statements about the influence of serious games on how sexual topics are handled in the personal environment [40-45,47]. Communication about sexual issues with parents was addressed in 5 of the 7 studies [40-44]. In this regard, 1 study found significant improvements in parental communication after the use of a serious game [40]. Three studies showed no positive effects on parental communication [42-44]. In the qualitative survey by Oliveira et al [41], evidence of improved parental communication was shown.

Risk Perception and Risk Assessment

Two of the 18 studies examined efficacy in aspects of risk perception and risk assessment. Overall, positive effects on this were found but only to a slightly weak level [38,47]. No positive effects were found on alcohol as a risk factor [43].

Normative Beliefs and (Social) Norms

Nine out of the 18 studies examined the influence of serious games on participants' (perceived) norms. In 6 studies, a positive influence of serious games on the perceived views of those around them about sex was found. Furthermore, in these 6 studies, a positive effect of serious games on perceived views in the personal environment about sexual abstinence was observed [33,40,42,43,45,46]. Among the 9 studies, 4 considered the aspect of perceived norms related to condom use, for which no study found a positive effect of serious games [33,43,44,46]. One of the 4 studies assessed norms related to HIV and STI and found a positive effect of serious games [43].

Aspects of User/Gaming Experience

Motivation

Ten studies considered the aspect of motivation related to the use of serious games. Seven studies asked whether the respondents were willing to recommend the serious game to friends or classmates and in all these studies, the majority of participants would recommend the respective serious game to others [30-35,38,47]. Four of these 7 studies additionally integrated the question whether the participants were willing to repeat the serious game [30,33,38,47], where 3 of them found that a majority of participants were willing to do so [30,38,47]. Three out of the 10 studies addressed the aspect of motivation in general [32,39,41]. One study assessed motivation using questions in the domains of attention, relevance, confidence, and satisfaction related to the serious game, showing increased motivation among intervention participants [39]. Oliveira et al [41] inferred a positive motivational performance in the serious

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game. Therefore, 10 of 11 studies found a positive motivational performance in the serious game.

Acceptability

Acceptability toward the use of serious games has been investigated in 6 studies. In 2 studies, the duration and pace of the intervention was perceived to be appropriate [31,33], which was shown as determinant of acceptability. In the remaining studies, the method for assessing acceptability was not transparent [36,38]. However, these 2 studies indicated that acceptability toward serious games can at least be assumed based on the answers related to the user experience [36,38].

Trustworthiness

The trustworthiness of the content of serious games is another aspect that 5 of the 11 studies included in the survey of participants after the intervention was used. Four of the studies refer to the assessment of truthfulness and accuracy [30-33], and 1 study considered only the truthfulness of the information [35]. These 5 studies found that the majority of participants rated the content as credible and accurate [30-33,35].

Comprehensibility

Six out of the 11 studies considered the aspect of comprehensibility [30-33,35,39]. Overall, the comprehensibility of the serious games has been judged positively. This relates to the content as well as wording and terminology used in the serious game [30,31,33]. Particularly, qualitative studies described that the participants described the content of the game as easily understandable [39,41].

Handling and Control

Five of the 11 studies evaluated the handling and control of serious games. Four studies investigated the aspect of handling, among others, by assessing the difficulty of operation [31,33,35]. This was rated as easy by the majority of participants in all 4 studies. An adult's assistance in using the serious game was reported in 3 of the 5 studies [30,31,33]. In these 3 studies, it was found that the majority of participants did not require adult assistance.

Perceived Effectiveness

Perceived effectiveness is another aspect explored in 10 of the 11 studies. Six studies considered the impact of serious games on perceived decision-making and conflict resolution skills [30-33,36,47]. Here, the majority of participants found the information conveyed through serious games to be helpful in making future decisions regarding sexual issues. Gariepy et al [38] found that most participants felt responsible for the decisions made in the game and the majority would transfer those decisions to real life.

Satisfaction

In all 11 studies, statements of satisfaction were recorded. Seven studies asked about personal enjoyment of the game, and the majority of participants indicated to have enjoyed the game and its features [30-34,36,47]. Gariepy et al [38] demonstrated an association between enjoyment and effectiveness outcomes. When comparing traditional school instruction to the use of serious games, participants responded to serious games significantly more positively in almost all cases. The exception was the comparison with their own favorite video game [31-33]. In summary, all 11 studies showed increased satisfaction with the use of the serious game.

Discussion

Overview

After reviewing previous studies conducted on serious games in the context of STI prevention, it can be summarized that both effectiveness and user experience have been investigated. However, a stronger focus on the parameters of effectiveness is needed by going beyond feasibility and usability studies and by applying adequate study designs such as RCTs and longitudinal studies. Knowledge about sexual health was the most commonly used dimension in studies investigating the effects of serious games in this area. Almost all studies found a positive effect of the respective serious game on participants' knowledge. The second most common dimension related to participants' attitudes and beliefs toward sexuality, sexual behavior, and other sexual topics. Here, just over half of the studies found that participants reported more positive attitudes after using the serious game. The positive effects were not evident in each study for all aspects related to attitudes. Furthermore, long-term effects related to intentions and behaviors related to sexual health need to be investigated.

Accordance With Previously Published Works

Evidence of nondigital curriculum-based sex and HIV education programs clearly shows that these programs do not hasten or increase sexual behavior. Instead, they either delay sexual behaviors or increase condom or contraceptive use [48]. However, a previous systematic review on digital media to improve adolescent health showed mixed results or effect in unexpected directions [49]. The results of the knowledge, attitudes, and behavior dimensions found in this systematic review on the effects of serious games show similarities to a meta-analysis published in 2015 [24] that investigated the effectiveness of disease prevention and health promotion interventions in the context of sexual health delivered via serious games. This meta-analysis also found an effect of serious games on sexual knowledge. However, no significant effects of serious games were found for the dimension of attitudes and behavior [24]. A parallel can be drawn with the ambiguous attitudinal and behavioral results presented in this systematic review. Further similarities can be seen in the positive effects on self-efficacy. For behavioral intentions, positive effects of serious games have been shown in the meta-analysis by DeSmet et al [24], which are divergent from those reported in this study.

Commonalities between the knowledge, attitudinal, and behavioral dimension results can also be found in a systematic review examining the impact of school-based skill-building behavioral interventions for STI prevention [50]. These behavioral interventions are primarily non–computer-based. Nevertheless, parallels to this work can be seen in the impact dimensions. For example, positive effects on knowledge and self-efficacy can also be found in the review by Picot et al [50]. Positive effects on behavior could only be shown in some studies and for certain aspects and subgroups, as in this work. In both

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reviews, the effects related to behavior were small. For the results related to attitudes and intentions, both reviews have in common that positive effects have not been observed in all studies [50].

Compared to the results of 3 meta-analyses, the results of this study show similarities and differences. The meta-analyses refer to interventions used to promote sexual health and prevent STIs [51-53]. One meta-analysis for this includes computer-based interventions that do not exclusively target adolescents [51]. The other 2 meta-analyses do not exclusively include computer-based interventions but narrow their analysis to target adolescents [52,53]. Overall, the 3 meta-analyses detected effects of the interventions on knowledge [51-53]. Two meta-analyses also showed effects on self-efficacy and behavioral intentions [51,53], with 1 meta-analysis additionally finding positive effects on attitudes [53]. Positive behavioral effects can be found in all 3 studies [51-53]. Thus, the knowledge and self-efficacy outcomes show parallels to the intervention effects analyzed in this systematic review. Differences in the results appear in the effects on attitudes, intentions, and behavior. For these, no unambiguously positive results can be found in our systematic review compared to the results of the meta-analyses.

Two further meta-analyses identified positive significant effects of computer-based interventions on sexual behavior [54,55]. These publications showed clearer effects of computer-based interventions compared to those shown in this study. However, none of these meta-analyses were limited to adolescents [54,55]. One meta-analysis focused exclusively on HIV prevention interventions [54] and 1 meta-analysis investigated further interventions that aim to promote health-seeking behaviors in addition to interventions related to sexual behaviors [55].

In summary, there is a need for further studies investigating the effects of serious games on knowledge, attitude, and behavior, which go beyond computer-based interventions and which compare their effects with established (nondigital or hybrid) STI prevention strategies among adolescents. Future studies need to consider specific challenges of evaluating impacts of interventions on sexual behaviors among adolescents, particularly among adolescents who may not yet be sexually active. For that reason, longitudinal study designs are needed, which understand serious games as complex interventions within complex systems.

Limitations in This Review

This systematic review has been able to provide an overview of the current state of evidence of serious games in the context of STI prevention. However, owing to the heterogeneity of studies (eg, differences in interventions, data collection methods, follow-up periods), a meta-analysis was not possible. Moreover, these variations may explain the partly divergent results regarding the effects of serious games. In addition, high attrition, low response rates, or refusal to participate among control and intervention participants, as well as the collection of self-reported information in some studies represent key limitations that must be considered when interpreting the results. Beyond the methodological and content-wise differences that may have influenced the comparison of the studies, there are further limitations related to the conduction of this systematic review. The search was based on 2 databases (PubMed and Web of Science). The dimensions of effects investigated in this systematic review are derived from the parameters used in the primary studies. It should be noted that the authors of the primary studies may have either a different understanding of or used different ways for operationalizing each dimension. An additional limitation is the fact that there are several interventions focusing on the same intervention (“It’s Your Game”), which may also impact the variety of dimensions under consideration in previous studies. Furthermore, it should be noted that all studies found effects of the respective serious game under consideration. It should be questioned to what extent intervention studies that did not find effects for one dimension were not published (publication bias) and, thus, a distorted picture exists regarding the effectiveness of serious games.

Conclusions

Overall, the effects of serious games in CSE and STI prevention have been shown in this systematic review. However, not all dimensions show comparable effects and some dimensions have only been considered in single or few studies. In addition, the data collection for investigating the effect dimensions is divergent, making comparisons difficult. Nevertheless, it can be stated that above all, knowledge is already comprehensively assessed and a positive influence of serious games on knowledge about sexual topics is evident. In contrast, only limited evidence is available for effects of serious games related to attitudes and behavior. Particularly for sexual behavior, there is a lack of results, as this dimension could only be surveyed in a few studies. This is due to methodological deficits in the surveys, which make it difficult to determine changes in attitudes and behavior, and because sexual topics continue to be taboo in many societies, which limits the ability to survey sexual behavior. According to the results of this systematic review, serious games show potential in the context of STI prevention. Owing to a lack of evidence regarding the effects on attitudes and behavior, no explicit benefit of serious games compared to established (nondigital) methods of STI prevention can be demonstrated. One aspect that should be pursued in this regard is the comparison with classical prevention activities that do not use (digital) media. Until now, there is missing evidence on long-term effects, particularly related to the impacts of serious games on attitudes and behaviors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Characteristics of the interventions.
[DOCX File , 15 KB - games_v10i1e30526_app1.docx]

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Abbreviations

CSE: comprehensive sexuality education
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
STI: sexually transmitted infection

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Original Paper

Development and Evaluation of a Virtual Reality Puzzle Game to Decrease Food Intake: Randomized Controlled Trial

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Abstract

Background: Virtual reality (VR) has gained popularity in daily life, and VR food cues seem to elicit food cravings, similar to real food cues. However, little is known about the impact of VR food cues on actual food intake.

Objective: In real life (RL), exposure to food cues in a situation in which the desire to eat food interferes with the completion of a food-related task reduces the subsequent food intake (ie, the pre-exposure effect). In this study, we examine, on the one hand, whether the pre-exposure effect could be replicated in RL and, on the other hand, whether this effect could be extended to VR contexts.

Methods: The study used a 2 (stimulus type: food vs nonfood) × 2 (mode: VR vs RL) between-subject design (n=175). Participants were randomly assigned to 1 of the 4 conditions.

Results: We found the main effect of mode on food intake, with a higher food intake after both VR conditions than after RL conditions (P=.02). In addition, among female participants, we found that exposure to both food cues (ie, VR and RL) resulted in lower food intake than exposure to both nonfood cues (P=.05). In contrast, this effect was not observed among male participants (P=.34). Additionally, VR and RL cues generated similar emotional and behavioral responses (eg, arousal and game difficulty).

Conclusions: We were unable to replicate the exposure effect in our complete sample. Subgroup analyses, however, showed that for women, exposure to food cues (either in VR or in RL) reduces food intake, indicating that a VR pre-exposure procedure may effectively be applied exclusively for women.

Trial Registration: ClinicalTrials.gov NCT05169996; https://clinicaltrials.gov/ct2/show/NCT05169996

(JMIR Serious Games 2022;10(1):e31747) doi:10.2196/31747

KEYWORDS

virtual reality; pre-exposure; self-control; hedonic consumption; food cravings

Introduction

Background

People are often said to *eat with their eyes* [1]. It is therefore not surprising that exposure to tempting foods has been linked to overeating and excessive food consumption in the past [2]. However, exposure to food temptations does not necessarily lead to higher food intake. Research has shown that when people perform a food-related task (eg, a puzzle-solving task with tempting candies), prior to being exposed to tempting foods, this can actually decrease (rather than increase) food intake [3].

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This mechanism, often referred to as the *pre-exposure effect*, was first described by Geyskens et al [4] and has since shown to be effective across cultures [5] and for children [6]. These diverse applications have made it a promising candidate effect to be turned into a behavioral change tool. However, the potential of implementing it as a behavioral change tool is relatively low because it seems to require real temptations to be effective [4]. Given that tempting foods may become perishable after a certain period and that upon being touched, the food needs to be thrown away, the usage of the pre-exposure procedure as a behavioral change tool can be costly and logistically inconvenient.

Recently, technological advances, such as virtual reality (VR), have made it possible to run the pre-exposure procedure in a cost-efficient and flexible way. VR can simulate a virtual environment with tempting food stimuli by delivering multisensory cues [7], which leads to a strong sense of physical presence in an immersive environment [8]. In other words, in the context of computer-generated artificial content, VR has made it easier for consumers to interact with tempting foods in an immersive environment. Research in the food domain has shown that VR food cues elicit similar emotional, psychological, and behavioral responses as compared to those produced by real food cues [9-11]. These studies have mainly focused on the relationship between VR food cues and food cravings, which is defined as "an intense desire to eat a specific food that is difficult to resist" [12]. Yet, little is currently known about the impact of VR food cues on actual food intake. Given that VR continues to grow in popularity [13], gaining a deeper understanding of how foods presented in VR could influence subsequent real food intake is becoming more important. Therefore, with this study, we seek to shed new light on the impact of VR on food intake and particularly examine how food cues can be used to stimulate self-regulation in food intake.

The Pre-exposure Procedure

The pre-exposure procedure is a 2-phase paradigm. In the original study that identified this procedure, participants in the experimental condition performed a consumer knowledge task in which they were asked to associate various wrappers of candies with the corresponding flavors [4]. In contrast, participants in the control condition were asked to link various colors to the corresponding concepts (eg, green with grass). Following that, participants engaged in a taste test of a similar tempting food (eg, chocolate candies), which was presented as a different study. The basic finding of this procedure is that exposure to physical temptations results in lower subsequent food intake than exposure to nontemptations. The pre-exposure procedure has also been replicated with other food-related tasks, such as a word formation task [14,15] and a puzzle-solving task [3]. The assumed mechanism accounting for the pre-exposure effect is that participants experience a behavioral conflict between food desirability (ie, food cravings) and the engagement of food-related tasks in the first phase [6]. In other words, participants engage in self-control efforts to curb food cravings in this phase [16]. When facing a similar tempting situation in the second phase (ie, a taste test), these participants exert similar self-control efforts in response to temptations. Florack et al [17] did not replicate the pre-exposure effect, but as their participants were under 6 years of age, this failure to replicate did not necessarily rule out the mechanism of coping with behavioral conflict, as self-control abilities are not fully developed among younger children [17].

In sum, the first aim of this paper is to replicate the pre-exposure effect with real food temptations among adults. We posit that exposure to real tempting food cues decreases subsequent intake of a similar tempting food as compared to exposure to nonfood cues. Moreover, the aim of the research is not only to replicate the pre-exposure effect with real foods but more importantly to better understand the potential of VR in the pre-exposure procedure. The next sections will focus on the extension of the pre-exposure effect to VR contexts.

Responses to VR Food Cues

There is a large body of research on how consumers respond to food cues in VR. Prior research has shown that VR food cues can produce emotional (eg, anxiety and arousal) or behavioral (eg, product selection) responses similar to those observed in real-life (RL) contexts [10,11,18,19]. Previous research has also focused on the relationship between VR food cues and food cravings [7,12,20-22]. For instance, food cravings triggered by VR food cues were significantly higher than those produced by VR neutral cues (ie, as a baseline condition) but were lower than those produced by real food [7]. In a similar vein, exposure to food cues induced stronger food cravings than exposure to nonfood cues in both VR and RL contexts; note that the difference was weaker in VR conditions than in RL conditions [22]. Additionally, exposure to hedonic food cues (eg, pizza) provoked high levels of food cravings than exposure to utilitarian food cues (eg, salad) in VR contexts [12,21]. The latter findings seem relevant to this research because the pre-exposure procedure has primarily focused on the intake of hedonic food. It should be noted that prior research mainly focused on the effect of VR cues on food cravings instead of food intake. To the best of our knowledge, only 1 study investigated how VR food cues affect food intake [23]; however, the authors focused on the difference in food intake between different eating environments (restaurant vs common room). This research fills this gap by examining the effect of food cues on food intake in both VR and RL contexts.

Overall, the prior literature suggests that consumers' emotional and behavioral responses in food-related VR contexts are similar (albeit weaker) to those in the RL [7,22]. In addition, VR-based food cues can produce higher levels of food cravings than VR-based nonfood cues. As mentioned earlier, an important assumption of the observed pre-exposure effect is that the food presented in the pre-exposure phase should be tempting and elicit a desire to eat. Only if the food is tempting will the desire to eat the tempting food interfere with the completion of a food-related task in RL contexts, which further reduces subsequent food intake. Could food cravings triggered by VR food cues produce a similar effect? The prior literature suggests that foods presented in VR are sufficiently lifelike to elicit such feelings of craving [22]. Therefore, we expect that the pre-exposure effect could be observed in the VR contexts as well.

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Aims of This Study

In sum, although there is a burgeoning body of research that focuses on how VR affects food cravings, marketers and researchers are struggling to fully understand the impact of VR on eating behaviors (eg, food intake). It is important to note that our research focuses on the actual food intake (instead of food cravings) after interacting with food or nonfood cues in both VR and RL contexts. For the application in the VR context, we designed a task context where people could interact with the food in VR. To validate that this procedure could be used to trigger the pre-exposure effect, we tested it both in an RL and in a VR context. We assume that participants' behavior in the VR context will be similar to their behavior after exposure to physical food temptations. In addition, prior research has shown that passive exposure to VR food cues induces high levels of food cravings as compared to VR nonfood cues [22]. Therefore, we assume that food cravings induced by VR food cues interfere with the completion of a food-related task (ie, puzzle game) in the exposure phase. Together, we expect that interaction with VR food cues in a pre-exposure paradigm decreases subsequent intake of a similar tempting food as compared to exposure to VR nonfood cues.

Methods

Design and Participants

This study used a 2 (stimulus type: food vs nonfood) × 2 (mode: VR vs RL) between-subject design. Participants were randomly assigned to 1 of the 4 conditions. A total of 218 participants (18-30 years old) were recruited with flyers and posters from a large Western European university. Participants received course credits or €7.50 for participation. This study was approved by the university ethical committee of the institution (file no. 2018-PC-9033) where the corresponding author was employed at the time of data collection. All participants provided written informed consent. In addition to the 4 conditions reported in this paper (n=175), an additional condition (branded VR, n=43) was collected with the aim to investigate the effect of brands presented in VR on brand memory and purchase intention, and the results are reported elsewhere [24,25].

Procedure

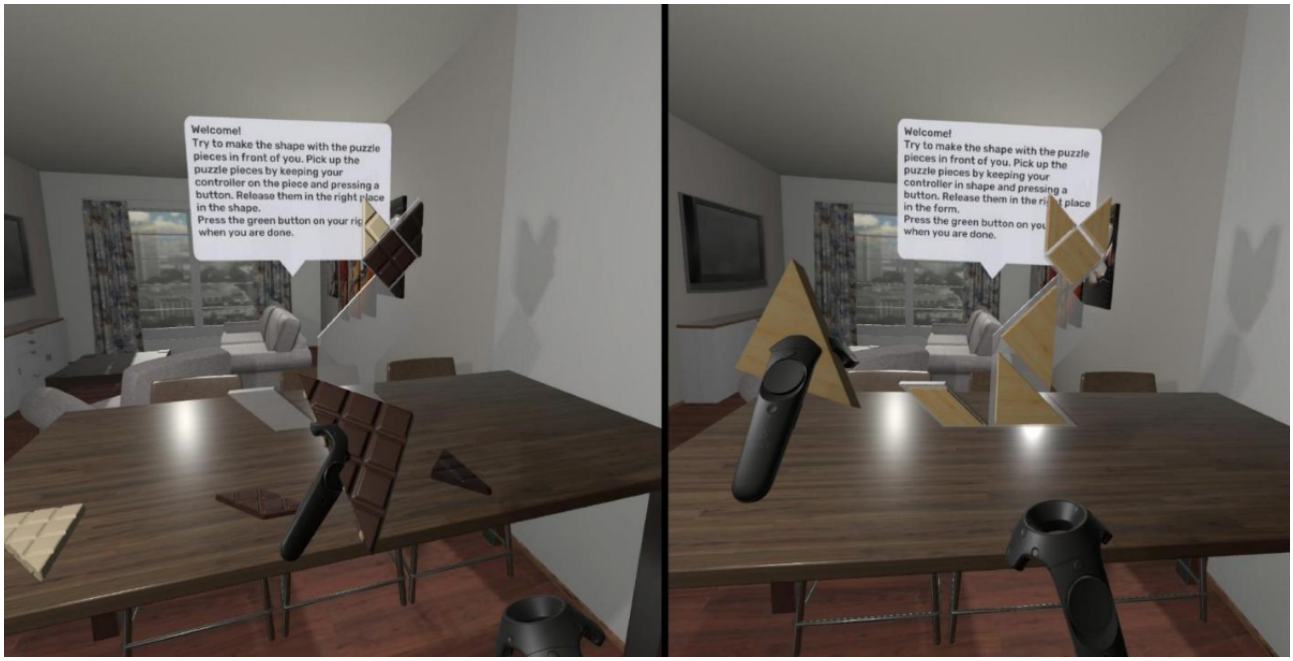
Participants were asked to refrain from eating 2 hours before the study. After entering the laboratory, participants were told that they were participating in 2 unrelated studies: a puzzle game and a taste test. First, they were asked to finish a tangram (puzzle game) with either food products (ie, pieces of chocolate) or nonfood products (ie, pieces of wood), either in VR or in RL (depending on their condition). Following that, they were asked to participate in a taste test of chocolate candies. Given the taste test, it was required that the participants were not allergic to peanuts (self-reported). Finally, they completed a questionnaire measuring game experiences (ie, entertainment and difficulty of the puzzle game) and emotional responses (ie, arousal and valence). We also measured the attractiveness of chocolate and the desire to eat chocolate for participants in the food cues condition (both VR and RL contexts). Participants also reported their demographic data (eg, age and gender) and data on height and weight. In addition, participants' hunger levels and the completion time of the puzzle game were measured as covariates. After all measurements, the participants were thanked for their participation and debriefed on the fact that both studies were related. Note that the groups that were in the RL conditions also got an opportunity to play the VR game at the end of the procedure after all measurements (as the study was advertised as a study involving VR and the participants were told in the factsheet that they would engage in a VR game during participation).

Stimulus Materials

An immersive VR game was developed with a gameplay based on the pre-exposure effect. The game is played by wearing a head-mounted display VR (HMD-VR; HTC Vive) instrument and players can interact in the virtual environment with handheld controllers in the lab. The task in the game is to finish a tangram puzzle. Two versions of the game were developed, one in which the tangram pieces were tempting food products (ie, pieces of chocolate) and the other in which the tangram pieces were plain pieces (see Figure 1). Players have to physically move the tangram pieces with the grab button on the controller and put them together. In total, participants were asked to complete 3 levels: in each of the levels, they had to puzzle a particular shape (eg, cat, house, and dog). A regular wooden tangram game was used in the nonfood product, non-VR condition, while pieces of real chocolate were used in the food product, non-VR condition (Multimedia Appendix 1). Chocolate is generally seen as a highly tempting food and can elicit a desire to eat [4,6,16]. In addition, VR chocolates elicit stronger food cravings than VR nonfood [22]. A conceptually similar task (forming a word with gummy bears) was shown to be effective for inducing the pre-exposure effect [14].

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Figure 1. Screenshot of VR puzzle game with chocolate (left panel; VR food condition) and wooden (right panel; VR nonfood condition) puzzle pieces. Participants could pick up puzzle pieces with the controller and place them in the outline in front of them.



Measures

Food Intake

In the taste test, participants were presented with 2 bowls of chocolate, one with chocolate-covered peanuts from the brand M&M's and the other with private label chocolate-covered peanuts. Participants were instructed to taste at least 1 of each bowl and were allowed to eat as much of the chocolate as needed to evaluate the products on several dimensions (eg, "Are they crunchy" and "Do they have an intense flavor?"). Food intake was measured by weighing the bowls before and after the test. The participants were left alone in the lab for 5 minutes during the taste test to avoid socially desirable behavior. The distribution of food intake was skewed, so we transformed the food intake with a logarithmic format.

Game Experiences

We measured the perceived entertainment and difficulty of puzzle games as indicators of game experiences. Specifically, the perceived entertainment was measured with 4 items (eg, "Playing the game has been exciting" and "I have had fun playing the game") on a 7-point scale [26]. The perceived difficulty was measured with 4 items (eg, "To what extent did you find the game easy" and "How well do you think you performed in the game") on a 7-point scale. In the study, both measures were reliable (entertainment: Cronbach α=.86; difficulty: Cronbach α=.71).

Emotional Responses

To assess whether emotional responses induced in VR contexts were similar to those generated in RL contexts, we measured arousal and valence using the Self-Assessment Manikin (SAM) scale [27]. The SAM scale was designed to measure the emotional state with a row of 5 nonverbal and graphic manikins that differ in levels of 2 affective dimensions (eg, valence and arousal). For the valence measure, the SAM scale ranges from a happy and smiling figure to an unhappy and frowning figure. For the arousal measure, the SAM scale ranges from an excited figure to a relaxed figure. Participants can indicate their current emotional state on any of the 5 figures or between any 2 figures. In other words, participants were asked to report their emotional state after playing the puzzle game on a 9-point scale.

The Appeal of Tempting Foods

In the food cues condition, we also measured the appeal of food. Specifically, the attractiveness was measured with a single item (ie, "How appealing was the chocolate you saw while playing the game?") on a visual analog scale (VAS) ranging from 0 ("not at all") to 100 ("a whole lot"). Similarly, the desire to eat chocolate was measured with a single item (ie, "How much did you feel like eating the chocolate?") on a 7-point scale ranging from 1 ("not at all") to 7 ("a whole lot"). The 2 measures were correlated with each other (r=0.75, P<.001).

Results

Data Cleaning

Data from 13 participants were excluded from analysis because of nonconforming to the study tasks (ie, refusing to eat or to eat less than 2 chocolate-covered peanuts [4 g] in the bogus taste task, n=4), impossible values (ie, eating more than 200 g of chocolate-covered peanuts in the bogus taste task, n=1), reporting a low preference for chocolate (ie, a score of 2 or less on a 7-point scale ranging from 1 for "not at all" to 7 for "a lot" for the question "How much do you like chocolate?", n=7), or spontaneous mention of not liking the peanut M&M's (n=1). The final sample consisted of 162 adults (118 [72.8%] females, 44 [27.2%] males) with a mean age of 22.4 years (SD 4.1) and a mean body mass index (BMI) of 21.9 kg/m^2 (SD 2.7). Table 1 presents the characteristics of participants for the 4 conditions; the conditions did not differ significantly on any of the characteristics.

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Table 1. Characteristics of the study population (N=162).

Characteristic	Real food (n=42)	Real nonfood (n=41)	Virtual food (n=40)	Virtual nonfood (n=39)	Difference between conditions
Age (years), mean (SD)	22.55 (5.11)	22.16 (3.30)	22.13 (4.46)	22.54 (3.50)	$F_{3,158}$=0.092, *P*=.97
BMI[a] (kg/m^2), mean (SD)	21.72 (2.58)	22.46 (3.53)	21.50 (1.98)	22.10 (2.35)	$F_{3,158}$=1.010, *P*=.39
Female participants, %	81.0	78.1	70.0	61.5	χ^2_3=4.612, *P*=.20
Weight concerns[b], mean (SD)	5.23 (2.22)	5.13 (2.03)	5.43 (2.31)	5.51 (2.13)	$F_{3,158}$=0.240, *P*=.87
Chocolate preference[c], mean (SD)	6.07 (1.00)	5.66 (1.35)	5.80 (1.29)	5.77 (1.33)	$F_{3,158}$=0.823, *P*=.48
Hunger[d], mean (SD)	51.10 (23.29)	52.13 (25.21)	56.78 (25.38)	52.80 (23.28)	$F_{3,157}$=0.423, *P*=.74
Time since last intake (minutes), mean (SD)	164.86 (72.09)	203.08 (148.70)	189.80 (136.39)	175.54 (120.85)	$F_{3,157}$=.754, *P*=.52

[a]BMI: body mass index.

[b]The question "To what extent are you concerned with your weight?" answered on a 9-point scale ranging from 1 ("not at all") to 9 ("completely").

[c]The question "How much do you like chocolate?" answered on a 9-point scale ranging from 1 ("not at all") to 7 ("a lot").

[d]The question "How hungry are you right now?" answered on a visual analog scale (VAS) scale ranging from 0 ("not hungry at all") to 100 ("very hungry").

Randomization Check

We conducted a randomization check to test whether the sample was distributed equally across conditions (see Table 1). We compared the difference between different conditions on age ($F_{3,158}$=0.092, *P*=.97), gender (χ^2_3=4.612, *P*=.20), BMI ($F_{3,158}$=1.010, *P*=.39), weight concerns ($F_{3,158}$=0.240, *P*=.87), chocolate preference ($F_{3,158}$=0.823, *P*=.48), hunger ($F_{3,157}$=0.423, *P*=.74), and time since last intake ($F_{3,157}$=0.754, *P*=.52). These results indicate that our randomization was successful.

Effects of Stimulus Type and Mode of Pre-exposure on Food Intake

ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and food intake (natural log transformed) as the dependent variable was performed. No significant main effect of stimulus type was found ($F_{1,158}$=2.234, *P*=.14, partial η^2=0.014). A main effect of mode was found ($F_{1,158}$=5.556, *P*=.02, partial η^2=0.034). Food intake (g) was higher in the VR condition (log-transformed M=3.202, SD 0.564; inverse-log-transformed M=24.581, SD 1.758) than in the RL condition (log-transformed M=2.990, SD 0.580; inverse-log-transformed M=19.886, SD 1.786). The interaction between stimulus type and mode was not significant ($F_{1,158}$=0.004, *P*=.95, partial η^2<0.001). R^2 of the complete model was 0.047 (adjusted R^2=0.029); we also performed an analysis controlling for the hunger level, liking of chocolate candies, and time since the last intake as covariates, and the significant level of the main effects was not substantially different.

Effects of Stimulus Type and Mode of Pre-exposure on Food Intake Separated by Gender

As previous studies have shown that pre-exposure effects are in some instances specific to males [15] or females [6], we explored this factor in this study as well. We tested the effect of stimulus type and mode of pre-exposure on food intake for females and males, respectively.

Females

ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and food intake (natural log transformed) as the dependent variable was performed. A significant main effect of stimulus type was found ($F_{1,114}$=3.986, *P*=.05, partial η^2=0.034). Food intake (g) was higher in the nonfood condition (log-transformed M=3.108, SD 0.530; inverse-log-transformed M=22.376, SD 1.699) compared to the food condition (log-transformed M=2.902, SD 0.595; inverse-log-transformed M=18.211, SD 0.813). A main effect of mode was found ($F_{1,114}$=4.478, *P*=.04, partial η^2=0.038). Food intake (g) was higher in the VR condition (log-transformed M=3.121, *SD* 0.568; inverse-log-transformed M=22.669, SD 1.765) than in the RL condition (log-transformed M=2.904, SD 0.562; inverse-log-transformed M=18.247, SD 1.754). The interaction between stimulus type and mode was not significant ($F_{1,114}$=0.052, *P*=.82, partial η^2<0.001). R^2 of the complete model was 0.070 (adjusted R^2=0.045).

Males

ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and food intake (natural log transformed) as the dependent variable was performed. No significant main effect of stimulus type was found ($F_{1,40}$=0.947, *P*=.34, partial η^2=0.023). No significant main effect of mode

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was found ($F_{1,40}$=0.025, P=.87, partial η^2=0.001). The interaction between stimulus type and mode was not significant ($F_{1,40}$=0.927, P=.34, partial η^2=0.023). R^2 of the complete model was 0.038 (adjusted R^2=–0.034).

Effects of Stimulus Type and Mode of Pre-exposure on Indicators of Game Experience (Entertainment, Difficulty)

To test whether the game experience produced by VR cues was similar to that produced by RL cues, ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and entertainment as the dependent variable was performed. No significant main effect of stimulus type was found ($F_{1,158}$=0.001, P=.98, partial η^2<0.001). No main effect of mode was found ($F_{1,158}$=0.045, P=.83, partial η^2<0.001). The interaction between stimulus type and mode was not significant ($F_{1,158}$<0.001, P=.99, partial η^2<0.001). R^2 of the complete model was <0.001 (adjusted R^2=0.019).

ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and difficulty as the dependent variable was performed. No significant main effect of stimulus type was found ($F_{1,158}$=1.588, P=.21, partial η^2=0.010). No main effect of mode was found ($F_{1,158}$=0.398, P=.53, partial η^2=0.003). The interaction between stimulus type and mode was not significant ($F_{1,158}$=2.952, P=.09, partial η^2=0.018). R^2 of the complete model was 0.031 (adjusted R^2=0.012).

Effects of Stimulus Type and Mode of Pre-exposure on Emotions (Valence, Arousal)

To test whether emotional responses produced by VR cues are similar to those produced by RL cues, ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and valence as the dependent variable was performed. No significant main effect of stimulus type was found ($F_{1,158}$=0.791, P=.38, partial η^2=0.005). No main effect of mode was found ($F_{1,158}$=0.281, P=.60, partial η^2=0.002). The interaction between stimulus type and mode was not significant ($F_{1,158}$=0.849, P=.36, partial η^2=0.005). R^2 of the complete model was 0.012 (adjusted R^2=–0.007).

ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and arousal as the dependent variable was performed. No significant main effect of stimulus type was found ($F_{1,158}$=0.826, P=.37, partial η^2=0.005). No main effect of mode was found ($F_{1,158}$=0.187, P=.67, partial η^2=0.001). The interaction between stimulus type and mode was not significant ($F_{1,158}$=0.119, P=.73, partial η^2=0.001). R^2 of the complete model was 0.007 (adjusted R^2=–0.012).

Effect of Mode (VR vs RL) on Food Attractiveness and Desire to Eat

To test whether food cravings produced by VR food cues are similar to those produced by real food, ANOVA with mode (VR vs RL) as the independent variable and chocolate attractiveness (answer to “How appealing was the chocolate you saw in the game?”) as the dependent variable was performed. Note that we only used half of the data set for subsequent analyses because only half of the participants were exposed to food cues. No main effect of mode was found ($F_{1,79}$=1.122, P=.29, partial η^2=0.014). R^2 of the model was 0.014 (adjusted R^2=0.002).

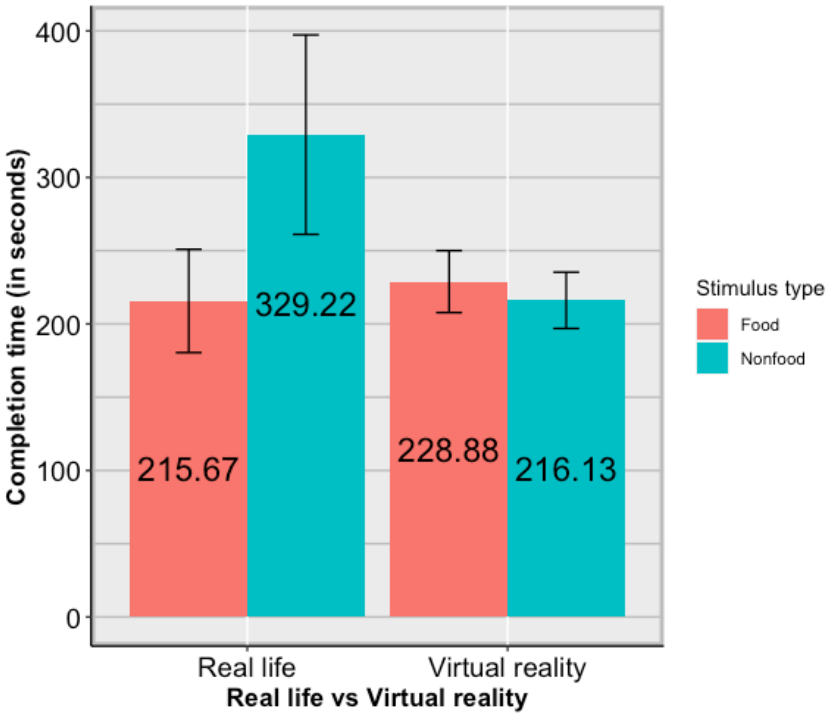
ANOVA with mode (VR vs RL) as the independent variable and the desire to eat chocolate (answer to “How much did you feel like eating the chocolate?”) as the dependent variable was performed. No main effect of mode was found ($F_{1,79}$=2.607, P=.11, partial η^2=0.033). R^2 of the model was 0.033 (adjusted R^2=0.020).

Exploratory Analysis

In this study, we also measured the completion time of the puzzle game. To test whether participants spent a similar amount of time in completing the puzzle game between VR and RL contexts, ANOVA with stimulus type (food vs nonfood) and mode (VR vs RL) as independent variables and completion time as the dependent variable was performed. As shown in Figure 2, a significant main effect of stimulus type was found ($F_{1,158}$=6.040, P=.02, partial η^2=0.037). The completion time was longer in the nonfood condition (M=274.088, SD 168.764) compared to the food condition (M=222.110, SD 92.864). A main effect of mode was found ($F_{1,158}$=5.930, P=.02, partial η^2=0.036). The completion time (seconds) was longer in the RL condition (M=271.759, SD 179.864) than in the VR condition (M=222.582, SD 62.765). The interaction between stimulus type and mode was also significant ($F_{1,158}$=9.482, P=.002, partial η^2=0.057). Simple contrasts revealed that when in RL mode, the completion time was longer in the nonfood condition ($F_{1,158}$=15.713, P<.001; M=329.220, SD 215.684) than in the food condition (M=215.667, SD 113.105). However, in VR mode, there was no significant difference in the completion time between the 2 conditions ($M_{nonfood}$=216.128, SD 59.299 vs M_{food}=228.875, SD 66.109; $F_{1,158}$=0.188, P=.67). Additionally, simple contrasts revealed that when the stimulus type was nonfood, the completion time was longer in the RL condition ($F_{1,158}$=15.016, P<.001; M=329.220, SD 215.684) than in the VR condition (M=216.128, SD 52.299). However, when the stimulus type was food, there was no significant difference in the completion time between the 2 conditions (M_{VR}=228.875, SD 66.109 vs M_{RL}=215.667, SD 113.105; $F_{1,158}$=0.210, P=.65). R^2 of the complete model was 0.120 (adjusted R^2=0.104).

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Figure 2. The interaction between stimulus type and mode on the completion time.



Discussion

Principal Results

Due to the rising popularity of VR in our daily life, it is necessary to better understand how VR food cues affect consumers' eating behavior (eg, food intake). However, prior research has mainly focused on the impact of VR food cues on food cravings [7,12,20,21]. In this study, we examined the effect of interaction with food cues (vs nonfood cues) on subsequent food intake in both VR and RL contexts, with the aim to replicate the pre-exposure effect and to extend this effect to VR contexts.

Unexpectedly, we found that the main effect of mode (VR vs RL) on food intake is significant. Specifically, we found a higher food intake after both VR conditions (puzzle game in VR with either food or nonfood cues) than after RL conditions. A possible explanation could be that playing a game in VR is arousing and that arousal leads to increased food intake. There is ample evidence that arousal may lead to increased food intake [28]. However, it should be noted that in this study, there was no significant difference in self-reported arousal between VR and RL conditions. In contrast, there is also some evidence that playing games may decrease food cravings [29], possibly because playing games distracts from feelings of hunger and craving. Given the unexpected nature of this finding, it is important that this be replicated.

We did not replicate the pre-exposure effect in the full sample. In addition, there was no interaction effect between stimulus type (food vs nonfood) and mode (VR vs RL) on food intake in the full sample. Prior studies have shown that pre-exposure effects are in some instances specific to males [15] or females [6]. Therefore, we examined whether our results were contingent on gender. In the male sample, 2-way ANOVA did not reveal any significant effects. In the female sample, however, we found that exposure to both food cues (puzzle game with food cues with either VR or RL) decreased food intake than exposure to nonfood cues. This is in line with one of the prior studies on the pre-exposure effect [6]. We found that females reported a higher chocolate preference (ie, liking for chocolates) than males, which suggests that females may be more tempted by chocolates than males; liking for chocolates was M_{female}=6.000 (SD 1.147) versus M_{male}=5.364 (SD 1.382), with $F_{1,160}$=8.792 and P=.003. Consequently, given that tempting chocolates may induce a behavioral conflict between the desire to eat and the completion of a food-related task among females, we observed the pre-exposure effect. In contrast, chocolates may not have been sufficiently tempting for males, therefore resulting in a lack of behavioral conflict and activation of control processes in males.

Moreover, we found that emotional and behavioral responses (eg, valence, arousal, entertainment, and difficulty) induced by VR cues are similar to those generated by RL cues. This suggests that there were no additional confounders between the conditions. In addition, this study showed that exposure to VR food cues elicits similar food evaluations (ie, attractiveness and a desire to eat) compared to exposure to RL food cues. Given that the appeal of food (measured in this study) was similar to food cravings (measured in prior studies), this study does not provide evidence that VR food cues induce weaker food cravings compared to RL food cues [7,22]. In the study by Ledoux et al [7], the impact of VR food cues (vs RL food cues) on food cravings was examined among nondieting women. This study conducted this investigation with a more general sample including both males and females, as well as both dieting and nondieting individuals. However, a more general sample was also used in the study by van der Waal et al [22]. We speculate that individual differences (eg, gender, age, and eating/dieting

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habits) may moderate the effect of VR food cues on food cravings. This needs further investigation with a more diverse sample before firm conclusions can be drawn.

Limitations and Future Research

Although this study provides useful insights into the impact of VR cues on food intake, 3 limitations should be considered. First, in this research, we found that manipulation affects the completion (exposure) time of puzzle games. Specifically, participants spent more time completing puzzle games in nonfood or RL conditions as compared to food or VR conditions. We tried to replicate the pre-exposure effect in RL contexts; however, the completion time was longer in the nonfood condition (around 5.5 minutes) than in the food condition (around 3.5 minutes). Prior research on the pre-exposure effect used a consumer knowledge task [4], a puzzle-solving task [3], or a word formation task [14]. In the puzzle-solving task (a total of 8 puzzles), participants were instructed to solve each puzzle within a time limit (40 seconds) in both food and nonfood conditions, indicating that the total exposure time (around 5.5 minutes) was the same between the two conditions. In addition, in the word formation task, both groups (candies vs foams) were instructed to complete the task in an allocated time of 4 minutes [14]. In other words, prior studies have revealed that an exposure period of 4-6 minutes may be necessary for the pre-exposure effect to occur after exposure to RL food cues. In addition, building on prior studies on the pre-exposure effect, there was no difference in the completion (exposure) time between food and nonfood conditions. In this study, therefore, we speculate that the time difference between the 2 conditions (food vs nonfood) and the insufficient exposure time in the food condition may account for the inability to replicate the pre-exposure effect in RL contexts. To rule out the impact of the completion (exposure) time, follow-up studies should allocate a fixed time duration in the exposure phase.

Second, this research used the pre-exposure paradigm (eg, a puzzle game and a taste test) to examine the effect of VR cues on food intake. Both tasks are more specific to laboratory contexts. Until now, we are not clear whether the pre-exposure procedure still works well outside laboratory contexts. Given the unlimited possibility of creating various eating environments with HMD-VR, future research could examine how VR affects food intake in different situations. Prior research on VR food cues focused on some daily environments, such as living rooms, kitchens, and restaurants. For instance, there was no significant difference in food intake between the restaurant scene and the blank scene in VR environments [23]. However, that study did not introduce the pre-exposure paradigm. Consumers' eating behaviors may be different between laboratory and RL contexts [23]. In a laboratory context, participants may feel that their eating behaviors are being observed and then behave differently as compared to their typical eating habits in RL environments [30]. VR can be used to recreate any eating environment similar to RL situations; thus, to generalize the pre-exposure effect, future studies could examine the pre-exposure procedure in VR cinema or a VR cafeteria.

Third, in this study, we exclusively used confectionery food products when manipulating pre-exposure (ie, chocolate) and when measuring food intake (ie, grams of M&M's). Both products belong to the same food category, which warrants caution with generalizing our results across all food products. Concretely, individual differences in perceptions of how appealing the stimulus food was, as well as strong preferences in particular brands of confectionery food products, could have affected food intake (at least) on the individual level. To rule out any potential product-specific bias, future studies could consider incorporating different or various food categories to manipulate pre-exposure as well as to measure food intake.

Theoretical and Practical Implications

Our findings contribute to 2 streams of literature: the pre-exposure procedure and the responses to VR food cues. Although prior research on the pre-exposure procedure has studied how food cues versus nonfood cues affect the subsequent intake of tempting foods in RL contexts [3,4,15], our research goes further by also exploring the role of VR in the pre-exposure procedure. Despite not replicating the pre-exposure effect in VR, our study did show that exposure to cues in VR, generally, leads to higher food intake than exposure to cues in RL. This seems particularly important for health practitioners developing (food-related) VR interventions, who should consider that the mere act of being in VR may elevate food intake, at least directly after the experience.

Furthermore, our research extends the VR food cues literature by examining the impact of VR on actual food intake, instead of food cravings, considering that actual food intake is critical to understanding whether VR food cues increase or decrease subsequent intake of tempting foods in more naturalistic settings. In addition, in line with prior research on the effects of VR food cues on eating behavior–related outcomes [9,10], the findings of this research offer additional insights into the similarity between VR food cues and RL food cues.

Conclusion

Overall, in this study, we were unable to replicate the exposure effect in our complete sample. Subgroup analyses, however, showed that for women, exposure to food cues (either in VR or in RL) does reduce food intake, indicating that a VR pre-exposure procedure may effectively be applied exclusively for women. Moreover, we found that exposure to cues in VR (either food or nonfood) results in a higher overall food intake as compared to exposure to cues in a similar RL setting. Finally, we demonstrated that VR and RL cues elicit similar emotional responses (eg, arousal and valence).

Acknowledgments

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Conflicts of Interest

None declared.

Editorial Notice

This randomized study was only retrospectively registered. The authors explained that this is due to them not being aware that it was required to register a lab study with a student-sample as a clinical trial. The editor granted an exception of ICMJE rules for prospective registration of randomized trials because the risk of bias appears low and the study was considered formative. 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
Chocolate tangram (puzzle game).
[PPTX File , 2495 KB - games_v10i1e31747_app1.pptx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1214 KB - games_v10i1e31747_app2.pdf]

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Abbreviations

BMI: body mass index
HMD-VR: head-mounted display virtual reality
RL: real life
SAM: Self-Assessment Manikin
VAS: visual analog scale
VR: virtual reality

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Original Paper

Evaluation of a Digitally Guided Self-Rehabilitation Device Coupled With Telerehabilitation Monitoring in Patients With Parkinson Disease (TELEP@RK): Open, Prospective Observational Study

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Abstract

Background: Parkinson disease is a neurodegenerative disease causing a progressive loss of autonomy. This requires long-term rehabilitation care. Currently, new technologies are being developed for use in daily life, and there is a progressive implementation of telerehabilitation.

Objective: The aim of this study (the TELEP@RK study) is to evaluate the uses of a digital self-rehabilitation device in patients with Parkinson disease and their independent physiotherapists on the scale of a health territory.

Methods: A total of 10 independent physiotherapists and 31 patients with Parkinson disease were followed for 1 year to evaluate the use of a telerehabilitation tool (digital tablet and inertial sensor) via questionnaires of the Unified Theory of Acceptance and Use of Technology (UTAUT). The questionnaires were submitted to participants at 0, 2, and 12 months from the start of follow-up. The averages of the scores of the different determinants and constructs of the UTAUT questionnaires were compared at the different follow-up times.

Results: Among professionals, the averages of the various determinants were generally high at the beginning of the study with an average (out of 5) performance expectancy of 4.19, effort expectancy of 3.88, social influence of 3.95, facilitating conditions of 4, and intention to use of 3.97. These averages decreased over time.

Conclusions: Acceptability, acceptance, and appropriation of the tool were very high among the physiotherapists as well as the patients, despite the tool's lack of evolution during the study. In the current health care context, these results allow us to envision a new organization of the care pathway for patients with chronic diseases, with the increased use of new technologies associated with telecare.

(JMIR Serious Games 2022;10(1):e24946) doi:10.2196/24946

KEYWORDS

Parkinson's disease; telerehabilitation; serious games; UTAUT; physiotherapist; acceptability; acceptance

Introduction

Parkinson disease is a neurodegenerative disease characterized by progressive motor and nonmotor symptoms. There is no curative treatment, but there are symptomatic treatments, including medication (dopaminergic treatment) and surgery (deep brain stimulation). Even with optimal treatment, there is a progressive deterioration of autonomy (sensitive non-dopa symptoms: posture, walking, and balance) which affects the patient's quality of life [1].

Rehabilitation plays an important role in the management of Parkinson disease and is considered complementary to drug and

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surgical treatments. This is why it is important to offer patients rehabilitative care as soon as possible [2,3]. It has been shown that exercise (eg, aerobic exercise, stretching, strengthening exercises, balance exercises, dance, resistance training, and walking) has positive effects on the quality of life of patients [4] and improves motor and nonmotor symptoms [5,6]. In addition, a review of the literature [7] suggests that physical activity improves the ability to perform activities of daily living, especially in the early stages of Parkinson disease. Self-rehabilitation, which consists of the autonomous practice of exercises at home, is becoming increasingly common, most often as a relay to hospital care or as a complement to outpatient care, and appears to be at least as effective as center-based rehabilitation [8]. Among patients with Parkinson disease, those who benefit from ambulatory rehabilitative care seem to have an improved quality of life [9].

At the same time, due to the development of new technologies for use in daily life, several studies [10,11] have evaluated tools aimed at offering independent home rehabilitation via rehabilitation games. The term *serious games* refers to game software combining serious aspects (eg, software with educational, informational, communicational, marketing, ideological, or training purposes) with interactive and playful aspects of video games [12]. The use of such tools seems to be effective on motor symptoms [13-15]. Several serious game programs have been tested, and their use by patients with Parkinson disease seems feasible [14,16-18]. The Beyond Your Motion (BYM) tool is a tool coupling a serious game via an app on a digital tablet to a motion sensor.

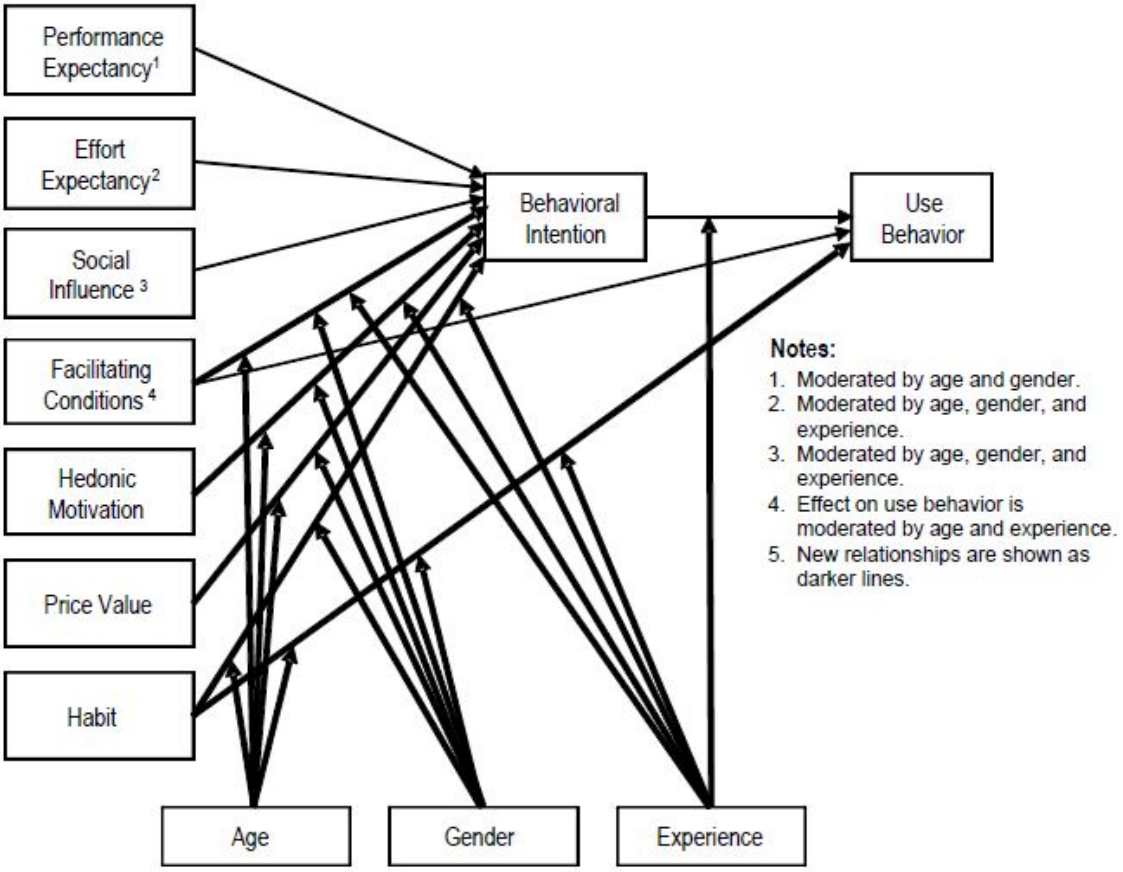
We are also witnessing the development of telerehabilitation, which is defined as a service using telecommunications technologies to provide remote rehabilitation services. A review of the literature [19] highlights an improvement in functional activities, symptoms (pain, insomnia), and quality of life in multiple sclerosis patients following telerehabilitation. Studies have shown its feasibility and safe application for stroke patients [20]. Since the beginning of 2020, the COVID-19 pandemic has led to increased use of the digital tools offered by telemedicine to ensure the safe continuity of care. In the context of this health emergency, new decrees have been issued to facilitate the use of these tools, notably with reimbursement, in the same way as face-to-face procedures, through health insurance for telecare and teleconsultations [21].

The use of new technologies is at the center of daily life. This use is intimately linked to the acceptance of these tools. The purpose of studying use is to evaluate how people appropriate and use products over time through three different processes: acceptability, acceptance, and appropriation. Acceptability corresponds to the subjective representation of the use of the technological tool before it is used. Acceptance refers to the experience (judgment and behavioral reactions) of individuals after the introduction and use of the product. Appropriation thus corresponds to the process by which the person invests in the product and the extent to which the product is in line with their personal and cultural values that make them want to act on or with the product and not just be subjected to its use [22]. Thus, we can speak of a continuum between these different notions, starting before use and continuing to prolonged use [23]. This process of acceptability has been the subject of numerous theories, some of which have led to explanatory theoretical models. The Unified Theory of Acceptance and Use of Technology (UTAUT) [24] is an integrative model (a review of 8 theoretical models) that synthesizes these different approaches. A total of 7 constructs were considered to be significant determinants of intent to use, and these were grouped into 4 determinants: (1) performance expectancy (the degree to which an individual believes that using the product will help them achieve a goal), (2) effort expectancy (the degree of ease associated with using the product), (3) facilitating conditions (the degree to which an individual perceives that an organization and support exists to help them use the product), and (4) social influences (the degree to which an individual perceives that people important to them believe that they should use the product). In addition to these constructs are moderators such as age, gender, experience, and voluntarism. These different constructs act on behavioral intention, under the influence of moderating variables, which leads to use behavior. The results of this model showed an explanatory power of the intention to use behavior of about 70%. A new version of the UTAUT, UTAUT 2, was also proposed in 2012 [25] and has 3 additional constructs, namely hedonic motivation, price value, and habits (Figure 1) [25].

The aim of this study (the TELEP@RK study) is to evaluate the use of two rapidly developing approaches (serious games and telerehabilitation) by patients with Parkinson disease and their physiotherapists.

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Figure 1. Unified Theory of Acceptance and Use of Technology 2 (UTAUT 2) model. Image taken from Venkatesh et al [25].



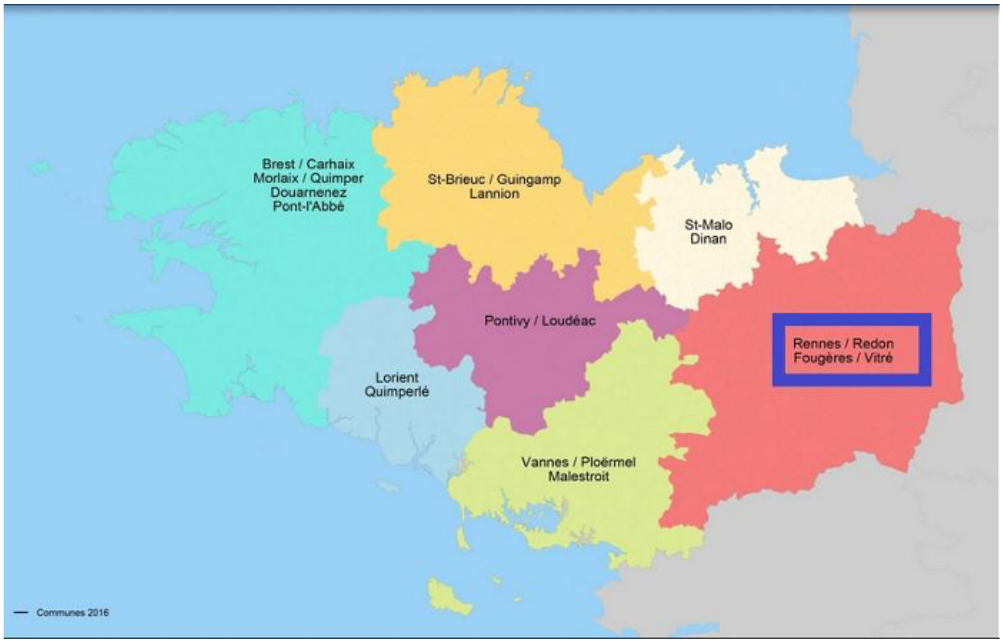
Methods

Scheme of the Study

This is an open, prospective observational study that took place from 2017 to 2020 over health territory 5 in Brittany, France (Figure 2) [26]. The patients were followed for 12 months.

The main evaluation criterion was the questionnaire on the acceptance of the tool and its use by professionals based on the 2-month UTAUT.

Figure 2. Health territories of Brittany, France. Territory number 5 is enclosed in the blue rectangle. Image taken from Agence Régionale de Santé Bretagne [26].



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The secondary judgment criteria were:

- Professional and patient (and patients' relatives) acceptability questionnaires at baseline.
- Questionnaire on acceptance of the tool by patients based on the UTAUT at 2 months.
- Rosenberg self-esteem score, which is a factor in social integration, at baseline, 2 months, and 12 months.

Pôle Saint Hélier, a physical medicine and rehabilitation center in Rennes, sponsored this study.

Population Studied

The criteria for inclusion differed based on the type of subject. For health professionals, the inclusion criteria were as follows: physiotherapists, physical and rehabilitation medicine hospital physicians, or independent practitioners in health territory 5 in Brittany, France, who agreed to participate in the study. For patients, the sample included men and women over 18 years of age presenting idiopathic Parkinson disease or a related syndrome, presenting a complaint concerning balance and/or walking on a perimeter of at least 100 meters with or without technical aid, at stage 4 or less on the Hoehn and Yahr scale, and formulating their free and informed consent in writing. The patients had not received prior rehabilitation in a rehabilitation center. The sample excluded patients with orthopedic and rheumatological pathologies that might prevent the performing of the measurements or comprehension disorders that might prevent the performing of the protocol. The first inclusions began in May 2018, and the study ended in June 2020.

Digital Tool

An interactive digital tool (tablet and inertial sensor; Figure 3) [27] selected by physicians or physiotherapists to support the self-rehabilitation of patients with Parkinson disease at home was made available to patients in this study. This tool was a digital support comprising bracelets equipped with motion sensors and a tablet with a serious game app with visual and auditory feedback for self-rehabilitation and reconditioning to autonomous effort. This was a tablet app that guided the patient's active work. In particular, the parameterization allowed the app to work according to predefined levels of difficulty, but in a self-learning form: depending on the patient's progress, the difficulty increased according to several parameters (duration of the session, frequency of the exercise, size of the pointer, etc). It was coupled to a miniaturized movement analysis device using inertial control units that the patient could position alone using Velcro strips, as indicated by the exercises, on either side of a joint. The patient performed repetitive movements with the largest possible amplitude with a defined pace and received visual feedback through a visual of a vessel catching coins and stars, and auditory feedback, according to the movements performed. The exercises were designed to target motor symptoms such as bradykinesia and hypokinesia. The connection with the field professional was made via the secure platform used for telemedicine. It was anticipated that the monitoring and regulation of self-rehabilitation would be done remotely by telerehabilitation (part of the regulatory framework of telemedicine).

Figure 3. The Beyond Your Motion (BYM) tool. Image taken from the BYM website. [27]



Conduct of the Study

Physiotherapists were contacted by mail or email and invited to an information session at which they could give their consent to participate in the study. The BYM tool was made available free of charge for 1 year to the physiotherapists who had given their consent. The physiotherapists recruited patients with Parkinson disease from among their patients. Patients were offered a medical consultation by a Pôle Saint Hélier investigating physician to verify the inclusion and exclusion criteria and they were included in the study after obtaining their

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informed consent. Physiotherapists had the choice of using the tablet in their office or in the patient's home.

The evaluation was done in the form of questionnaires. The study subjects, as well as their relatives and the professionals taking care of them, were required to fill out these questionnaires at baseline, 2 months, and 12 months from the beginning of the study.

UTAUT Questionnaires

The distribution of the various items and constructs was modified after data collection for the statistical analysis. It should be noted that the item concerning the price was not asked of the independent physiotherapists at the beginning of the follow-up.

Statistical Analyses

We analyzed the data using the statistical software R (R Foundation for Statistical Computing). A first descriptive analysis was performed with numbers and percentages for the qualitative variables and means, standard deviations, ranges, and medians for the quantitative variables. The Wilcoxon test was used to compare the various means. The main criterion of judgment, obtained via use evaluation questionnaires (UTAUT), is quantitative. The analysis of this criterion consists of the comparison of the means obtained at baseline and at 2 months using the Wilcoxon test. All tests were performed with a significance threshold of 5% ($P<.05$). We applied imputation models for missing data when necessary.

Patients gave their free, informed, and written consent to participate in the study. The study protocol and an information and nonopposition note to the study were submitted and accepted by the CPP Sud Est II Lyon Bron ethics committee on December 13, 2017 (2017-A02834-49, RIPH 2).

Results

Study Population

A total of 72 independent physiotherapists were contacted based on the directory of professionals who have taken training courses at the Réseau Park through the NeuroBretagne Association. Of the contacted physiotherapists, 13 responded to the invitation to participate in the study and were preincluded. Then, 380 independent physiotherapists were contacted via the Union Régionale des Professionnels de Santé. Of the 380, 2 responded. Among the preincluded physiotherapists, 5 were excluded because they did not recruit any of their patients for the study. Of the 10 physiotherapists included, 3 (30%) were men and 7 (70%) were women. The average age was 39.3 years (SD 10.2 years). The average number of years of experience as an independent practitioner was 12.7 (SD 10.7).

A total of 31 patients were included in the study by their independent physiotherapists, including 17 men (55%) and 14 women (45%). The mean age was 69 years (SD 8 years). Of the 31 patients, 28 had idiopathic Parkinson disease, 2 had progressive supranuclear paralysis, and 1 had an extrapyramidal syndrome of undetermined etiology. The average duration of disease progression was 7 years (SD 5 years). The average stage on the Hoehn and Yahr scale was 1.87 (SD 0.86), indicating moderate disease impact in these individuals, all living at home. No participants had deep brain stimulation electrodes implanted. The mean motor Unified Parkinson's Disease Rating Scale (UPDRS) score was 10.9 (SD 6.97) and the score for Motor Aspects of Experiences of Daily Living (UPDRS M-EDL scale) was 10.4 (SD 7.3). Out of the 31 patients, a total of 17 (55%) already had a tablet, 16 (52%) had a smartphone, and 27 (87%) had internet access. Among those with a smartphone and/or tablet, 17 of 19 (89%) used their devices regularly or daily. A total of 4 (13%) of the 31 patients lived alone, 27 (87%) lived with a family caregiver, and 2 (6%) had professional caregivers. For 27 of the 31 patients (87%), shifting was considered easy with or without aids. Out of the 31 patients, 12 patients (39%) said they lived far from a physiotherapy practice and 7 (23%) were far from a rehabilitation center. See Table 1 and Table 2 for patients' baseline demographic and clinical characteristics.

Initially, it was anticipated that self-rehabilitation would be monitored and regulated remotely at the request of the independent physiotherapist. However, there were no requests for teleconsultation by the independent physiotherapists during the study.

Table 1. Patients' baseline demographic and clinical characteristics (n=31).

Characteristics	Mean (SD)	Range
Age, years	69 (8)	50-83
Hoehn and Yahr stage	1.87 (0.86)	1-4
Duration of disease progression, years	7 (5)	1-20
Unified Parkinson's Disease Rating Scale: Motor	10.9 (6.97)	1-24
Unified Parkinson's Disease Rating Scale: Motor Aspects of Experiences of Daily Living	10.4 (7.3)	1-36

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Table 2. Patients' baseline demographic and clinical characteristics, continued (n=31).

Characteristics	Patients, n (%)
Sex	
Male	17 (55)
Female	14 (45)
Numeric tablet	17 (55)
Smartphone	16 (52)
Internet	27 (87)
Disease	
Parkinson Disease	28 (90)
Progressive supranuclear paralysis	2 (7)
Undetermined	1 (3)
Use of tablet and smartphone	
Never	0 (0)
Sometimes	2 (10)
Regularly	10 (53)
Daily	7 (37)
Daily living context	
Alone	4 (13%)
Family caregiver	27 (87)
Professional caregiver	2 (6)
Shifting difficulty	
Easy without help	22 (71)
Easy with help	5 (16)
Difficult without help	2 (6)
Difficult with help	2 (6)
Home far from physiotherapist's practice	12 (39)
Home far from rehabilitation center	7 (23)

Results for the Main Criterion

Concerning the evaluation of use via the UTAUT questionnaire among professionals, the means of the various determinants were globally high at the beginning of the study, with average scores (out of 5) as follows: performance expectancy of 4.19 (SD 0.33), effort expectancy of 3.88 (SD 0.57), social influence of 3.95 (SD 0.60), facilitating conditions of 4 (SD 0.62), and intention of use of 3.97 (SD 0.66).

There was a decline in the averages of the different determinants and constructs over time.

There was a significant decline (P=.03) in the means of perceived usefulness between the beginning and end of follow-up. The mean at month 0 was 4.25 (SD 0.38), while the mean at month 12 was 3.76 (SD 0.45). This decline predominated between the 2nd month and the 12th month (P=.049); the mean at month 2 was 4.1 (SD 0.34). This particularly concerned the usefulness of the tool in the office (P=.04) and in the patient's home (P=.04) between the 2nd and 12th months of tool use. The job fit, as in, the use in daily practice, decreased significantly between the beginning of follow-up and 12 months of use (P=.001), with a more marked decrease between 0 and 2 months of use (P=.02) (mean at month 0 was 4.1, SD 0.45; mean at month 2 was 3.56, SD 0.47; mean at month 12 was 3.04, SD 0.71).

Intention to use also decreased over time. The mean at month 2 was 2.84 (SD 0.88), while the mean at month 12 was 2.14 (SD 0.63); there was a significant difference between month 0 and month 2 (P=.007), and between month 0 and month 12 (P<.001).

For the social influence determinant, physiotherapists believed that patients became increasingly less favorable toward the use of this tool, with a significant difference (P=.04) in the means between the 2nd and 12th month of use. The mean at month 2 was 3.92 (SD 0.6), while the mean at month 12 was 3.47 (SD 0.57).

The means of the credibility construct decreased between the beginning and end of follow-up (P=.005), especially between 2 and 12 months of use (P=.01). The mean was 3.9 (SD 0.88)

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at month 0, 3.8 (SD 0.52) at month 2, and 3.23 (SD 0.55) at month 12.

The averages of the effort expectancy and price value determinants were stable. The average effort expectancy at month 0 was 4 (SD 0.61) and that at month 12 was 3.71 (SD 0.25), for P=.26. The average price value at month 2 was 2.53 (SD 0.96) and that at month 12 was 2.32 (0.87), for P>.99.

Results for the Secondary Criteria

Concerning the evaluation of the determinants and constructs of UTAUT in patients, the averages were also high initially, with an average (out of 5) performance expectancy of 4.14 (SD 0.55), effort expectancy of 4.22 (SD 0.69), social influence of 4.21 (SD 0.66), facilitating conditions of 4.18 (SD 0.59), price of 2.84 (SD 0.97), and intention of use of 3.53 (SD 0.96).

There was a decrease in the averages of the various constructs and determinants over time.

The averages for the performance expectancy determinant decreased throughout the study (P=.004), especially between the beginning of the study and 2 months of use (P=.02). The average at month 2 was 3.81 (SD 0.64), and that at month 12 was 3.75 (SD 0.55). It could be observed that patients find the tool less and less useful; the mean of the perceived usefulness construct was 4.09 (SD 0.60) at month 0 and 3.71 (SD 0.56) at month 12. The reduction in the perceived usefulness of the tool was especially true for intense exercise (P<.001), for patients to see themselves progressing (P=.01), and for use at home (P=.002), between the beginning of the study and 12 months. On the other hand, the perception of the usefulness of auditory feedback was better (P=.002) at 2 months, with a mean of 4.16 (SD 0.82), compared to the beginning of the study, when the mean was 3.58 (SD 1.03).

The intention to use decreased (P=.02) over time, especially between the 2nd month, when the mean was 2.54 (SD 1.08), and the 12th month of use, when the mean was 1.95 (SD 0.73).

Moreover, various determinants and constructs were stable during the study.

Initially, patients' self-esteem self-assessment was low, with a mean of 25.5; at the end of the study, it was considered very low, with a mean of 24.3 (Table 3).

Table 3. The change in the patients' self-esteem evaluated using the Rosenberg Self-Esteem Scale.

Month of follow-up	Mean self-esteem value (SD)	Range
Month 0	25.5 (2.6)	19-31
Month 2	26.3 (2.8)	21-34
Month 12	24.3 (2.6)	19-30

Discussion

The scores obtained by the UTAUT questionnaires were globally very high (higher than 4 out of 5 for most of the determinants), which is synonymous with good acceptability, acceptance, and appropriation of the tool. Over time, there was a downward trend in the various scores, which can be explained by many factors.

Important Expectations of the Tool

The fact that the performance expectancy is initially high is synonymous with high expectations on the part of the physiotherapists. This must be placed in the context of a neurodegenerative disease where physiotherapists can sometimes feel powerless against the inevitable degeneration of their patients' conditions. Over time, they may have been disappointed, which was probably related to a weariness of the app interface that did not evolve during the study (the serious games that had been developed for the prototype remained the same during the year the participants were followed). This phenomenon can be described as a wow effect. In marketing, this phenomenon corresponds to an initial craze for new technologies and is very frequent and well described [28].

The decrease in patients' intention to use the tool can be explained by the fact that the wow effect is more pronounced in chronically ill patients because they are typically waiting for a treatment that will stop the progression of their disease. Regular updates, different game interfaces, and web-based challenges between different patients could improve long-term adherence.

The decrease in self-esteem is statistically significant, but this is not clinically relevant because it only decreases by 1 point on average. There is only one low extreme value that does not explain alone that the average goes from low (between 25 and 30) to very low (<25). In addition, Parkinson disease is a neurodegenerative disease whose natural progression cannot be stopped by the use of a rehabilitation tool.

A Tool That is Easy to Use for Parkinson Disease and Remains So

The effort expectancy was stable during the study, which demonstrates that the activities proposed by the tool are easy and accessible to this population of patients with Parkinson disease.

The fact that the averages of the social influences determinant and the image construct decrease over time is rather positive. Once the wow-effect is over, appropriation does take place because patients consider the tool part of their daily life and unexceptional.

The scores concerning the usefulness of visual and auditory feedback (increasing significantly between month 0 and month 2) are very good, which confirms the importance of using feedback controls for the rehabilitation of gait and limb motor disorders in patients with Parkinson disease [29].

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The exercises are well explained, and the activities are easy to understand (stable and very high scores), making the tool easy to use. It reflects a positive image of rehabilitation and physical activity. It is a playful and adaptive tool with an adapted progressiveness (scores of the facilitating conditions are very high and stable).

Patients experience greater benefits when using the BYM tool compared to paper exercises and exercises alone. (very high and stable scores for the relative advantage construct).

A Study Impacted by the Economic Context of BYM

The BYM company experienced financial difficulties during this study, which resulted in a hindrance to the development and evolution of the product. This explains the decrease in the playful aspect (weariness of the proposed exercises) and credibility (lack of progressiveness) constructs.

The scores concerning the price are biased because the devices were free of charge during the study.

The decrease in intention to use can be explained by the lack of evolution of the tool and the absence of after-sales service. The study took place over 2 years (1 year of recruitment and 1 year of follow-up), which is an important length of time considering the economic context of start-ups. These results raise the question of the adaptability of clinical research methods in France to economic models that are increasingly fast and flexible to bring innovation to the health care sector.

A Recent Change of the Health Context

The last questionnaires for patients and their private physiotherapists were filled out in June 2020 (ie, at the time of the lockdown of the French population in the context of the COVID-19 pandemic). The need for telecare was increased during and after the lockdown to prevent the spread of the virus while continuing to provide the necessary care to people with chronic diseases. In this context, an application decree was issued in April 2020, published in the Journal Officiel de la République Française on April 23, 2020, concerning telecare and aimed at facilitating its use by codifying its implementation and pricing [21].

Given this unprecedented health situation, technological devices such as the BYM tool, associated with a monitoring organization via telerehabilitation, have their place in an innovative reflection on the care pathways of patients with chronic diseases. Such digitally guided self-rehabilitation devices could enable real-time monitoring of self-rehabilitation by maintaining a link between the hospital and private sector and the patients' homes. Long-term physical activity has now well-proven its effectiveness in slowing down the loss of autonomy in patients with neurodegenerative diseases [30,31]. Tools are to be developed to enable a slowing of this loss of autonomy by promoting motivation, which is often lacking in patients with Parkinson disease in connection with the impairment of dopaminergic systems. These tools can supplement the therapeutic rehabilitation arsenal, complementing other rehabilitation techniques without replacing them.

It should be noted that of all the independent physiotherapists contacted, few of them responded to the proposal to participate in this study. This shows the low enthusiasm of the private physiotherapists for the use of this tool and therefore a reluctance to change their practice. It has been shown that multidisciplinary management of patients with Parkinson disease was beneficial, with an overall improvement of motor skills, improved quality of life, and functional independence for daily life activities [32]. It is therefore important to be able to anchor this multidisciplinary practice in the health territory network via technological devices associated with telecare. During the study, many independent physiotherapists did not take advantage of this telemedicine offer, but their attitudes may have changed in the last few months [33].

Conclusion

In conclusion, the acceptability, acceptance, and appropriation of the BYM tool are very high among private physiotherapists as well as patients, despite the lack of evolution of the tool during the study. It is important to present BYM as a rehabilitation and movement training tool and not as a substitute for physiotherapy management. This implies a global reflection on the place of new technologies within the patient's care pathway, a real-time link between the hospital sector, the private sector, and the home. The recent health context requires a profound change in the organization of the care pathway for people with chronic diseases in particular, and this type of technological tool could accompany the increased use of telemedicine.

Conflicts of Interest

None declared.

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Abbreviations

BYM: Beyond Your Motion
UPDRS: Unified Parkinson’s Disease Rating Scale
UPDRS M-EDL: Unified Parkinson’s Disease Rating Scale Motor Aspects of Experiences of Daily Living
UTAUT: Unified Theory of Acceptance and Use of Technology

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Case Report

Immersive Virtual Reality and Vestibular Rehabilitation in Multiple Sclerosis: Case Report

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Abstract

Background: Dizziness and imbalance are common and disabling symptoms in patients with multiple sclerosis (MS) and are caused by a central, peripheral, or mixed vestibulopathy. Central vestibular disorder is the most frequently reported vestibular problem in the MS population due to demyelination. Vestibular rehabilitation ameliorates these symptoms and their repercussions and improves quality of life. Immersive virtual reality (VRi) is an emerging tool in this field; however, no previous research has been performed studying its effects in MS.

Objective: The aim of this study was to apply a VRi vestibular training protocol to a patient with MS and assess the effects induced by the experimental intervention.

Methods: This case study included a 54-year-old woman with relapsing-remitting MS. We developed a standardized VRi exercise protocol for vestibular rehabilitation based on the gold-standard Cawthorne-Cooksey vestibular training protocol. The 20-session intervention was made up of 10 initial sessions and 10 advanced sessions. Each 50-minute session was performed two to three times per week for 7 weeks. Four evaluations were carried out over the study period: at baseline (T0), between initial and advances phases (T1), postintervention (T2), and 1 month after the experimental procedure (T3). The research outcomes were dizziness, balance, gait, impact of fatigue, quality of life, repercussions in muscular tone, and usability of the head-mounted display device.

Results: After implementing the VRi vestibular protocol, improvements were seen in the following patient parameters: Dizziness Handicap Inventory score (62 points at T0; 4 points at T2); Berg Balance Scale score (47 points at T0; 54 points at T2); instrumented Timed Up and Go time (8.35 seconds at T0; 5.57 seconds at T2); muscular tone of the erector spinae, rectus femoris, and soleus; Modified Fatigue Impact Scale score (61 points at T0; 37 points at T2); and Multiple Sclerosis Quality of Life-54 values (67.16% in the physical health area at T2; 33.56% in the mental health area at T2). The patient rated the usability of the system as 90%, based on the System Usability Scale, and gave the system a grade of A.

Conclusions: Although further research is needed, this study provided initial evidence that the first VRi vestibular protocol for the MS population can improve dizziness, balance, gait, impact of fatigue, quality of life, and muscular tone through an exergame intervention. This study may help establish a standardized VRi protocol for vestibular rehabilitation.

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KEYWORDS

immersive virtual reality; vestibular rehabilitation; multiple sclerosis; exergames

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Introduction

Relapsing-remitting multiple sclerosis (RRMS) is the most frequent phenotype of multiple sclerosis (MS) and is characterized by relapse or attacks [1,2]. Among the symptoms or sequelae of relapse are vertigo, dizziness, and postural balance disorders [3]. Vertigo is defined as a rotative illusion that can affect 20% to 50% of patients with MS along the disease course [4,5]. Dizziness is usually accompanied by balance problems and affects 49% to 59% of patients with MS [6]. Central, peripheral, or mixed vestibular disorders are possible etiologies in patients with MS, which explain the presence of dizziness, vertigo, and postural disorders [5,7,8]. In spite of the peripheral affection of the vestibular system being quite common in MS, central vestibular disorder is the most common due to the demyelination process in MS [8,9]. The scientific literature has reported that the MS population could benefit from the effects on dizziness and postural balance of vestibular rehabilitation, whether the vestibular lesion is central, peripheral, or a combination of the two [10]. Vestibular rehabilitation involves exercises targeted to improve vertigo, dizziness, and imbalance and its repercussions during basic activities of daily living [11]. Vestibular exercises are performed to train the vestibulo-ocular reflex (VOR) and vestibulo-spinal reflex (VSR), promoting the neuroplastic mechanisms of adaptation, habituation, and substitution [12,13]. Adaptation will train the VOR through head and ocular movements. Habituation aims to eliminate dizziness symptoms by exposing the subject to several environments and repetitive exercises. Substitution compensates for vestibular deficits through visual or somatosensory systems [14,15].

An emerging tool within vestibular rehabilitation and neurorehabilitation is immersive virtual reality (VRi) [16,17], which immerses patients through a head-mounted display (HMD) in a 360° virtual environment and enables interactions for achieving a specific objective [18]. Some of the advantages of VRi in rehabilitation are the direct auditory and visual feedback provided to the patient, multitasking, a wide variety of environments, and the sense of presence and immersion [18-21]. Exergames are a combination of exercises and video games; these are the principal choice of intervention in VRi for improving the physical condition of users [22,23]. Exergames provide task-oriented training, motivation, and distraction during exercise [22,24]. A recent systematic review reported these additional clinical benefits from VRi compared to conventional vestibular rehabilitation [25]. The same study supported the need for designing a standardized VRi vestibular intervention protocol [25-27].

Regarding the absence of a VRi vestibular exercise program for the MS population and the need to achieve a standardized VRi protocol for vestibular rehabilitation, we chose to design and develop both a program and a protocol. To the best of our knowledge, this is the first VRi vestibular exercise protocol for the MS population. Thus, the primary goal of research was to apply this innovative intervention and evaluate its effects on dizziness and balance in a patient with RRMS. Changes in gait parameters, the impact of fatigue, quality of life, muscular tone repercussion, and usability were assessed as secondary objectives.

Methods

Ethics Statements

Ethical approval was provided by the Regional Ethical Review Board in Andalucía, Spain, on March 25, 2020 (ID 2148-N-19). Before recruitment, the participant was provided with written and oral information. Informed consent, which adhered to the principles of the Declaration of Helsinki, was given by the subject in order to be included in the experimental intervention.

Outcomes and Measurements

Four evaluations of the following five outcomes were performed to detect changes in the patient: dizziness, postural balance, gait parameters, fatigue impact, and quality of life. These assessments were carried out at baseline (T0), between initial and advanced phases (T1), postintervention (T2), and 1 month after the experimental procedure (T3). After VRi, the vestibular protocol usability of the Oculus Quest HMD (Facebook Technologies) was measured using the System Usability Scale (SUS) and a semistructured interview.

Patient Information

The participant was a 54-year-old woman who was diagnosed with RRMS in 2013 by an expert neurologist and met the McDonald diagnostic criterion. The patient's Mini-Mental State Examination score was 25 out of 30 due to a memory impairment caused by an MS attack. Her Expanded Disability Status Scale score was 3.0 out of 10.0, which indicated that ambulation was preserved without a walking aid. In 2019, she suffered from an MS attack combined with vertigo and nausea, which lasted more than 24 hours and was unassociated with a specific postural position of onset. Furthermore, in a posterior magnetic resonance imaging (MRI) scan, demyelinating lesions were observed on the right lateral margin of the fourth ventricle, where vestibular nuclei are located [28]. This MRI finding could be related to the vertigo episode. Considering the duration and characteristics of the vertigo episode, along with a negative semicircular canal affection dismissed by the Dix-Hallpike maneuver and Miniconi test, a central vestibular disorder was confirmed. At the initial evaluation, the participant reported severe dizziness (62/100 points) as assessed by the Dizziness Handicap Inventory (DHI) [29,30], accompanied by postural problems and a reluctance to move her head while walking or performing abrupt cephalic movements. Balance examination was carried out through the Berg Balance Scale (BBS) [31], where the participant obtained a total of 47 out of 56 points. It is necessary to highlight the existence of a pronounced imbalance in three specific conditions of the scale: Romberg with closed eyes, tandem position, and single-leg support. The patient was unable to reach or maintain the first two conditions, and she was only able to stand for less than 10 seconds during the last one. A combined analysis by inertial sensors—myoMOTION inertial sensors and software (Noraxon)—and the instrumented Timed Up and Go (iTUG) test [32,33] was carried out to determine the baseline gait parameters of the patient with RRMS. The iTUG global time

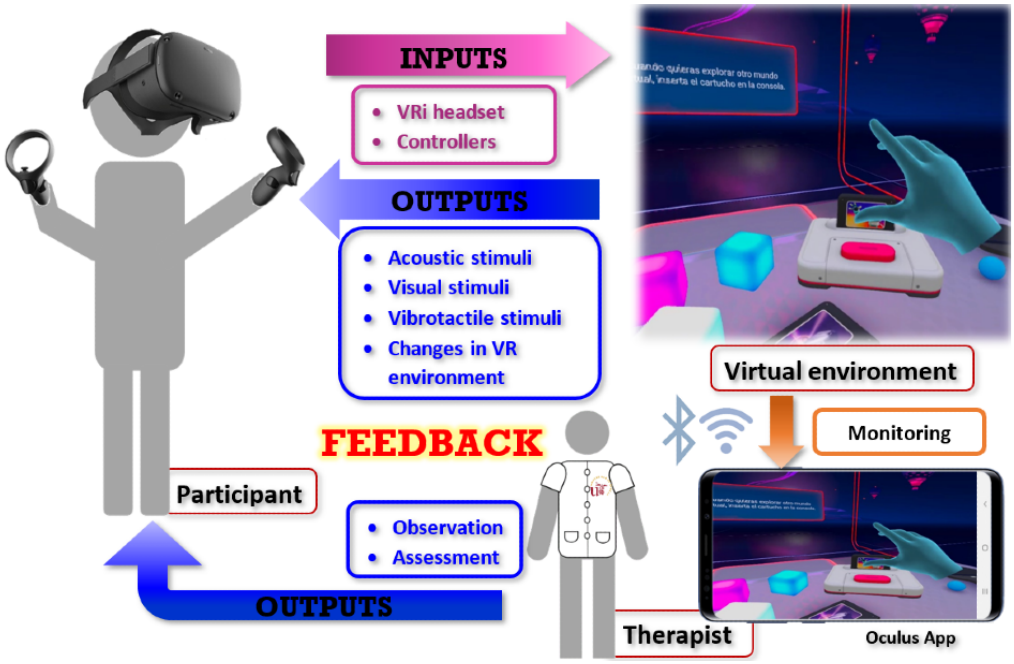
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was 8.35 seconds; the iTUG times for the first and second 180° turns were 0.90 seconds and 0.69 seconds, respectively. Additionally, the sit-to-stand transition time was 1.20 seconds, and the stand-to-sit transition time was 1.03 seconds. The mean gait speed was 1.2 km per hour, and the step cadence was 106 steps per minute. The complete analysis of the gait parameter data is shown in the Results section. The patient's perceived fatigue impact was 61 out of 84 points on the Modified Fatigue Impact Scale (MFIS) [34]. Quality of life before the experimental intervention was measured using the Multiple Sclerosis Quality of Life-54 (MSQoL-54) [35]; the patient obtained a result of 45.62% for physical health and 25.75% for mental health. Bilateral muscular tone assessment in the erector spinae, the rectus femoris, and the soleus was performed using the MyotonPRO digital palpation device (Myoton AS) [36] during standing after vestibular stimulation through the Miniconi test [37]. All baseline data are listed in detail in the Results section.

Materials and Intervention

The Oculus Quest is a wireless VRi device with high-quality graphics that is economically affordable, as compared to other options on the market [38,39]. VRi systems work via an input and output flow (Figure 1). Inputs are recorded by a VRi headset and controllers in response to external actions of the participant; these inputs then induce changes in the virtual environment through the software. Outputs are changes in the virtual environment providing the subject with a multisensory stimulation source (ie, visual, acoustic, and vibrotactile information). Minimal requisites to start interacting with the Oculus virtual environment include a space greater than 2 × 2 meters to ensure a safe play area and a Wi-Fi connection. The experimental intervention was carried out at the participant's home and was supervised by a therapist.

Figure 1. Inputs and outputs in immersive virtual reality (VRi) systems.



Selected VRi exergames are freely available in the Oculus App and include the following: First Steps, Beat Saber, and Sports Scramble. The environments in First Steps include the main room of First Steps, Dance with Robot, and Shots in Space. The first one is a room where the subject can interact with virtual objects (cubes, paper planes, etc). In Dance with Robot, the patient must dance while following some orders. Finally, Shots in Space is a shooter game in which the participant shoots random targets that move over a spatial station (Figure 2). Beat Saber is a rhythm game in which blocks are cut in a specific direction with sabers (Figure 3). Sports Scramble is a sports game where the user can play tennis, baseball, and bowling, with funny virtual elements (eg, a cheese ball instead of a bowling ball; Figure 4). The complete VRi vestibular intervention was carried out over 20 sessions, which occurred two to three times per week over 7 weeks. Each session lasted for 50 minutes. The VRi vestibular protocol can be divided into initial and advanced phases of 10 sessions each. All above-mentioned vestibular exercises were designed to enhance the neuroplastic mechanisms of adaptation, habituation, and substitution and to train the user's VOR and VSR. Also, to design and create vestibular exercises for this new VRi vestibular protocol, we considered the gold-standard vestibular training from Cooksey [40] as well as key points from Han et al [12] and Whitney and Sparto [13]. Each session from both phases consisted of 15 exercises, which were performed from the easiest to the most complex. Therefore, this gradual exposure of the patient to exercises during sessions prevents the development of dizziness and cybersickness. Exercises and the duration of both phases are described in Table 1. The initial phase consisted of three blocks of exercises, two of which were done seated and the last of which was done in the standing position. Exercises in the advanced phase were performed by disturbing the somatosensory system, reducing the support base, using alternating single-leg support, adopting the tandem position, or adding an unstable surface. This was done to

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enhance the participation of the vestibular system in maintaining postural balance by the substitution mechanism. New vestibular parameters were added in this second phase of the intervention with quicker head and eye movements, sit-to-stand transitions or vice versa, and 360° turns.

Figure 2. Study participant interacting with First Steps virtual environments. Main room of First Steps (top); Dance with Robot (middle); Shots in Space (bottom).

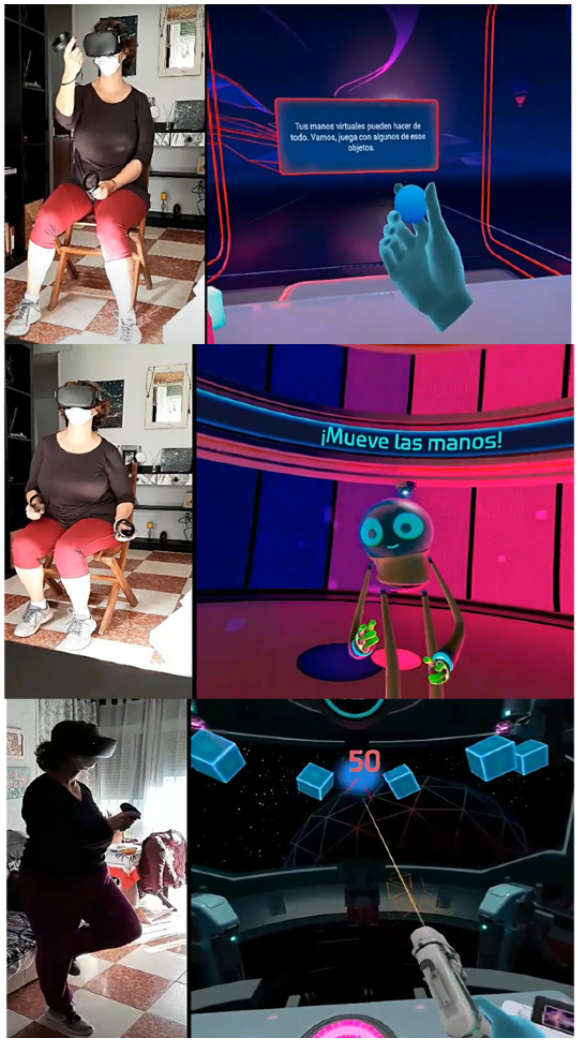
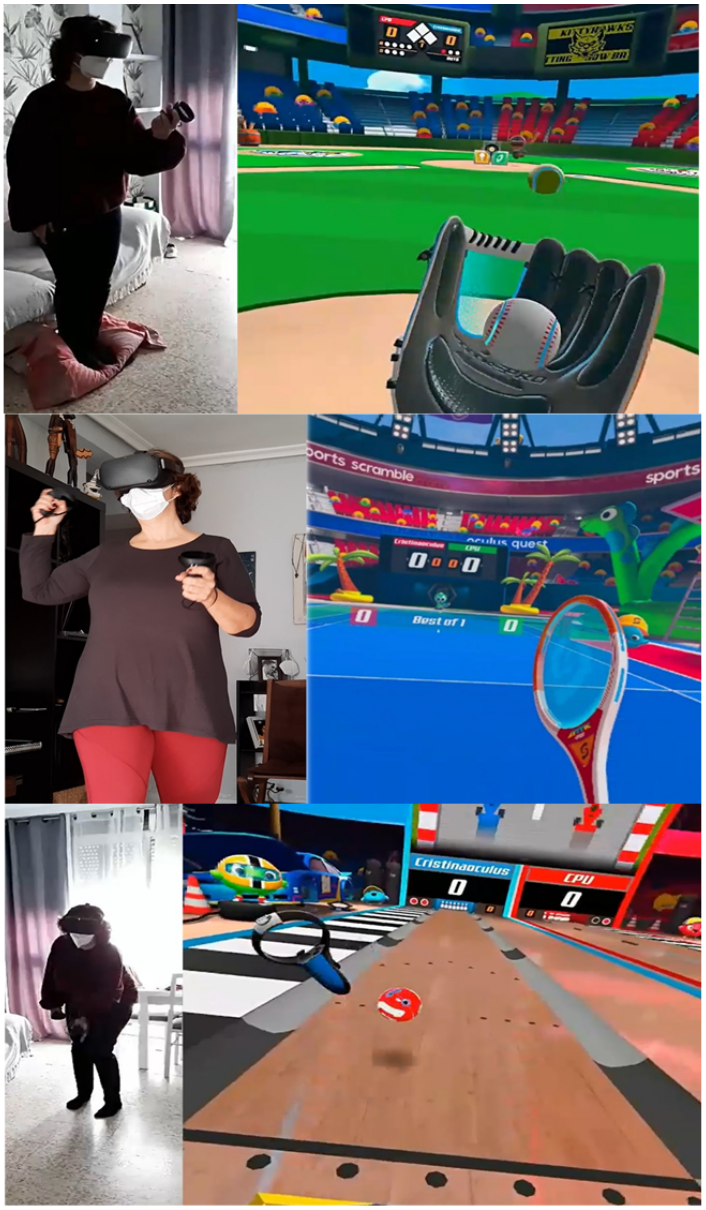


Figure 3. Study participant interacting with Beat Saber environment.



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Figure 4. Study participant interacting with Sports Scramble virtual environments. Baseball (top); tennis (middle); bowling (bottom).



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Table 1. Exercises performed as part of the immersive virtual reality vestibular intervention.

Phases and exercise instructions	Virtual environments	Duration	Repetitions
Initial phase: 50 minutes (45 min of intervention + 5 min of rest)			
Before rest time: 24 minutes (all First Steps environments and Beat Saber)			
Take the ping-pong ball and put it in front of your face and move it closer and farther	Main room of First Steps	11 minutes[a]	10 slow repetitions, then 10 fast repetitions
Move an object in front of your eyes and follow it; shoot targets that appear in the exergame	Main room and Shots in Space (First Steps)	Main room: 11 minutes; Shots in Space: 7 minutes[b]	Main room: 10 slow repetitions, then 10 fast repetitions; Shots in Space: 1 repetition for each gun
Shoot targets that appear randomly inside the virtual environment	Shots in Space (First Steps)	7 minutes	1 repetition for each gun
Cut blocks with a saber while your head is fixed; hit a ball in the main room and fixate your gaze on its movement while your head is fixed	Beat Saber and main room of First Steps	Beat Saber: 3 minutes; main room: 11 minutes	Beat Saber: 1 repetition; main room: 10 slow repetitions, then 10 fast repetitions
Take a block from the virtual desk, bring it to the floor, and then move it above your head, while staring at it	Main room of First Steps	11 minutes	10 slow repetitions, then 10 fast repetitions
Shrink your shoulders while dancing with a robot	Dance with Robot (First Steps)	3 minutes	1 repetition
Bend forward and move a virtual block between your knees	Main room of First Steps	11 minutes	10 slow repetitions, then 10 fast repetitions
After rest time: 21 minutes (Beat Saber and Sports Scramble)			
Sit down and stand up, and vice versa, with your eyes open	Beat Saber	3 minutes	1 repetition
Stand up and move to the right while standing	Bowling (Sports Scramble)	6 minutes[c]	3 repetitions
Stand up and move to the right or the left while taking a bowling ball	Bowling (Sports Scramble)	6 minutes	3 repetitions
Throw or hit a ball in front of your face	Baseball and tennis (Sports Scramble)	Baseball: 8 minutes; tennis: 4 minutes	Baseball: 1 repetition; tennis: 1 repetition
Throw the ball to hit the bowling pins under knee level	Bowling (Sports Scramble)	6 minutes	3 repetitions
Advanced phase: 50 minutes (45 min of intervention + 5 min of rest)			
Before rest time: 24 minutes (main room of First Steps)			
Take a block from the virtual desk and when you stand up, throw it at a virtual sign situated inside the virtual environment	Main room of First Steps	2 minutes	10 repetitions
Move a virtual block at eye level; take a virtual block and throw it from one hand to the other	Main room of First Steps	5 minutes	10 repetitions moving the object, then 10 repetitions throwing the object
Take a virtual block, turn 360°, and throw the block to a located target in the environment	Main room of First Steps	5 minutes	10 repetitions to the right, then 10 repetitions to the left
In a standing position with a narrow base of support, hit a ball and follow its movements with your head	Main room of First Steps	2 minutes	5 repetitions (eg, 1 repetition lasts until the ball stops)
Take the ping-pong ball and put it in front of your face, then move it closer and farther away	Main room of First Steps	5 minutes	10 slow repetitions, then 10 fast repetitions

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Phases and exercise instructions	Virtual environments	Duration	Repetitions
Take the ping-pong racket and hit blocks to one side and the other, following them with your head	Main room of First Steps	2 minutes	15 repetitions
Take a virtual block from the desk, then move it to the floor and bring it above your head while standing on a foam surface	Main room of First Steps	3 minutes	10 repetitions
After rest time: 21 minutes (Shots in Space in First Steps, Beat Saber, and Sports Scramble)			
Shoot targets with a single gun while supported on a single leg, then the other	Shots in Space (First Steps)	2 minutes	1 repetition
Shoot targets with a double gun while maintaining a tandem position	Shots in Space (First Steps)	2 minutes	1 repetition
Shoot targets with a machine gun while standing on a foam surface	Shots in Space (First Steps)	2 minutes	1 repetition
Hit and cut blocks in a specific direction with sabers while standing on a foam surface; the head is fixed while you make ocular movements	Beat Saber	3 minutes	1 repetition
Throw the ball in a baseball stadium while standing on a foam surface	Baseball (Sports Scramble)	4 minutes	1 repetition
Bowl with your feet together	Bowling (Sports Scramble)	2 minutes	1 repetition
Bowl while standing on a foam surface	Bowling (Sports Scramble)	2 minutes	1 repetition
Walk down a bowling alley while moving your head from side to side and the throw the bowling ball	Bowling (Sports Scramble)	4 minutes	2 repetitions

[a]Within this set of exercises, all exercises in the main room of the First Steps environment combined were performed in 11 minutes.

[b]Within this set of exercises, all Shots in Space exercises combined were performed in 7 minutes.

[c]Within this set of exercises, all bowling exercises in Sports Scramble combined were performed in 6 minutes.

Results

All outcome results at T1, T2, and T3, as compared to T0, are shown in Table 2.

Regarding baseline dizziness that evolved from a severe condition (DHI score = 62 points) as compared to the absence of it after the combined VRi vestibular protocol, there was a reduction of 58 points on the DHI (T2 DHI score = 4 points). This improvement in dizziness examined by the DHI continued for 1 month after the end of the VRi sessions.

Between phases of the experimental intervention, no changes were assessed for postural balance, but balance impairments improved postintervention. The participant's BBS score reached a maximum of 56 points at T3. Pathological conditions of Romberg with closed eyes, unstable single-leg support, and the inability to stay in the tandem position were reverted by achieving stable balance.

The participant ameliorated their global iTUG time by 2.35 seconds after the intervention, adding 0.43 seconds to this time 1 month after the VRi program. The rest of the iTUG parameters (ie, sit-to-stand transition and vice versa and both 180° turns) showed a remarkable reduction, as observed in Table 2. Stance and swing phase equated to 50% in both feet, while double support time was 291 milliseconds less in T2 compared to baseline. The minor stride time and the higher stride length were recorded in T3 as 862 milliseconds and 63 centimeters, respectively. The speed of gait and step cadences increased by 1.4 km per hour and 45 steps per minute in T3 from T0, respectively.

Regarding fatigue impact of the subject, a score of 38 was considered when determining the difference between fatigued and nonfatigued [41]. The MFIS score reached 35 points in T1 and 37 points in T2, which reflected a nonfatigued perception of the patient, but this improvement was not maintained 1 month after the intervention ended (MFIS score = 47 points).

The study participant experienced a gain in physical health of 21.54%, as measured by the MSQoL-54, when baseline and postintervention data were assessed. Then, 1 month later, her physical quality of life reached 69.44%, and her mental health reached 42.79%.

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Table 2. Results and changes in study outcomes at the four measurement points.

Outcome (measurement)	Measurement point			
	Baseline (T0)	Between initial and advanced phases (T1)	Postintervention (T2)	1 month after the experimental procedure (T3)
Dizziness (Dizziness Handicap Inventory[a]), points				
Global	62	26	4	6
Physical	20	18	4	6
Emotional	14	2	0	0
Functional	28	6	0	0
Postural control (Berg Balance Scale[b]), points				
Global	47	47	54	56
Spaciotemporal parameters of gait (instrumented Timed Up and Go test)				
Total time, seconds	8.35	7.00	6.00	5.57
Sedestation to bipedestation time, seconds	1.20	0.97	0.95	0.77
First turn, seconds	0.90	0.91	0.79	0.78
Second turn, seconds	0.69	0.61	0.58	0.50
Bipedestation to sedestation time, seconds	1.03	0.64	0.58	0.50
Stance phase, left foot, %	70.8	71.7	68.8	51.1
Stance phase, right foot, %	70.9	66.3	65.5	49.6
Swing phase, left foot, %	29.2	28.3	31.2	48.9
Swing phase, right foot, %	29.1	33.7	34.5	50.4
Double support time, ms	631	329	340	79
Stride length, cm	40	46	50	63
Velocity, km/h	1.2	1.6	1.9	2.6
Stride time, ms	1205	1031	941	862
Step cadence, steps/min	106	129	298	151
Impact of fatigue (Modified Fatigue Impact Scale[c]), points				
Global	61	35	37	47
Physical effort	21	8	7	15
Cognoscitive effort	36	24	29	30
Psychosocial effort	4	3	1	2
Quality of life (Multiple Sclerosis Quality of Life-54), %				
Physical health area	45.62	53.14	67.16	69.44
Mental health area	25.75	36.15	33.56	42.79
Muscular tone (MyotonPRO[d]), Hz				
Right erector spinae	13.0	12.7	13.1	12.3
Left erector spinae	12.9	12.3	11.7	11.6
Right rectus femoris	13.9	12.4	13.5	12.4
Left rectus femoris	13.7	11.8	14.4	12.5
Right soleus	26.3	23.7	21.9	21.7
Left soleus	24.0	21.4	20.6	19.4
Usability (System Usability Scale), %	N/A[e]	N/A	90[f]	N/A

[a]Dizziness Handicap Inventory scores range from 0 to 100 for the global scale; the physical subscale ranges from 0 to 28; the emotional and functional

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subscales range from 0 to 36.

[b]Berg Balance Scale scores range from 0 to 56: 41-56 (low fall risk); 21-40 (medium fall risk); 0-20 (high fall risk).

[c]Modified Fatigue Impact Scale scores range from 0 to 84; the physical effort subscale ranges from 0 to 36; the cognoscitive effort subscale ranges from 0 to 40; the psychosocial effort subscale ranges from 0 to 8.

[d]The MyotonPRO takes three consecutive measurements and reports the final value as the mean; however, the SD is not reported.

[e]N/A: not applicable; the System Usability Scale was only administered at T2.

[f]A 90% value on the System Usability Scale represents a grade of A.

A reduced trend for muscular tone was found in the MyotonPRO data for the three examined muscles. In some cases, there were disparities, primarily in the left erector spinae and bilateral rectus femoris at T2. However, all mean results for the erector spinae, the rectus femoris, and the soleus were lower at T3 compared to T0. The tone of the erector spinae was 19.2% lower for the right side and 21.2% lower for the left side when compared to baseline. Also, 1 month after the experimental intervention, decreases in tone compared to the baseline data were recorded in the rectus femoris (T3 right: –11.4%; left: –9.2%) and in the soleus (T3 right: –19.2%; left: –21.2%).

Postintervention (T2) usability of the Oculus Quest device and perceived satisfaction with the experimental intervention was assessed using the SUS and a semistructured interview. A SUS score of 90% for usability and a grade of A were marked by the participant with RRMS for the Oculus Quest headset. During the interview process, the following impressions were reported by the patient:

> *I enjoyed the intervention through the virtual device so much. I would continue with it.*
>
> *These kinds of physiotherapy sessions are more motivating than usual ones in which I get bored really soon because exercises are repetitive.*
>
> *I have improved my postural balance a lot; now I can take a shower with my eyes closed without falling or I can put my pants on without sitting down.*

Discussion

Principal Findings

The VRi vestibular training protocol was successfully performed by a participant with RRMS, improving their basal conditions of dizziness, postural balance, gait, fatigue, quality of life, and muscular tone repercussion after the intervention.

HMDs have been described as proper tools with which to apply vestibular rehabilitation by previous studies [16,39,40]. One of the reasons why VRi devices have become a suitable option is because of their accurate tracking systems that record movements by gyroscopes, magnetometers, and accelerometers in six degrees of freedom [42]. Likewise, the control of movement, visual information, and changes in the virtual environment are broken down into cephalic movements, just as the information is provided by the vestibular system [42,43]. Furthermore, thanks to the characteristics of these devices, the neuroplastic mechanisms by which the vestibular system recovers can be trained. Among them, habituation stands out due to the large number of environments to which the subject is exposed and because of the possibility of performing repetitive exercises in a motivational way [12,13].

Improvements in dizziness conditions measured by the DHI have been reported before by Micarreli et al [44] and Viziano et al [45] in peripheral vestibular impairments after combined VRi and vestibular rehabilitation. In these studies, the HMD intervention was implemented using a smartphone; however, commercial HMDs, such as the Oculus Quest, present higher usability and graphic quality compared to these devices [46,47]. Both groups of researchers implemented home-based virtual reality (VR) vestibular programs combined with conventional vestibular therapy in their experimental groups to ensure adherence to treatment. The adherence and security related to these home-based exercise VR programs should be studied deeply [48]. Even though the selected VR devices were wireless and portable, the home-based intervention was discarded. Despite the intervention being performed at the subject's home due to their physiological characteristics (ie, imbalance and dizziness) and progression of exercises (unstable surface, tandem, etc), the therapist needed to be next to the patient to prevent falls. Also, due to her memory problems, adherence to treatment was not guaranteed, which also required monitoring, as described by Micarreli et al [44] and Viziano et al [45].

Moreover, dizziness is related to imbalance or postural problems, like positive Romberg with closed eyes, unstable single-leg support, or difficulty in the tandem position. Equally, dizziness during cephalic movements while walking is one of the main clinical manifestations in vestibular disorders [49]. Global postural control ameliorated after the VRi intervention was conducted. BBS scores increased by 7 points when comparing measurements at T2 with those at T0, and the maximum score was reached 1 month later by the participant. Once the intervention finished, the patient with RRMS was able to stand in the eyes-closed Romberg position and maintain single-leg support and the tandem position for more than 30 seconds. Ozkul et al [50] confirmed better results in postural balance after an experimental intervention with the Oculus Quest HMD after 16 sessions, as compared to conventional balance training. However, this author did not examine vestibular rehabilitation effects; reported results were similar to those obtained in this case report. In the vestibular framework, Yeh et al [51] and Hsu et al [52] reported better balance performance assessed by posturography in Meniérè disease (ie, peripheral disorder) after a VR vestibular intervention that combined Wii, Kinect, a smartphone HMD, and big screens. Better balance and dizziness were reported by Hsu et al [52] in VR groups compared to groups performing Cawthorne-Cooksey traditional exercises (P<.001).

To the best of our knowledge, this is the first study to examine gait parameters in a subject with MS to evaluate changes caused by vestibular training. Gait parameter assessment was carried out because of its remarkable role during walking [53]. The

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higher gait speed and step cadence during the iTUG test seen in this case study could be related to enhancement of the postural balance of the subject, due to a better vestibular function [54]. A reduction in double stance time could also be explained by the greater performance of the vestibular system [55]. Other studies based on vestibular training for peripheral vestibular problems support the gait data we collected during the iTUG test for global time [56,57]. According to Witchel et al [58], a lower sit-to-stand transition time could be related to greater balance performance, as reported in our case study. Additionally, a vestibular intervention has been shown to be effective in the achievement of a shorter time to perform 180° turns as measured by the iTUG test [59]. In this case study, there was a reduction of 0.11 seconds in both turns after the experimental intervention.

Fatigue is one of the most disabling symptoms among patients with MS and can contribute to postural disorders or a worse performance in the iTUG test [60,61]. In this case, better results in the iTUG test and balance could be related to lower fatigue impact. Vestibular rehabilitation and VR interventions have shown positive effects on fatigue impact in people with MS [50,62]. Dizziness, postural balance impairments, and fatigue are considered the most disturbing symptoms affecting patients' quality of life [63]. Therefore, after improvement in the above-mentioned symptoms, an increase in quality of life, as measured by the MSQoL-54, was registered in this participant; this was also seen in Ozgen et al [56]. In the Ozgen et al study, after 16 sessions (20 minutes per session) of vestibular balance and ambulation exercises to ameliorate vestibular disturbances in a sample of patients with MS, an improvement in quality of life was recorded within the group, as compared to no intervention (P<.001) [56].

Regarding muscular tone repercussion after VRi vestibular training, disparities obtained in the left erector spinae and rectus femoris at the end of the intervention might have been related to the demyelination process that is characteristic of patients with MS, which alters VSR [64]. Also, the general reduction of muscular tone found in the aforementioned muscles may be explained by better balance performance and decreasing VSR activity, according to Forbes et al [65,66].

Lubetzky et al [67] declared acceptable usability (73% in the SUS) for the forerunner of the Oculus Quest, as compared to 90% usability reported by our participant. Furthermore, that author confirmed that the existence of wires reduced immersion and the presence of the users within the VRi environment. This problem is solved with the wireless Oculus Quest HMD. Additionally, thanks to the selected HMD and the design of our vestibular exercises, intrinsic Cawthorne-Cooksey protocol limitations can be addressed. These limitations are overcome by adopting a multimodal approach, providing extrinsic feedback, task-oriented focus, and exposure to different environments [68,69]. Also, considering the VRi vestibular protocol design and the portable and wireless HMD device, one future field of research could be telerehabilitation strategies. This field of study is still poorly investigated regarding vestibular rehabilitation and VR.

Limitations and Strengths

The main limitations of this study were derived from the study design; thus, selection bias may have been present, and it is not possible to establish cause-and-effect relationships nor to make general statements regarding the MS population. Another limitation would be the question as to whether this intervention would be favorable in all phenotypes of MS or in central, peripheral, or mixed vestibular disorders. Because of this, the results must be interpreted with caution. To provide additional scientific evidence, a randomized controlled trial will be performed.

A principal strength of this study is that it provides the first standardized VRi vestibular training protocol for an MS population. Thanks to the design of the exercises and the characteristics of the selected HMD, the limitations of the gold-standard Cawthorne-Cooksey protocol are overcome. This innovative VRi vestibular protocol was designed to allow its implementation at clinic, hospital, and home and as a telerehabilitation strategy. In addition to the expected effects of vestibular rehabilitation, this protocol shows benefits from VRi. Lastly, the selected exergames are freely available, which allows professionals who have HMD devices to implement this VRi vestibular protocol without additional costs.

Conclusions

The first standardized VRi vestibular protocol based on a gold-standard protocol was carried out on a subject with RRMS. The protocol showed promising results for dizziness, postural balance, gait, fatigue, and quality of life after the experimental intervention, although the results should be interpreted with caution due to the design of the study. The intervention described in this case study could set a precedent for future VRi vestibular interventions for vestibular disorders, specifically in the MS population. To achieve solid results in relation to this innovative protocol, it is necessary for further research to be conducted, such as a randomized controlled trial. Another future approach that could evaluate the effects of this VRi vestibular intervention would be a telerehabilitation strategy.

Authors' Contributions

CGM, MDCV, and MJCH conceptualized and designed the study and the intervention. CGM recruited the study participant. MDCV assessed the clinical outcomes. MJCH analyzed the participant data. CGM wrote the first draft of the manuscript with critical input from MDCV and MJCH. MDCV, MJCH, JCHR, LMFS, and IEP contributed significantly to the revision of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BBS: Berg Balance Scale
DHI: Dizziness Handicap Inventory
HMD: head-mounted display
iTUG: instrumented Timed Up and Go
MFIS: Modified Fatigue Impact Scale
MRI: magnetic resonance imaging
MS: multiple sclerosis
MSQoL-54: Multiple Sclerosis Quality of Life-54
RRMS: relapsing-remitting multiple sclerosis
SUS: System Usability Scale
T0: baseline
T1: between initial and advanced phases
T2: postintervention
T3: 1 month after the experimental procedure
VOR: vestibulo-ocular reflex
VR: virtual reality
VRi: immersive virtual reality
VSR: vestibulo-spinal reflex

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Original Paper

A Serious Puzzle Game to Enhance Adherence to Antirheumatic Drugs in Patients With Rheumatoid Arthritis: Systematic Development Using Intervention Mapping

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Abstract

Background: Patients' implicit attitudes toward medication need and concerns may influence their adherence. Targeting these implicit attitudes by combining game-entertainment with medication-related triggers might improve medication adherence in patients with rheumatoid arthritis (RA).

Objective: The aim of this study was to describe the systematic development of a serious game to enhance adherence to antirheumatic drugs by using intervention mapping.

Methods: A serious game was developed using the intervention mapping framework guided by a multidisciplinary expert group, which proceeded along 6 steps: (1) exploring the problem by assessing the relationship between medication adherence and implicit attitudes, (2) defining change objectives, (3) selecting evidence-based behavior change techniques that focused on adjusting implicit attitudes, (4) designing the intervention, (5) guaranteeing implementation by focusing on intrinsic motivation, and (6) planning a scientific evaluation.

Results: Based on the problem assessment and guided by the Dual-Attitude Model, implicit negative and illness-related attitudes of patients with RA were defined as the main target for the intervention. Consequently, the change objective was "after the intervention, participants have a more positive attitude toward antirheumatic drugs." Attention bias modification, evaluative conditioning, and goal priming were the techniques chosen to implicitly target medication needs. These techniques were redesigned into medication-related triggers and built in the serious puzzle game. Thirty-seven patients with RA tested the game at several stages. Intrinsic motivation was led by the self-determination theory and addressed the 3 needs, that is, competence, autonomy, and relatedness. The intervention will be evaluated in a randomized clinical trial that assesses the effect of playing the serious game on antirheumatic drug adherence.

Conclusions: We systematically developed a serious game app to enhance adherence to antirheumatic drugs among patients with RA by using the intervention mapping framework. This paper could serve as a guideline for other health care providers when developing similar interventions.

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KEYWORDS

medication adherence; serious game; eHealth; rheumatoid arthritis; intervention mapping; intervention development

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Introduction

Rheumatoid arthritis (RA) is an autoimmune disease characterized by symmetric chronic polyarthritis which, if untreated, leads to pain, joint damage, and decreased quality of life [1,2]. The cornerstone of RA treatment is the use of antirheumatic drugs (disease-modifying antirheumatic drugs [DMARDs]), which reduce disease activity, radiological progression, and increases patient's functioning [3,4]. These benefits are not achieved when patients are nonadherent to their long-term therapy [5,6]. It is estimated that around one-third of the patients with RA are nonadherent to antirheumatic drug therapy [7-9]. As such, achieving medication adherence remains a major challenge for a substantial proportion of patients with RA. Understanding medication nonadherence and its causes helps to identify targets for the development of adherence interventions. Practical barriers (eg, forgetfulness, costs) and patient's attitudes toward medication (eg, balance between necessity and concerns) are associated with medication nonadherence [10,11]. Thus, these factors have frequently been the main target of interventions aiming to improve adherence [12]. Unfortunately, adherence interventions have been only partly effective [13-16].

Part of this ineffectiveness might be because the medication-taking behavior is not yet fully elucidated. Behavioral intentions such as taking medication are driven by a person's explicit (conscious) and implicit (unconscious) attitudes [17]. These attitudes do not necessarily have to be congruent. Someone might explicitly say that medication helps alleviate symptoms but implicitly regard medication as chemical rubbish [17,18]. Habitual behavior, like medication-taking behavior, happens mainly on an unconscious level and is more likely to be guided by implicit attitudes [19]. Therefore, targeting implicit attitudes might be an effective strategy to improve medication adherence.

Implicit attitudes are targeted by reinterpretation training, that is, exercising the brain to interpret a stimulus differently [20]. This can, for instance, be achieved by performing tasks that lead to pairing of a medication stimulus with another positive stimulus [21]. Such a reinterpretation training needs rigorous and repetitive exercising to be successful or, in other words, a multidose intervention is required. eHealth can be a suitable mode of delivery for a multidose intervention as it is easily accessible and allows patients to perform these tasks at a convenient time and place. Retention of a multidose intervention is best achieved when participants are intrinsically motivated to prevent dropout prior to the effect of the intervention being reached.

Motivation can be maintained by formatting the intervention as a serious game [22,23]. Serious games are games that intend to entertain and achieve at least one additional goal [22]. In order to motivate patients to play the serious game, the self-determination theory may be used to guide serious game development. According to this theory, intrinsic motivation is most likely to occur when 3 needs are satisfied: competence, autonomy, and relatedness [24,25]. A serious game can satisfy these 3 needs, creating intrinsically motivated players who will adhere to a multidose intervention. Thus, serious games can positively influence behavior [26] even by targeting implicit attitudes [27].

Taken together, this paper describes the systematic development of a serious game by using the intervention mapping framework [28]. This serious game should provide entertainment as well as positively influence medication adherence by targeting implicit attitudes.

Methods

Development Process

Intervention mapping was used to systematically develop the intervention [29]. Intervention mapping considers and applies theory and empirical evidence to maximize the effectiveness and usability of the intervention, covers the complete range from problem identification to scientific evaluation, and ensures that the intervention is compatible with the target population [29]. A complex problem such as a medication-taking behavior demands a multidisciplinary approach. Therefore, the intervention mapping process was guided by meetings of an expert group consisting of a pharmacist, rheumatologist, rheumatology nurse, psychologist, innovation manager, representative of the pharmaceutical industry, and a game developer named Games for Health.

Intervention Mapping Framework

The intervention mapping framework comprises 6 steps, where each step leads to a product that guides the subsequent step. See Table 1 for an overview of intervention mapping steps with associated tasks and intermediate development products. The goal of the first step is to assess the health problem. The main task in this step is to identify the determinants for the at-risk population of the problematic behavior (nonadherence). Step 2 builds on the previous step by using the identified determinants to formulate the change objectives. The change objectives specify who and what will change as a result of the intervention. In step 3, theory-informed methods and practical strategies are searched for that are most likely to accomplish the formulated change objectives. During step 4, the intervention is produced based on the outcomes of the previous steps and refined after pilot testing. The goal of step 5 is to increase program adoption, implementation, and maintenance by creating an implementation plan. Finally, in step 6, the effect of the intervention is evaluated to ensure that the desired behavioral outcome is achieved.

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Table 1. Intervention mapping steps with associated tasks and applied methodology.

Intervention mapping steps	Intervention mapping tasks	Methods
Step 1: Logic model of the problem	Describe the context for the intervention Identify determinants for the at-risk population of the problem	PubMed literature search on determinants of nonadherence (2010-2015) Explorative study in 52 patients on relation between attitudes and medication adherence
Step 2: Program outcomes and objectives	State expected outcomes for behavior Specify performance objectives for behavioral outcomes Select determinants for behavioral outcomes Create a logic model of change	Multiple expert group discussions (both face-to-face and electronic)
Step 3: Program design	Generate program themes, components, scope, and sequence Choose theory- and evidence-based change methods Select or design practical apps to deliver change methods	Literature search and expert opinion on behavior change techniques Multiple expert group discussions Iterative game development
Step 4: Program production	Refine program structure and organization Prepare plans for program materials Draft messages, materials, and protocols Pretest, refine, and produce materials	Iterative game development Stage 1 user testing: 54 disease-modifying antirheumatic drug users played at home in 2 rounds for 2 weeks Stage 2 user testing: 8 disease-modifying antirheumatic drug users performed a live walk-through
Step 5: Program implementation plan	State outcomes and performance objectives for program use Construct matrices of change objectives for program use	Iterative game development guided by self-determination theory
Step 6: Evaluation plan	Write effect and process evaluation questions Develop indicators and measures for assessment Specify the evaluation design	Develop a randomized clinical trial study protocol to examine effectiveness on medication adherence of antirheumatic drugs (GAMER [Gaming for Adherence to Medication using E-health in Rheumatoid arthritis patients] study)

Logic Model of the Problem

As the first step, the context of the intervention (population and setting) is described. Next, 2 methods were used to identify the determinants for patients with rheumatic disease being at-risk for nonadherence: (1) a literature search and (2) an explorative study on the implicit and explicit determinants toward antirheumatic drug use performed by research team members [30]. The literature search was performed in PubMed in 2015, and it focused on recent (2010-2015) studies, including systematic reviews, using the MeSH terms *medication adherence* and *rheumatic diseases* coupled with free text term *determinant*. Both primary studies and systematic reviews were included. All determinants mentioned in the selected studies and their association with medication adherence were collected and split into nonmodifiable and modifiable factors. Nonmodifiable factors aid in identifying the target population, whereas modifiable factors aid in identifying target behavior. Habitual behavior such as medication-taking behavior is likely to be guided by implicit attitudes as well as explicit attitudes [19]. However, it is unclear how explicit and implicit attitudes relate to medication adherence. Therefore, this was explored by research team members in a sample of patients with RA and published elsewhere [30]. In short, the sample consisted of 52 patients on oral methotrexate therapy at Sint Maartenskliniek, a Dutch tertiary rheumatology clinic. Patients were approached when collecting their medication refill, and assessment took place immediately after providing informed consent. Patients performed a computerized task (Single Category Implicit Association Test) to measure the implicit measures of medication attitudes and associations, which is a well-established and valid measure of implicit associations [31]. Additionally, they completed a questionnaire on demographics and questionnaires on explicit attitudes and associations (Beliefs about Medication Questionnaire [BMQ] [32-35]) and medication adherence (Compliance Questionnaire on Rheumatology [CQR] [36-38]), both proven valid and reliable in patients with RA. Clinical outcomes (erythrocyte sedimentation rate and C-reactive protein) were obtained from patients' medical files. Because of the explorative character of this study, Pearson correlations were used to examine the relationship between patients' explicit and implicit attitudes, associations, beliefs, adherence, clinical outcomes, and demographics.

Program Outcomes and Objectives

The behavioral outcome of the intervention is to become adherent and maintain medication adherence of antirheumatic drugs. As the patient is the one who has the main influence on the medication-taking behavior, we only defined change objectives at the patient level. Thus, there are no change objectives at the interpersonal, organizational, communal, or societal level. The change objective of the intervention was guided by the outcomes of step 1 and established through multiple (electronic) discussions of the expert group through an organic iterative process.

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Program Design

The fundament of the behavioral change for our intervention was the Dual-Attitude model. The Dual-Attitude model postulates that implicit and explicit attitudes coexist and do not necessarily have to be congruent [17,30]. When dual attitudes exist, the implicit attitude is activated automatically, whereas the explicit one requires more capacity and motivation to retrieve from memory. As such, habitual behavior such as medication-taking behavior is more likely to be guided by implicit attitudes [19]. Implicit attitudes can be targeted by a behavior change technique called bias modification [20]. Google Scholar and PubMed were narratively searched for suitable behavior change techniques. The search terms consisted of free text words, that is, *behavior change technique*, *bias modification*, and *health*. To narrow the search results, the terms *review* and *overview* were added to the search strategy. The behavior change techniques shown to effectively address health behaviors were selected and presented to the game developer for applicability. Next, the game type was carefully chosen to suit the context (target population and setting) of the intervention from step 1.

Program Production

The serious game was developed using an iterative design process. Based on the theory of the previous steps, the expert group prepared the outline of the intervention components in multiple sessions. Games for Health used their expertise to create the components within the technical possibilities and merged them to form the game. The game was tested by patients and the feedback used to adapt the game after which this process was repeated. Thus, the final product is a practical interpretation of the theory. The test panel members were representative of the target group and were recruited from Sint Maartenskliniek, Nijmegen, The Netherlands. They were patients aged 16 years or older who used antirheumatic drugs. Ethical approval for user testing was asked for and waived by the local medical research ethics committee of Arnhem-Nijmegen under code 2017-3355. A random sample of 500 patients using DMARDs received an invitation with informed consent enclosed through mail. Additionally, participants needed to possess a tablet and be proficient in the Dutch language.

Stage 1 consisted of 2 rounds of 2 weeks of user testing at home after which data on acceptability were collected. Acceptability was determined using the Technology Acceptance Model as underpinning, which is a well-established model for usability evaluation of eHealth [39-41]. This model postulates that ease of using a technology influences the perceived usefulness and the attitude toward using and together form the behavioral intention to use a technology, which leads to actual use. Ease of use was measured using the System Usability Scale questionnaire taken directly from the Technology Acceptance Model [39,42,43]. The perceived usefulness of a game was operationalized as enjoyment and assessed using the GameFlow questionnaire, which has been successfully applied to distinguish between the high-rated and low-rated games and identify why one succeeded and the other failed [44,45]. Attitude toward using was assessed using 4 questions of the user version of the Mobile App Rating Scale (uMARS), which is a simpler end-user version of the validated MARS [46,47]. The questions of the uMARS that captured the overall feeling of the app and its potential use were selected by authors BPHP and BJFvdB until consensus was reached. All other questions were omitted, as they related to other aspects of mobile apps and even overlapped with ease of use and usefulness. Actual use was collected using Google Analytics and determined to be time played and number of sessions. In addition, participants were asked for their overall experience and suggestions for improvement (open-ended questions) to inform the game developers.

Stage 2 was a live walk-through where patients performed tasks within the serious game environment under supervision. A team of game developers from Games for Health and author BPHP observed the participants and took notes. Participants were recruited from players in stage 1 (experienced users) and from the patient representatives of Sint Maartenskliniek (new users). Suggestions for improvement were collected with the aim of improving gameplay and increasing retention.

Program Implementation Plan

Intrinsic motivation is key to ensure adoption and implementation of a serious game. The self-determination theory posits that motivation is a continuum between extrinsic motivation (ie, external factors such as rewards or grades) and intrinsic motivation (ie, internal factors such as interest, curiosity, or care). Intrinsic motivation can be reliably enhanced by supporting the satisfaction of 3 psychological needs: competence, autonomy, and relatedness [24,25,48]. Competence denotes the experience of mastery. It becomes satisfied when capably engaging in activities and experiencing opportunities for using and extending skills. Autonomy denotes the experience of willpower and willingness without external pressure. Relatedness denotes the experience of bonding and care and is satisfied by connecting to others. In the Results section, we have described how our serious game addresses these needs.

Evaluation Plan

To assess whether the developed intervention positively affects antirheumatic drug adherence, a research proposal was drafted for a multicenter randomized controlled trial: the GAMER (Gaming for Adherence to Medication using E-health in Rheumatoid arthritis patients) study.

Results

Logic Model of the Problem

The intervention is set within the context of RA. RA mainly affects people older than 50 years and is more common among women [1]. Because most antirheumatic drugs are used at home, our adherence-enhancing intervention should be utilized in the home setting. The literature search on determinants of nonadherence resulted in 73 publications, of which 12 detailed on determinants of medication adherence in rheumatic diseases [7,10,11,49-57]. There were no nonmodifiable patient characteristics that indisputably predicted medication nonadherence. Therefore, we decided that our intervention should be aimed at all patients with RA. The modifiable determinants that remained were psychosocial and therapy-related factors. As our intervention should not interfere

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with RA treatment, we focused on psychosocial factors. Supportive evidence was found for the following modifiable psychosocial factors influencing medication adherence: perceived treatment necessity, treatment concerns, satisfaction with care, treatment self-efficacy, coping, practical barriers, social support, disease or treatment understanding, illness beliefs/perceptions, and lifestyle. The necessity/concerns balance and practical barriers had the strongest association with medication adherence [10,53]. As stated in the introduction, behavioral intentions are driven by both explicit (conscious) and implicit (unconscious) attitudes [17]. Habitual behavior such as medication taking is guided stronger by implicit attitudes than by explicit attitudes, which play a stronger role in conscious (planned) behavior [19]. To understand the possible role of implicit attitudes regarding medication-taking behavior, we performed an explorative study with 52 patients who showed that explicit attitudes were positive and health-related. Implicit attitudes were, however, negative and illness-related. Half of the patients displayed explicitly positive but implicitly negative attitudes [30]. The relationship between implicit attitudes and medication adherence is worth being further explored to potentially make interventions more effective.

Program Outcomes and Objectives

The primary outcome of the intervention is to become adherent and maintain adherence to antirheumatic drugs, which was defined as taking at least 80% of the prescribed doses. This cutoff is widely used in (RA) adherence research and associated with improved in clinical outcomes in RA [5]. It is increasingly recognized that medication adherence is not an order from a clinician for the patient to execute (“compliance” to therapy) but requires active patient participation and stimulation (adherence). Thus, an intervention enhanced with positive affect is more successful in increasing adherence [58]. In addition, the explorative study learned that patients’ implicit and explicit attitudes do not correlate and that implicit attitudes are generally negative and illness-related. Therefore, the expert group considered that reconditioning implicit negative attitudes to more positive ones could shift the necessity/concerns balance. In that light, the expert group drafted a change objective that was adjusted and refined over several rounds of discussion. Ultimately, this led to the following change objective: after the intervention, participants have a more positive attitude toward antirheumatic drugs.

Program Design

The explorative study in patients with RA performed in step 1 learned that, generally, explicit attitudes are positive and implicit attitudes are negative [30]. To enable change to occur, the expert group aimed at reducing negative explicit attitudes and reinforcing positive implicit attitudes (see Table 1). The idea was that the net result of these 2 actions would be overall a more positive attitude toward medication. Medication concerns can be targeted by patient education [12,51]. Thus, our strategy was to explicitly reduce concerns by educating patients on how to best use antirheumatic drugs. The literature search on bias modifications to change implicit attitudes led to multiple reviews with examples of gamified behavior change techniques [20,21]. To positively influence the associations between medication beliefs and medication use on an implicit level, 3 mental domains can be addressed: cognition (knowing), affect (feeling), and motivation (willing) [20].

Cognitions/beliefs can be altered using attentional bias modification training [21]. During training, attention is shifted in a positive direction by repetitively drawing attention to positive associations between medication beliefs and medication use. Similarly, *affect* can be modified by training participants to pair medication with another positive stimulus—so called evaluative conditioning. Lastly, *motivation* can be implicitly targeted by goal priming: passive and unobtrusive activation of people without them being aware of it. Taken together, we applied 1 explicit and 3 implicit strategies as underpinning for behavior change to occur. Implicit attitudes are activated automatically, but like old habits, are harder to change [17]. Thus, a multidose intervention in the form of a serious game was chosen. The expert group identified game types that fit the target population, which in the case of RA are mainly women over the age of 50 years. One of the favorite leisure time activities is solving puzzles, and therefore, it was decided to develop a serious puzzle game [59,60].

Program Production

The design of the game environment needed to merge medication and puzzles and simultaneously be positive and energizing. The game was named Medi and Seintje, which is a Dutch wordplay on medication and signaling. Medi and Seintje are icon characters that look like a tablet and capsule, respectively (see Figure 1A). To ensure that participants would relate to the game, game personification was built in. If participants allowed camera use, they could take a picture of themselves and of their medication, which was used in the behavior change techniques (see below). Next, the behavior change techniques had to be integrated into the puzzle game in such a way that participants would encounter them without being too obtrusive to disturb gameplay. The behavior change techniques were added to the puzzle environment as so called “triggers” that allowed participants to open the game or a puzzle. A total of 5 triggers were developed: multiple choice medication quiz, dot-probe task, visual search, slide to unlock (see Figure 1B), and a barcode scanner (see Multimedia Appendix 1). These triggers were gamified behavior change techniques and considered important game components (see Table 1). After completing the trigger at start-up, the game offered 4 puzzle types (see Figure 1C and Figure 1D), each with 3 levels of difficulty: crossword, sudoku, wordsearch, and tangram. The game environment adhered to the Medi and Seintje theme. The first 4 steps of intervention mapping have been summarized in Table 2 and Table 3.

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Figure 1. Screenshots of the serious puzzle games. A. Icon characters Medi and Seintje introduce themselves. B. Users are instructed to slide the pill down the screen toward a picture of the user to unlock trigger. C. The puzzle menu showing the 4 puzzle types: crossword, sudoku, word search, and tangram. D. Example of the crossword puzzle screen.

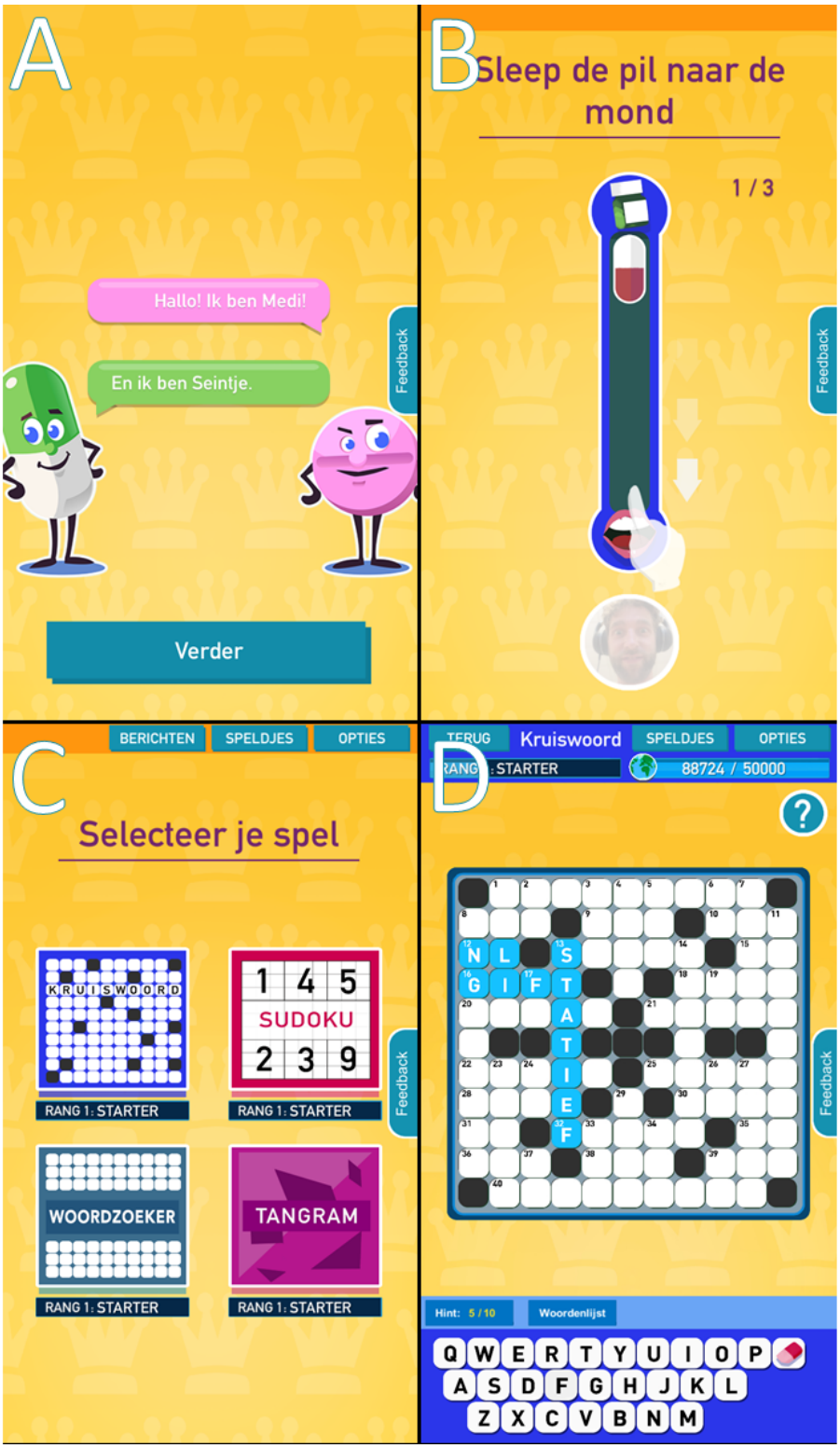


Table 2. From change objective to intervention strategies—the first 2 steps of intervention mapping.

Step	Goal	Outcome
Step 1	Determinants	• Treatment necessity • Treatment concerns
Step 2	Change objective	After the intervention, participants have a more positive attitude toward antirheumatic drugs.

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Table 3. From change objective to intervention strategies—step 3 and step 4 of intervention mapping.

Step, goal	Strategies and outcomes			
	1	2	3	4
Step 3				
Domain	Motivation-implicit	Affective-implicit	Cognitive-implicit	Cognitive-explicit
Strategy	Goal priming: passive, subtle, and unobtrusive activation by external stimuli such that people are not aware of the influence exerted by those stimuli.	Reinforcing the positive valence of antirheumatic drug use by strengthening the positive associations through pairing antirheumatic drugs with a positive stimulus.	Reinforcing attention toward medication using positive stimuli. Part of the techniques applied are based on attention bias modification training.	Reduce concerns by educating patients on how to best use antirheumatic drugs.
Step 4				
Game component	• Personalization of the game • Icon characters "Medi and Seintje" • Come-and-play reminder • Barcode scanner	• Personalization of the game • Icon characters "Medi and Seintje" • Energizing/positive gaming environment • Slide to unlock • Visual search	• Personalization of the game • Icon characters "Medi and Seintje" • Dot-probe task • Visual search	• Multiple choice • medication quiz

Out of 500 invitations, 54 DMARD users (11%) agreed to test the game at stage 1. Their median age was 63 years and the median number of years since diagnosis was 10 years. Thirty-three participants were female (61%) and 39 (72%) used their tablet daily. Stage 1 consisted of 2 rounds, where the feedback of round 1 was incorporated in the game before testing in round 2. Of the 52 participants, 39 participants completed the study: 9 participants did not download the app (reason unknown), 2 stopped owing to technical issues, and 2 stopped because of medical reasons. In round 1, 19 participants used the app and 22 participants used the app in round 2, of which 12 used the app in both rounds. On average, in round 1, users played 1.4 sessions per day that lasted 12 minutes, and in round 2, users played 1.7 sessions per day that lasted 16 minutes. Although playtime increased, there were no significant differences in the scores for ease of use, perceived usefulness, and attitude toward using between the 2 rounds. User experiences indicated a broad spectrum of views from joy from playing to annoyance. Suggestions for improvements given by participants were mainly about the barcode scanner, as the scanner malfunctioned in round 1. Other technical improvements that were suggested were a lower frequency of push notifications, larger display buttons, and preventing puzzles from causing the app to crash. Prior to the live walk-through in stage 2, the app received a major update to incorporate further improvements, such as instruction screens for all puzzles. During stage 2, eight DMARD users performed a walk-through under supervision at Sint Maartenskliniek. Four participants participated in stage 1, and 4 were new to the app. When seeing how users performed the various tasks, the app builders learned which steps were intuitive and which steps needed improvement. Overall, the design process led to valuable insights in patient acceptance, usability, and suggestions for improvement. Consequently, the latest version of the app complied with the needs of end users.

Program Implementation Plan

Implementation was ensured by evoking the intrinsic motivation of participants through addressing the following 3 needs: competence, autonomy, and relatedness [24,25,48]. The complete puzzle environment consisted of 3 puzzle types—crossword, sudoku, and wordsearch—with 3 levels of difficulty and at least 50 puzzles at each of these levels and 82 tangram puzzles across 4 themes: animals, letters, objects, and humans. To meet the need for *competence*, puzzles with increasing difficulty were available. Players could board a puzzle on the difficulty level they could master and develop skills by playing numerous puzzles in increasing difficulty. For players new to the game, there was an option to receive hints or help. The mastery of an individual was tracked by gaining experience points when playing puzzles, and they could view their progression level. Additionally, players could complete challenges such as "find a word within 5 seconds" after starting wordsearch to be rewarded with badges allowing them to track and visualize their progress.

To meet the needs of *autonomy*, players had the freedom to choose which puzzle to play (individual choices were reflected in the badges collected) and the opportunity to solve a puzzle in multiple ways. Finally, to meet the need of *relatedness*, the world record playing crossword puzzles was incorporated in the game. By playing crossword puzzles, each player contributed to breaking the world record crossword puzzles, which was a group effort. Prior to starting a new crossword puzzle, the individual's contribution to the world record and total progress was shown. To protect the privacy of the individual participants, it was decided not to incorporate social interaction elements at this stage. To further prevent dropout, we sought to balance triggers versus puzzles. Balance turned out to be one trigger when starting the game and when opening a new puzzle after at least 10 minutes of solving puzzles. Triggers appeared in random order to maintain variety in gameplay.

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Evaluation Plan

The intervention is currently being evaluated in a multicenter randomized clinical trial: the GAMER study [61]. This study aims to examine the effect on medication adherence and clinical outcomes in patients with RA treated with antirheumatic drugs. A total of 220 patients will be randomized 1:1 to intervention or usual care and followed for 3 months. The intervention group will be instructed to install and play the puzzle game on their tablet or mobile phone. Playing the puzzle game is encouraged at the start of the study but otherwise completely voluntary. The main study parameter is adherence using the validated CQR in an intention-to-treat analysis. Additionally, a pill count will be performed and the BMQ will be collected. Secondary clinical outcomes are the Health Assessment Questionnaire (HAQ) and the self-reported Rheumatoid Arthritis Disease Activity Index (RADAI). The CQR, BMQ, HAQ, and RADAI have been proven valid and reliable in patients with RA [32-38,62-66]. Disease activity [67,68] will be gathered if available. Lastly, the Technology Acceptance Model, a well-established model for evaluating usability of eHealth, will be applied to collect patient acceptance of the puzzle game. Data collection will be similar to stage 1 of the user testing: the System Usability Scale will assess ease of use, GameFlow will assess perceived usefulness, part of the uMARS will assess the attitude toward using, and Google Analytics will collect actual use [39-46].

Discussion

This paper describes the design rationale of a serious game aimed at improving medication adherence in patients with RA. Our formative work with patients with RA in combination with the literature search and explorative study described above led us to develop a mobile serious game as an intervention. Focal points of this serious game were implicit medication attitudes, positivism, and retention.

As Abraham et al [69] stated, development of serious games should detail on the extent of the theoretical framework incorporated into the game design and evaluate success by testing the player's retention of learning objectives. This is why we chose to develop our intervention according to the intervention mapping framework while being guided by the Dual-Attitude Model and self-determination theory [17,24]. Even though the development was guided by the systematic intervention mapping framework, several choices still had to be made by the expert group. To ensure deliberate decisions, we sought to incorporate many different areas of expertise among group members from clinical to psychological and technical. Patients were not represented in the expert group but extensively consulted throughout the intervention mapping process: from the explorative study to elaborate user testing. The developed intervention did not contain medication-taking (reminder) components in contrast to other serious games aimed at improving medication adherence [69]. We decided not to incorporate the actual medication-taking behavior because we feared that this would be perceived as coercive and would lead to loss of retention because the act of medication taking would take playfulness and positivity out of the game.

The behavior change techniques we have applied as medication-related triggers have not previously been tested to improve medication adherence. Even though there is no solid evidence for improving medication adherence, the extensive research on these techniques for stimulating healthy behavior was considered a strong enough premise to apply these techniques in our serious gaming intervention [21]. Another reason for applying these behavior change techniques was the fact that they have been successfully and effectively gamified [26,27]. It should be noted that the test conditions for these behavior change techniques were generally well-controlled: playing the gamified behavior change techniques for a set period of time (at least for several minutes) without distractions. When applying these techniques in a mobile app as medication-related triggers, there is no control over the participants' setting, which leads to variable exposure to the triggers. To ensure that the triggers were sufficiently dosed, participants need to be intrinsically motivated to play the game. When developing a serious game, a trade-off has to be made between the serious (ie, the behavior change techniques) and the game (ie, the puzzles), which is why the usability testing is so important. The results from our usability testing indicated a positive response toward the app. However, these findings were prone to selection bias and limited to patients willing to test the app. This type of testing, while appropriate for app development, may not reveal barriers to implementation in practice. The app was carefully designed to quickly engage users, sustain motivation for long-term app use, and simultaneously apply behavior change techniques. The success of these strategies will not be known until the app is tested in clinical practice. To be considered effective, serious games must sustain their impact over the long term and offer more than a short-term novelty effect [69]. The results of our evaluation study will hopefully answer if our serious game is successful in improving medication adherence [61]. If proven effective, additional studies should be performed to assess effectiveness in the longer term (6-12 months) and to investigate the effective components more closely.

In conclusion, we systematically developed a serious game app to enhance adherence to antirheumatic drugs among patients with RA by using the intervention mapping framework. Evaluation in a multicenter randomized controlled trial will determine intervention uptake and effectiveness. This paper could serve as a guideline for other health care providers when developing similar interventions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Triggers of serious game Medi and Seintje explained.
[DOCX File , 413 KB - games_v10i1e31570_app1.docx]

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Abbreviations

BMQ: Beliefs about Medication Questionnaire
CQR: Compliance Questionnaire on Rheumatology
DMARD: disease-modifying antirheumatic drugs
GAMER: Gaming for Adherence to Medication using E-health in Rheumatoid arthritis patients
HAQ: Health Assessment Questionnaire
RA: rheumatoid arthritis
RADAI: Rheumatoid Arthritis Disease Activity Index
uMARS: user version of the Mobile App Rating Scale

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Original Paper

Experiences of Patients Undergoing Chemotherapy With Virtual Reality: Mixed Methods Feasibility Study

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Abstract

Background: Current research into virtual reality (VR) use during chemotherapy shows that it can be an effective distraction intervention. However, there is limited research in adult patients and to investigate how VR can be sustainably implemented in health care organizations.

Objective: The aim of this study was to explore the feasibility and acceptability of using VR for adult patients undergoing chemotherapy, and to identify the factors that would enable the sustained use of VR during chemotherapy in health care organizations.

Methods: Patients undergoing chemotherapy were recruited to participate in a VR intervention during chemotherapy infusion. Participants were observed during the session and completed a postintervention survey. Each participant was invited to participate in a semistructured interview about their experience.

Results: A total of 18 patients participated in the study, 5 of whom participated in semistructured interviews. Findings indicated that the use of VR was acceptable for patients undergoing chemotherapy and the intervention was also feasible. Some participants felt that the VR was an effective distraction during chemotherapy infusion, although most still seemed to be aware of how long their treatment was taking. Although VR was acceptable and feasible to patients, interviews identified several barriers to sustained implementation, including access to a reliable app library and impact on staff workloads.

Conclusions: VR was acceptable to patients with a diagnosis of cancer undergoing chemotherapy treatment. Patients found VR beneficial for breaking up the monotony of treatment, to provide an additional choice of activity in addition to other recreation, and in some instances as a distraction from the treatment itself. However, there are challenges to address if VR is to be implemented in practice for this patient group.

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KEYWORDS

eHealth; digital health; virtual reality; cancer; chemotherapy; mixed methods research; virtual health; serious games; treatment

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Introduction

Background

Virtual reality (VR) describes the use of sophisticated hardware to generate virtual environments. Although VR has existed for several decades, the technology became particularly prominent in the mid-2010s with the release of affordable (from thousands of dollars to a few hundred dollars) commercially available VR head-mounted display (HMD) devices [1]. Since then, considerable innovation has occurred in the space, which has led to the development of a range of VR HMD solutions from high-end products that require the support of a powerful computer to less sophisticated VR solutions that can be powered by a smartphone [2].

The availability of affordable commercial VR hardware has paralleled a growing interest in the use of the technology in the health sector [3]. To date, VR has been used to support burn victims [4,5], as exposure therapy for phobias [6], in the management of traumatic brain injury [7], and to increase physical activity undertaken by members of the general public [2,8]. In addition to being used to support health care consumers, VR has been used to enhance medical training by augmenting existing approaches to surgical skills training [9], advanced life support training [10], and for developing empathy skills [11].

In the context of cancer care, there is a small but growing body of research into the use of VR technology, primarily in the pediatric setting. There is literature exploring the use of VR as a distraction from anxiety in children during painful procedures related to cancer treatment or its side effects [12,13]. This research extends the literature on mechanisms for distracting patients undergoing chemotherapy, such as music therapy [12], social media use, and reading [13]. Research to date has shown that active distractions can be more effective than passive distractions for pediatric patients [14] and in adult populations [15]. The immersion caused by VR creates a more active distraction than other mechanisms, which may be effective for patients undergoing certain procedures. For cancer patients, VR has been shown to be more effective than other forms of distraction for relieving anxiety, depression, and fatigue during chemotherapy [12].

There is a small body of research indicating that VR can distort the perception of time during clinical procedures. One study showed that patients undergoing chemotherapy for breast and colon cancer perceived the procedure as being shorter than it was in reality [16]. Although not in the context of cancer care, a study of dental patients found that VR distorted the perception of time, with patients reporting that the procedure they were undergoing took less time than it actually did [17]. A recent systematic review evaluated the evidence supporting the use of VR among patients in acute inpatient medical settings, and found only two studies that reported findings related to the temporal distortion effect of VR [18]. However, it should be noted that in the context of those two studies, the temporal distortion measured was a change in time thinking about pain while using VR, which is distinct from measuring a change in time a person perceives to have passed due to the use of VR. This would suggest that temporal distortion relating to the change in time a person perceives to have passed because of VR-induced distraction is an underexplored area of research. Addressing this gap in the context of cancer care may be advantageous because there are some groups of patients who report greater satisfaction with treatment if they perceive their chemotherapy duration to be shorter than it is [19]. Other areas where there may be benefits of further researching temporal distraction from VR include certain pediatric groups such as those undergoing painful dental procedures, where greater levels of distraction can improve patient rapport and reduce disruptive behavior [14].

The role of serious games as a distraction technique during chemotherapy and to improve experiences of care in cancer patients has also been explored in the literature. A recent review of serious games exploring whether they can positively impact children with cancer found that such research has largely focused on the use of games in three categories: education, motivation, and distraction [20]. In adult cancer patients, serious games have been shown to be effective for improving patient self-management of nausea resulting from chemotherapy [21]. Researchers have also explored the role of serious games to improve the quality of life for breast cancer patients undergoing chemotherapy, demonstrating that patients are generally satisfied with the use of serious games for this purpose [22]. However, to date, there has been less research undertaken on the use of serious games via VR with adult cancer patients undergoing chemotherapy, or the use of other types of VR apps with this cohort.

Additionally, researchers have explored the use of VR to support psychological well-being in children hospitalized with cancer [23]. A smaller number of studies have been undertaken on the use of VR with adult cancer patients. There is some research to suggest that VR may be a cost-effective distraction technique for patients undergoing chemotherapy infusion [16], and that VR may help manage the adverse effects of chemotherapy infusion in older women with breast cancer [24]. A recent mini-review of the use of VR with patients undergoing chemotherapy concluded that there were several gaps in the research in this area, including limited research on the potential adverse events of using VR during chemotherapy infusion and a lack of research into the barriers to implementing VR in practice [12].

Patients with cancer are a notably diverse group. This is because “cancer” describes a group of over 100 different diseases that involve the inappropriate proliferation of cells [25]. Cancers can be diagnosed in pediatric, adolescent, young adult, and adult individuals, and the prevalence of different cancers can also vary according to genetic background and geographic region [26,27]. Medical interventions vary considerably depending on the diagnosis and the prognosis. Interventions include systemic therapies such as chemotherapy and immunotherapy, surgical interventions, and radiation therapy. Cancer patients can be receiving medical interventions for different reasons, including to prevent disease recurrence or palliatively to manage symptoms of the disease [28,29]. Systemic therapies can be delivered as an outpatient therapy where appropriate, which means that patients must go to the hospital for a scheduled

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appointment to receive treatment but are not admitted to hospital.

In light of this diversity, patient-centered VR interventions for cancer patients should be flexible or appropriately varied to respond to the needs and interests of patient groups [30]. It has been noted in the literature that there is limited research seeking to understand the characteristics of patients that will gain the greatest benefit from immersive technology such as VR [31,32]. This would enable a more personalized "prescription" of VR interventions to patients for whom it would be most useful. More recent research has noted the importance of considering patient characteristics such as motor, visual, or vestibular impairments in the design and implementation of VR for patients with acquired brain injuries, as lack of such consideration could be a barrier to the use of VR by this group [33].

In addition to the limited understanding of the characteristics of patients who will likely respond well to VR interventions, there is limited understanding of the VR interventions that are suitable for, and of interest to, patients with chronic conditions [34]. Understanding what makes VR acceptable and feasible to patients with chronic conditions may be used to inform decisions around which features should be prioritized in different applications. For cancer patients, this gap is particularly problematic because there are specific limitations on the use of VR with this group, including a potential need to operate the device with one hand to avoid interfering with drips or cannulas, and ease of learning the game mechanics and controls due to varied experiences with VR or video games.

Objectives

The aim of this study was to explore the feasibility and acceptability of using VR to improve the quality of life of adult patients undergoing chemotherapy, and to identify the factors that would enable the sustained use of VR during chemotherapy in health care organizations.

The following research questions were addressed: How feasible is the use of VR for patients undergoing chemotherapy? How acceptable is the use of VR for patients undergoing chemotherapy? How distracting is VR for patients undergoing chemotherapy? How challenging would it be to implement VR in routine clinical practice?

Methods

Study Design

This study used a mixed methodology with observations, followed by online surveys, semistructured interviews, and analysis of uptake metrics for the intervention. The feasibility of the intervention was primarily assessed via observation data. The acceptability was primarily assessed via postintervention survey data and interview data. The extent to which VR was an effective distraction during chemotherapy was assessed through data collected from the postintervention survey and interviews. The implementation barriers and enablers were primarily assessed via interview data, along with some observation data.

Setting and Participants

The study was undertaken at a large metropolitan health care organization specializing in care for patients with a diagnosis of cancer. The health care organization has a day therapy suite to deliver chemotherapy and immunotherapy to cancer patients. Patients undergoing chemotherapy visit the day therapy suite to have their scheduled treatment. The length of the treatment on an individual day can vary considerably depending on the patient's protocol, but most patients generally have at least 1 hour of treatment. At the start of a chemotherapy session, patients are usually cannulated, injected with their chemotherapy dose, receive an infusion of the required drugs until the end of their therapy session, and have their lines flushed before removing the cannula. Prior to the session, patients often have blood tests and await results, which means they have often already spent a substantial amount of time on site before treatment.

Inclusion criteria for the study required potential participants to be patients 18 years old or over with a histologically confirmed diagnosis of cancer, who were undergoing chemotherapy. The exclusion criterion for the study was that potential participants could not be part of a commercial phase I trial.

A member of the health care team at the intervention site approached patients and provided them with an Expression of Interest (EOI) form and a copy of the Participant Information Statement and Consent Form. If patients were interested in participating in the study, they shared their contact details via the EOI form. A member of the research team would telephone the potential participants to explain the study further, answer questions, and identify a suitable chemotherapy session for receiving the VR intervention. Participants provided written consent prior to participating in the intervention.

Procedure

The intervention was delivered using the Samsung Gear VR HMD headset. The VR hardware was chosen as the study site had previously invested in the technology and wanted to further understand the feasibility of implementing it in practice. Each participant only undertook a VR session once during the study. Figure 1 shows an image of the study site and Figure 2 shows an image of the Gear VR headset.

Once participants had been set up with their chemotherapy infusion, a member of the research team provided them with the VR headset and a brief overview of how the hardware worked, how to navigate the interface, and the apps that were available to use during the intervention. Participants then completed a brief survey on their previous experience with digital games and VR.

Upon completion of the survey, participants selected an app they would like to play during their chemotherapy appointment from a list of 10 apps. The researcher was available for support while the participant was engaged in VR. Participants could choose to play with more than one VR app during their chemotherapy appointment, although they were limited by the overall time of the appointment. If they chose to play additional

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VR app(s) during their appointment, the researcher would assist them in selection.

To measure the feasibility of the intervention, usage behaviors were captured during the intervention. A researcher observed participants during the intervention and took notes. Data collected through observation notes included apparent ease of the use of controls, duration of the VR session, number of apps the participant chose to use during the intervention, and comments about the experience.

Figure 1. Image of the location where the participants undertook their virtual reality sessions.



Figure 2. The Gear VR headset used in the study.



Upon completion of the VR intervention, participants completed a postintervention survey (see Multimedia Appendix 1) informed by the Player Experience of Needs Satisfaction (PENS) instrument [8] and an adverse event checklist that allowed them to visually indicate any adverse events experienced (see Multimedia Appendix 2). The postintervention survey consisted

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of nine items about the VR experience, including eight items ranked on a 1-7 Likert scale and one yes-or-no question. In addition to the survey, participants completed the Edmonton Symptom Assessment System (ESAS-r) questionnaire postintervention. The ESAS-r describes the individual's symptom severity based on a scale ranging from 1 to 10 to quantify the level of distress in cancer patients for nine common symptoms of the disease [35]. Responses were averaged and higher scores indicated higher levels of distress. The ESAS-r has high internal consistency, convergent validity, and construct validity (α=.87, .84, and .82, respectively [36]), and has been used to monitor symptoms of distress in a range of contexts, including cancer, palliative care, and nephrology [37].

Participants were invited to participate in semistructured interviews 4-6 weeks after the intervention. Interviews were not undertaken directly after the intervention so as to give the participants some time to reflect on their experience prior to the interview, enabling them to provide richer responses on the benefits and disadvantages of VR for individuals undergoing chemotherapy. These interviews explored participants' experience of the VR intervention. The interviews were conducted over the phone, took between 15 and 20 minutes, and were conducted by a different researcher from the researcher who administered the VR intervention. The interview schedule was designed to gain a high-level understanding of the participants' experiences with the VR intervention, identify challenges they encountered, or indicate opportunities for improvement in future. Questions in the interview included: How was your experience with VR during the study? How effective did you find the VR for reducing your anxiety about treatment? Were there any benefits you experienced from the use of VR during treatment? Were there any concerns or issues you had with the use of VR during your treatment? Interviews were audio-recorded, transcribed by an external company, deidentified, and analyzed.

Data Analysis

Descriptive statistics of quantitative data were analyzed using IBM SPSS 24.0. Due to the small sample size of this feasibility study, there was not sufficient power to conduct inferential statistical analyses.

Observation and semistructured data were reviewed using content analysis. Interview transcripts and observation notes were read to obtain an overall sense of the themes, and then the content was grouped into categories related to the research questions, or into new categories if the data did not align with any of the existing categories. Categorization of transcript and observation data was discussed by two authors (AJ and JF) to align each researcher's categorization. Fully analyzed data were grouped in response to the research questions.

Statement of Ethics

This research project received ethics approval from Sydney Local Health District Human Research Ethics Committee (protocol number X18-0313).

Results

Demographics

A total of 19 individuals participated in the VR intervention. One participant was unable to complete the intervention due to technical issues with the VR hardware. As such, only 18 participants, 10 men and 8 women, completed both pre- and postintervention surveys and the intervention, 5 of whom participated in a follow-up interview. Presurvey data for the participant who did not receive the intervention are included in the results presented herein, whereas no observational or postintervention data from this participant were included in this analysis.

Of the 18 participants, the majority (n=14, 78%) had no experience with VR, and all felt inexperienced using the technology (n=18, 100%). Several participants had no experience playing video games (n=6, 33%), although more of the participants had experience playing video games than in using VR. The majority of participants (n=12, 67%) had no experience playing smartphone games. Of the remaining six participants who had experience playing smartphone games, two were different from the six who had experience playing digital games.

Feasibility of VR for Patients Undergoing Chemotherapy

During the VR intervention, participants were given a choice of which apps and the number of apps they played. The apps used in the intervention were shortlisted from the Occulus store based on rating, price, genre, comfort, and potential to play one-handed. After shortlisting based on this information, all games were play-tested to evaluate their functionality and confirm the ability to play one-handed (required for patients undergoing chemotherapy treatment). The majority of participants opted to play both game apps and experience apps. However, two participants only played apps that were experiences and three participants only played apps that were games. Table 1 provides a list of the apps the participants could choose from during the intervention.

Observations during the VR sessions showed that some of the issues that the researcher anticipated would make the intervention potentially unfeasible were actually less problematic than expected. The researcher anticipated some difficulty with adjusting the headset due to the headwear of the participants, and therefore explained what the headgear would be like prior to the session. All participants seemed to be at ease with adjusting their headwear and were happy to remove any scarves or hairpieces for the session. Two participants struggled to find an ideal focus for the lenses and reported that it was slightly blurry at times. The hand controller was used to navigate through games. For most participants, it was easy to use; however, occasionally, it did need to be reset by the researcher because its "direction" function went out of synchronization. The "direction" function going out of synchronization typically made the cursor appear in spots that were not directed by the participant or would disappear off the user screen.

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One participant was wearing cooling mitts (hand coverings with ice packs) but could still use the VR hand controller with ease, inside the mitts. For the sessions, the researcher requested that participants be cannulated in their nondominant arms. Two participants did use the VR controller with the hand of the arm they were cannulated in but reported that this was still comfortable for them. The selected games did not require any wild arm movements.

Analysis of postsurvey responses indicated that the majority of participants did not experience motion sickness (14/18, 78%). The researcher observed that in the four cases of reported motion sickness, the feeling was mild and only one participant asked to change the game due to the sensation.

Table 1. Apps patients could choose from during the virtual reality intervention.

App Name	Description	Publisher	Date published	App type
Sphæres	A series of cinematic virtual reality experiences to improve mindfulness and help with relaxation	Atmosphæres	November 2018	Experience
Smash Hit VR	An abstract game where a sphere is shot at glass objects in order to progress the level and get a high score	Mediocre	September 2015	Game
Invasion	An animated film about two aliens who try to take over Earth, but are thwarted by two bunnies	Baobab Studios Inc	March 2016	Experience (short film)
Meeting Rembrandt	An immersive experience for exploring the world of the Renaissance painter Rembrandt van Rijn in his studio as he creates the painting the Night Watch	Oculus Studios	September 2017	Experience (short film)
Ocean Rift	An aquatic safari park that enables exploration of an underwater world	Picselica Ltd	March 2015	Experience
Bait	A fishing game where the goal is to catch a rare fish to save the local aquarium	Resolution Games	March 2016	Game
Espr	A puzzle game where psychic abilities are used to solve challenges	Coatsink	May 2015	Game
Happy Place	A virtual environment that promotes positive emotions and calmness at a lakeside campsite in the mountains	Mimerse	October 2016	Experience
Forest of Serenity	A guided tour through a forest populated by exotic plants and animals, narrated by Sir David Attenborough	Holosphere VR	July 2018	Experience
Zen Garden	A relaxing environment that uses musical instruments controlled by the player's gaze to encourage calm and tranquility	Carry Castle AB	November 2016	Experience

Acceptability of VR for Patients Undergoing Chemotherapy

Experience with VR During Chemotherapy

The majority of participants (14/18, 78%) indicated that they found the VR intervention enjoyable by giving a ranking of at least 5 out of 7. Most participants (15/18, 83%) indicated they would use VR again. Table 2 highlights the participant responses to survey questions 2-9.

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Table 2. Participant responses to survey questions 2-9.[a]

Participant	Enjoyed activity	Activity fun	Activity boring	Activity did not hold my attention	Activity was interesting	Activity was enjoyable	I thought about enjoying the activity while I did it	I would try virtual reality again
VR001	5	4	2	2	6	5	5	6
VR002	6	6	1	1	5	6	6	7
VR003	7	7	1	1	7	7	4	7
VR004	7	7	1	1	6	7	7	7
VR005	6	7	1	1	4	7	7	7
VR006	6	6	1	2	6	6	2	7
VR007	7	7	1	1	7	7	6	1
VR008	3	3	3	2	4	4	3	4
VR009	7	7	1	1	7	7	7	7
VR010	4	4	3	3	4	4	5	4
VR011	7	7	1	1	7	7	7	7
VR012	7	7	1	1	7	7	7	7
VR013	3	5	1	1	5	6	5	6
VR015	3	3	1	1	4	3	3	7
VR016	7	7	1	1	7	7	5	7
VR017	7	6	1	1	7	7	5	7
VR018	6	6	1	1	7	7	6	7
VR019	5	6	1	1	5	7	4	7

[a]The survey asked participants to indicate a response on a 1-7 scale, where 7 was strongly agree and 1 was strongly disagree.

Recreation During Appointments

Participants reported reading, working on laptops, and playing on smartphones during their other chemotherapy sessions as forms of recreation they engaged in during appointments. Several participants stated that they sometimes sleep through the chemotherapy and some were accompanied by a family member or friend.

Participants laughed, smiled, and conversed about the scenery in the VR intervention, the rules, and game play while engaged in VR. Participants reported the experiences as relaxing and the games to be fun. Some participants liked the competition aspect of the games and were reluctant to stop (even at the end of their chemotherapy session).

When interviewees were asked about their experiences with VR as an alternative recreation during chemotherapy, the majority were positive about the experience. The reasons the VR intervention was considered to be engaging for interviewees varied. Several interviewees noted that chemotherapy was boring and that VR provided a good distraction from the monotony: "...that's why it would be quite useful to have the VR because you get a bit bored." [Participant VR003]

Several interviewees indicated that having chemotherapy can cause a lot of anxiety, and depending on the appointment, it can be more or less difficult to show up. One interviewee noted that the idea of the VR session motivated them to attend their chemotherapy appointment, when they previously were anxious about going.

> *…I was like, "I can totally do this chemo session now." From that perspective it [VR] was brilliant, I definitely was looking forward to it. I remember when I walked in, I said "are we doing it?" It definitely made the experience. It made it so much easier to go into it and I was so looking forward to it. It was all I talked about.* [Participant VR007]

By far the most consistent feedback from interviewees was that they liked having the choice of VR during chemotherapy. While many interviewees felt they would continue to use other forms of recreation during their appointments, the idea that VR was an option was very appealing: "…Look, it's just another option there for us...The fact that there's a choice, I think that's always a good thing." [Participant VR004]

Experience With Hardware

Overall, interviewees found the VR hardware relatively easy to use and not uncomfortable to wear during their chemotherapy appointment.

> *…I don't remember it being a problem. I think once we sit it on my head properly, it was much better. But yeah, it was perfectly lightweight and all good to go. It was interesting. I've never used virtual reality before, but I really enjoyed it.* [Participant VR007]

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Some participants did mention that there were some issues with the fit of the headset, and that it could slide off the head during some activities.

> *…With the headset and all that, when you're sitting there and someone says something to you and you reach down to do something. It comes off…because it's an ordinary iPhone, we were having problems.* [Participant VR002]

One interviewee commented that the VR hand controller was not reliable or user-friendly. Participants were provided a handheld controller accessory they could use to navigate the apps. However, the apps did not require the use of this controller and participants could use the touch controls on the headset if they chose.

Several interviewees gave feedback about aspects of the VR operating system itself. One set of issues focused on aspects of the system such as inability to adjust the lens focus, which led to blurry images and resulted in limited immersion within the VR world. Several interviewees also reported that the home screen of the VR product was difficult to navigate, which was a challenge for launching individual apps.

Patients' Perspectives of the VR Apps

Observations during the VR sessions suggested that participants were enthusiastic to try out several different apps to get an overall feeling of the range of VR capabilities. The majority of participants who tried a relaxation app got the idea of the app fairly quickly and then wanted to also try a game-style app. During the relaxation apps, participants generally relaxed, turning their heads to see more of the scenery, and some describing the setting they were in. Several asked to stop the app because they were going to fall asleep.

During gaming apps, the mood of the participants seemed to be quickly elevated, indicated by participants laughing and smiling, and making comments about what was going on. Many participants wanted to know what the highest score of the previous participant was (so they could try to beat it).

Interviewees described playing a considerable variety of apps during the VR intervention. Several interviewees commented on the amount of choice being a positive aspect of the experience, although most interviewees preferred using game-based rather than experience-based VR apps. Experience-based VR apps did not have any overt rules or game mechanics, and included activities such as guided meditation. Participants reported that games were preferred because they allowed the participant to actively do something, whereas experiences could make it difficult to disconnect from the busy clinical environment.

> *…I prefer gaming things. I prefer doing things. I prefer keeping busy personally, rather than sort of just lying back and I think maybe if you relaxed or concentrated too much, you'd focus too much on the chemotherapy.* [Participant VR001]

VR as a Distraction for Patients Undergoing Chemotherapy

Distraction and Temporal Distortion

Participant VR sessions ranged from 7 to 68 minutes (mean 29.9, SD 17.8). When asked to approximate how long they thought they spent in the VR sessions directly after completing the session, participants' perception of the session duration ranged from 8 to 90 minutes (mean 35.6, SD 22.4). The majority of participants estimated the duration spent in the VR session fairly accurately (mean 5.12, SD 3.8). Table 3 provides an overview of participant time spent in the VR intervention, mapped against estimated time spent in the intervention.

During the VR sessions, participants seemed very aware of how long their treatments take, and therefore were able to accurately estimate how long they spent in the VR session. For the majority of participants, they enjoyed the experience so much that they were engaged with VR for their entire treatment session.

One participant requested before the session that the VR be playing during cannulation because they find the cannulation and drug administration to be very painful. The clinical nurse specialist allowed the researcher to set up the VR first. The participant found the VR experience to completely distract from the pain. Interestingly, each time the participant came out of an app to try another, they reported that they suddenly noticed the pain. This participant noted that the VR was a complete distraction from the strong pain he experiences during treatment. For two different participants, an accompanying visitor mentioned to the researcher that the participant was having a particularly bad day and that their mood had picked up substantially.

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Table 3. Overview of participant time spent in the virtual reality intervention, mapped against estimated time spent in the intervention.

Participant	Actual intervention time (minutes)	Perceived intervention time (minutes)	Difference
VR001	34	30	+4
VR002	45	23	+22
VR003	90	55	+35
VR004	30	15	+15
VR005	30	28	+2
VR006	35	36	–1
VR007	15	15	0
VR008	20	14	+6
VR009	15	36	–23
VR0010	8	14	–6
VR0011	60	62	–2
VR0012	40	16	+24
VR0013	7	7	0
VR0015	60	—[a]	—
VR0016	15	18	–3
VR0017	40	34	+6
VR0018	—	21	—
VR0019	60	68	–8

[a]Missing data, which occurred because of unanticipated interruptions to the intervention session for the individual participants, leading to inaccuracies in collection of observation data or inability to collect data.

Well-being and Physical Health

Participants reported low scores for each of the nine symptoms of cancer on the ESAS-r: pain (mean 1.22, SD 2.42), tiredness (mean 2.11, SD 2.52), drowsiness (mean 2.06, SD 2.44), nausea (mean 0.61, SD 1.20), lack of appetite (mean 0.76, SD 1.95), shortness of breath (mean 0.22, SD 0.55), depression (mean 0.72, SD 1.74), anxiety (mean 1.11, SD 2.08), and well-being (mean 2.41, SD 2.60). Table 4 shows the participant scores for each ESAS-r domain.

Participants were instructed to provide feedback on any physical discomfort they had experienced during the intervention to ensure they did not require any support from a cancer care nurse. No participants experienced physical discomfort as a result of the intervention. Two participants indicated pain from the site where the chemotherapy intravenous infusion was on their arm.

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Table 4. Participant responses to the Edmonton Symptom Assessment System (ESAS-r) scale.[a]

Participant	Pain	Tiredness	Drowsiness	Nausea	Lack of appetite	Shortness of breath	Depression	Anxiety	Well-being
VR001	4	2	1	3	UA[b]	2	1	0	5
VR002	0	0	0	0	0	0	0	0	0
VR003	0	3	3	0	0	0	0	0	4
VR004	1	1	1	0	0	0	0	1	__[c]
VR005	0	5	5	0	1	0	0	2	1
VR006	5	8	5	1	1	1	7	7	8
VR007	0	5	5	0	0	0	0	5	2
VR008	0	0	0	0	0	0	0	0	0
VR009	1	0	0	0	0	0	1	0	1
VR010	0	5	5	0	8	0	0	0	5
VR011	0	0	0	0	0	0	0	0	0
VR012	0	0	0	0	0	0	0	0	0
VR013	0	0	0	4	0	0	0	0	5
VR015	0	0	0	0	0	0	0	0	0
VR016	1	1	1	1	1	1	1	1	1
VR017	9	5	7	0	0	0	0	0	6
VR018	0	0	0	0	0	0	0	0	0
VR019	1	3	4	2	2	0	3	4	3

[a]The questionnaire asks participants to rate cancer symptoms on a 0-10 scale where 10 indicates the worst distress and 0 the least distress.

[b]UA: unanswered.

[c]Missing data, which were excluded for the calculation of well-being but response data were included for the other eight symptoms. Pairwise deletion was used to calculate means and SDs, which was only necessary for the missing well-being score for one participant.

Barriers and Enablers of Implementing VR in a Day Therapy Suite

Technological Literacy

Participants reported concern that, being "older," they would find it difficult to use the controls, but this did not eventuate. Other participants were concerned about falling asleep with the headset on because the experiences were very relaxing, and that they would likely need practice at setting up before they could negotiate doing it on their own in the day therapy suite.

App Choice

As mentioned above, participants highlighted that having a choice of recreational activities during an appointment was very appealing, and the variety of VR apps was an enabler to sustained use. Participants' feedback highlighted the need for a wider variety of apps available to patients, but acknowledged that curating this content could be difficult. Participants also stressed that the apps would need to be reliable (nonglitchy) and having more choice would exacerbate this issue.

Hardware Usability and Need for Technical Support

Staff workload was identified as a factor influencing the sustained use of VR during chemotherapy. Interviewees noted that many patients would need some support learning to navigate the platform, and without a researcher present, this burden would fall on staff. One participant enjoyed the experience so much, she said she would gladly be a volunteer to set chemotherapy patients up with games in the future. They also mentioned that many chemotherapy facilities have volunteer groups that assist with recreational activities.

> *…I think it's a really good idea [VR]. The only setback I see is something that may possibly occur, the nursing staff having to deal with anything with the machinery, because they're incredibly busy and to then have to come back because something's not working to some technical things, not working might be problem for them. And also infection control issue with the machinery, so how it's cleaned afterwards and how it is maintained?* [Participant VR001]

> *…I think you definitely would need to have someone there to troubleshoot. Most anyone 40 and under, all have phones and know how things work and there's always a back button and there's always a click on this and then that takes you somewhere. That sort of stuff is really simple. But yeah, it's the setting up originally like connecting it to the headset. Connecting it to the phone I guess, because the phone is just in the headset and connecting the remote. If there was any issues with that, then you would*

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definitely need someone for it. But I think if you were doing it, if you did it on a regular enough basis, if a person was having the chemo do them on a regular basis, then after about two sessions they'd be comfortable. I reckon you're just giving it to them and they working it out. [Participant VR007]

Setting for Using VR

Several interviewees discussed the location of VR interventions as a factor for sustained use. Participants indicated a preference for privacy, both because of security concerns and also because of uncertainty as to how they looked with the hardware on. As a result, interviewees felt that VR would not be suited for use while waiting for an appointment in an open environment.

… Also you'd got your belongings there when you're in a room of strangers. So, I don't know how you'd feel about your bag just sitting there with all your Medicare information and everything in it? So, I don't know. Probably safety point of view might be an issue also. [Participant VR001]

Multiplayer VR Apps

Interviewees were also asked to give feedback on whether they would like to use VR collaboratively while having chemotherapy. Interviewees were mixed in their views of this, in part because they were unsure how this would work. One interviewee thought that having a collaborative VR experience during chemotherapy might be beneficial for engaging carers, friends, and family waiting around during the appointment. This is important as several participants mentioned that they felt conscious of their visitors' boredom, and in the future they would only be likely to use the VR if they were unaccompanied.

…Oh my goodness. If I had done that with one of my friends, I think it would be good. It was nice having [the researcher] there because whilst I was playing I could still hear her and my mother in law talking, so I felt like my mother in law was being entertained or I can imagine if it was my husband and I going, and I was doing this and he was just sitting there. Not that he wouldn't have anything to do, but it'd be fun to play, two playing games or something if you could. All like challenge each other to see if you can get through the farthest. [Participant VR007]

Other interviewees thought it would add another level of engagement being able to play VR apps with others, as it would add another layer of competition.

…That'd be absolutely fantastic. Well, it's competing with another person again. So, you know, and also, well it may not even be a person there. It could be someone anywhere in the world that you're competing with. But yes, competing against other people is always even better than competing against yourself. [Participant VR001]

Discussion

Participant Experience

This study explored the feasibility and acceptability of using VR during chemotherapy appointments for adult patients. Patient participants reported high levels of engagement and interest in the VR intervention, the majority of whom indicated they would like to use it again for future chemotherapy sessions. Very few reported discomfort, and where it was reported, it could easily be rectified by readjusting the headset. Some patients reported VR to be a useful distraction during chemotherapy, particularly for reducing anxiety or alleviating boredom.

Although patients indicated that the VR did distract them from boredom during the chemotherapy appointment, it was interesting to note that it did not noticeably change their perception of time. Although several studies have evaluated the role of VR during chemotherapy as a distraction from anxiety and pain [16,38], there has been less research on how it influences perception of time. In one study, patients consistently underestimated the time of their chemotherapy due to the VR intervention [12]. One explanation is that our participants were aware of the duration of their chemotherapy session and used that as a guide to estimate the duration of the VR intervention. As such, time estimates are not necessarily an indicator of the acceptability of VR in this study. Other research has also suggested that coping style may affect the extent to which VR is distracting during chemotherapy [16]; however, this requires further investigation.

The intervention did not alter temporal perception, but some patients noted that it may reduce anxiety about attending an appointment. This was an unexpected finding of the study, which may warrant further research to understand the role of VR for improving treatment adherence. Patients undergoing medical treatment for cancer are known to experience anxiety [39]; however, unlike psychosocial factors such as depression, the role of anxiety on treatment adherence is unclear [40]. Nonattendance at scheduled appointments is a known burden on health care organizations [41]. Psychosocial factors are among the wide range of variables that have been identified as influencers of a patient's likelihood not to attend a scheduled appointment [42].

Findings from this study showed that patients did not experience any significant nausea from the VR, except in instances where the lenses could not be sufficiently adjusted for the appropriate focal length. This finding addresses a recognized gap in research into the side effects of VR for patients undergoing chemotherapy [38]. Although findings from this study showed minimal adverse events from the VR intervention, the intervention was not sufficiently powered to test a reduction in side effects of treatment, such as nausea, fatigue, and pain.

Finally, based on the study results, we can provide three main recommendations for the implementation of VR for patients undergoing chemotherapy. First, additional resources (eg, volunteers) are needed to orient patients to the technology. Participants indicated that at-elbow support was preferred and that staff may not have the capacity to provide this. Second, it

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is important to ensure there are a range of reliable, pretested VR apps available, including both game-based and experience-based programs. Apps could support both individual and collaborative experiences that would allow visitors to play with the patient. Third, VR interventions should be conducted in private places where patients' belongings can be securely stored.

Limitations

A key limitation of this study is the small sample size, which limited the analyses that could be performed. Despite this, data saturation was reached for the qualitative analyses. Recruitment issues that may be of interest to other researchers in VR and chemotherapy included late cancellations due to blood tests, which precluded patients from chemotherapy at their scheduled time. In addition, due to the COVID-19 pandemic and the vulnerability of the patient participants, the researchers cancelled some scheduled sessions.

The study also used the Samsung Gear headset, which is an older type of technology that was discontinued commercially during the study. Future researchers should consider further investigating the temporal aspects of VR as a distraction for patients undergoing chemotherapy. As the findings of this study did not align with the results from broader research, it would be interesting to better understand whether cancer patients have unique experiences with VR, or whether there are characteristics of the type of treatment patients underwent that limited the ability for VR to act as an effective distraction.

Finally, we believe that this is one of the first studies to explore the effect of VR on a patient's perception of time passing. This finding emerged from use of an observational methodology, but there would be value in attempting to replicate this study or to further explore this effect using alternative methodologies. Future researchers should consider exploring the temporal distortion effect of VR for patients undergoing chemotherapy. This could include developing a richer understanding as to why patients undergoing chemotherapy may or may not have their perception of time altered due to the use of VR during infusion, as well as the use of robust measures such as validated scales to understand the temporal effect VR has on the perception of pain, discomfort, and immersion.

Conclusions

Patients undergoing chemotherapy enjoy having access to VR during their appointments, particularly if there is a choice of apps for them to use. It is feasible to implement VR during appointments in the controlled confines of a research study. However, sustained implementation of VR requires additional resources to provide at-elbow support for patients using the technology, to review apps for inclusion for patients, and to ensure that the VR intervention is able to be conducted in a private and secure location.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Postintervention survey informed by the Player Experience of Needs Satisfaction (PENS) instrument.
[PDF File (Adobe PDF File), 28 KB - games_v10i1e29579_app1.pdf]

Multimedia Appendix 2
Adverse event checklist that allowed participants to visually indicate any adverse events experienced.
[PDF File (Adobe PDF File), 255 KB - games_v10i1e29579_app2.pdf]

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Abbreviations

EOI: Expression of Interest
ESAS-r: Edmonton Symptom Assessment Scale revised
HMD: head-mounted display
PENS: Player Experience of Needs Satisfaction
VR: virtual reality

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Original Paper

Immersive Virtual Reality–Based Cognitive Intervention for the Improvement of Cognitive Function, Depression, and Perceived Stress in Older Adults With Mild Cognitive Impairment and Mild Dementia: Pilot Pre-Post Study

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Abstract

Background: The incidence of dementia is increasing annually, resulting in varying degrees of adverse effects for individuals, families, and society. With the continuous development of computer information technology, cognitive interventions are constantly evolving. The use of immersive virtual reality (IVR) as a cognitive intervention for older adults with mild cognitive impairment (MCI) and mild dementia (MD) is promising, although only few studies have focused on its use.

Objective: The Chinese virtual supermarket (CVSM) IVR system was developed to provide a comprehensive and individual cognitive intervention program for older patients with MCI and MD. The aim of this study was to explore the feasibility and clinical effectiveness of this 5-week IVR-based cognitive intervention.

Methods: A pretest-posttest study design was conducted with 31 older adults with MCI and MD from August 2020 to January 2021. All participants participated in a 5-week immersive virtual cognitive training program using the CVSM system. Feasibility was assessed as the incidence and severity of cybersickness symptoms and participant satisfaction based on questionnaires conducted after the intervention. Clinical effectiveness was evaluated using neuropsychological assessments, including several commonly used measures of cognitive function, depression, perceived stress, and activities of daily living. Measurements were obtained at baseline and after the intervention period.

Results: A total of 18 patients with MCI (mean age 82.94 [SD 5.44] years; 12 females) and 13 patients with MD (mean age 85.7 [SD 4.67] years, 10 females) participated in this pilot study. Both groups showed significant improvements in all cognitive function measurements (P<.001). The MD group had a significantly greater improvement in general cognitive function compared to the MCI group in Montreal Cognitive Assessment Scale, Symbol Digit Modalities Test, Shape Trail Test, and Auditory Verbal Learning Test. Furthermore, an intervention effect was observed in the improvement of perceived stress (P=.048 for MD group, P=.03 for MCI group).

Conclusions: The use of the CVSM system may be effective in enhancing the cognitive function of patients with MCI and MD, including general cognitive function, memory, executive function, and attention. IVR technology enriches cognitive intervention approaches and provides acceptable, professional, personalized, and interesting cognitive training for older adults with cognitive impairment.

Trial Registration: ClinicalTrials ChiCTR2100043753; https://trialsearch.who.int/Trial2.aspx?TrialID=ChiCTR2100043753

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(JMIR Serious Games 2022;10(1):e32117) doi:10.2196/32117

KEYWORDS

cognitive intervention; dementia; immersive virtual reality; mild cognitive impairment; cognitive impairment; virtual reality; VR; older patients; usability; memory; stress

Introduction

China is rapidly transforming into an aging nation. Based on the seventh national survey conducted by the National Bureau of Statistics, the number of older adults (aged ≥60 years) in China was 264.01 million (18.7% of the total population) at the end of 2020, including 190.63 million individuals aged ≥65 years (13.5% of the total population). It is predicted that there will be 400 million Chinese citizens aged ≥65 years by 2050, including 150 million aged ≥80 years [1]. Population aging is accompanied by an increased prevalence of mild cognitive impairment (MCI) and mild dementia (MD). In China, the prevalence of MCI in individuals ≥65 years is 10%-20%, and over 50% of these patients progress to dementia within 5 years. The incidence of dementia among individuals ≥60 years of age in China is predicted to increase from 14% in 2015 to 33% by 2050 [2,3]. The high prevalence of dementia in the older population is a significant social and economic burden on patients, patient families, and the existing health care system in China. The total cost associated with dementia is increasing at an alarming rate in China and is expected to exceed US $9.12 trillion by 2050 [4].

Although several studies regarding pharmacological treatments for MCI and MD have been conducted, the effectiveness of pharmacological treatments is limited. Therefore, safe treatment alternatives for MCI and MD have been developed, including cognitive interventions [5]. Cognitive training is among the most frequently used cognitive interventions and typically involves the repeated practice of a set of structured tasks [6,7]. In recent decades, many different cognitive training approaches aimed at improving and maintaining cognitive ability have been developed to reduce the progression of MCI and MD. However, most traditional cognitive training programs conducted by a neuropsychologist are based on face-to-face exercises [8,9], requiring the identification of a convenient meeting location, the coordination of schedules, and a dedicated training time. With the rapid development of computer science and technology, cognitive training exercises can now be delivered via computers or mobile technology, resulting in better patient compliance owing to the convenience of cognitive training [10-12]. Therefore, an increasing number of studies have focused on cognitive interventions based on computer technology.

Virtual reality (VR) is a new computer technology that was created with the development of multimedia technology and used in military science before being applied to the medical sciences [13]. VR is a computer-generated effect that can simulate a given scene through 3D graphics and other sensory experiences (vision, touch, and motion feeling) [14] by using special electronic devices such as computer keyboards, computer mice, speech/voice recognition, motion sensors, and haptic devices [15]. VR can be divided into 2 types according to the degree of immersion: nonimmersive and immersive virtual reality (IVR). The nonimmersive system is a desktop-based VR with low interaction (such as with a keyboard and joypad). IVR is characterized by the use of more interactive tools, including a head-mounted display or a cave automatic virtual environment, which allows patients to interact with such a virtual environment from the first-person perspective [16]. Nonpharmacological interventions based on IVR have been applied in clinical settings for pediatric patients, patients with psychotic disorders, older adults, and patients with MCI and MD [17-21]. Meta-analyses and systematic reviews have reported the effectiveness and advantages of VR for patients with MCI and MD. A recent systematic review reported that IVR has a potentially positive effect on global cognitive function, attention, and emotion [22]. Compared to traditional cognitive training, the VR environment is highly flexible and allows for cognitive training in environments that are either impossible or unsafe in real life. For example, IVR enables older adults with limited physical abilities to go shopping [23], ride a bicycle in a city [24], and cook [25] in a safe environment. In addition, the flexibility of VR allows for the adjustment of various parameters such as the duration of recall, types of stimuli [26], and numbers or similarities of distractors [27], ensuring that the settings match the patient's individual capabilities.

Although IVR in the clinical setting has many advantages, the feasibility of its use among older adults remains controversial. A mixed method pilot study (n=10) examined the effects of a 15-minute interactive IVR forest experience on the level of engagement, apathy, and mood states of people with dementia and found that the use of IVR brought pleasure to participants but also increased their levels of fear and anxiety [28]. In addition, the extent to which IVR-based cognitive training can benefit cognition in patients diagnosed with MCI or MD is unclear. Systematic reviews have also reported mixed results [29-31]. Therefore, more research regarding IVR-based cognitive training for patients with MCI and MD is needed. In this study, an IVR-based cognitive training program, the Chinese virtual supermarket (CVSM), was developed for use in older adults with MCI and MD, and a pretest-posttest study was conducted to evaluate the effects on neuropsychological outcomes in older adults with MCI and MD. We hypothesized that after the 5-week IVR-based cognitive training session, patients with MCI and MD would have significantly improved cognitive function and other health-related outcomes.

Methods

Recruitment

The proposed virtual cognitive assessment platform was installed for clinical testing at the Fujian Good Health Care Center. Older adults were recruited for the study via popular science lectures on VR, virtual game demonstrations, and VR experience activities. The participants were screened according to the inclusion and exclusion criteria. This study included 35

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participants (21 with MCI and 14 with MD). All participants were ≥60 years of age, had normal or corrected-to-normal vision, and could communicate in Mandarin Chinese. Participants with MCI were diagnosed according to the Peterson diagnostic criteria [32]: clinically confirmed memory loss, intact or slightly impaired activities of daily living (score <23 for patients <75 years of age and <25 for patients >75 years of age), cognitive impairment based on the Chinese-Changsha version of the Montreal Cognitive Assessment Scale (MoCA) (abnormal value: MoCA score <13 for illiterate individuals, <19 for individuals with a primary school diploma, and <24 for individuals with a junior high school diploma or above), and preserved general cognitive function assessed using the Mini-Mental State Examination (MMSE) (24-30 points). Participants with MD were diagnosed by an experiential psychiatrist according to the International Classification of Diseases 10th revision [33] with a Clinical Dementia Rating score ≤1. Participants with severe audiovisual impairments (deafness, cataracts, or glaucoma), psychiatric and logic disorders (bipolar disorder, schizophrenia, stroke, Parkinson disease, or epilepsy), or a history of taking drugs affecting cognitive function in the 6 months prior to this study were excluded. All participants provided written informed consent for their participation in this study. This study was approved by the ethics committee of Fujian Provincial Hospital (K2020-06-006).

Intervention Instruments

Virtual Environment

The CVSM has applied for national computer software copyright, registration 2021SR0993516, which was developed by Fujian Provincial Hospital in collaboration with the School of Mechanical Design Manufacturing and Automation, Fuzhou University, and the Rhino Technology Group. The virtual environment of the CVSM was developed and rendered using a Unity 3D engine and was run on a Dell Precision T3600 PC with a CPU Intel I5-6400 processor and a GTX 1600 graphics card. The system required a capacity of 277 MB. The 3D virtual supermarket was presented using HTC VIVE Pro Eye, which provided a stereoscopic vision via 2 screens in front of the eyes (the resolution of the binocular combination was 2160×1200 pixels). The HTC Pro Eye allowed the participant to rotate his or her head for a 360° view of the virtual scene and to interact and walk freely in the virtual environment. With the help of an assistant, participants were asked to stand in an open room wearing a VR helmet (Figure 1). Through the headset, the participant viewed a rectangular virtual supermarket (9.8 m×18 m). Participants used a wireless remote control to select items within the virtual scene.

Figure 1. The Chinese virtual supermarket system.



IVR-Based Cognitive Intervention

The CVSM system was designed as a simple, easy-to-learn, personalized immersive VR cognitive management program for older adults and was divided into 3 modules: an operation learning module, a cognitive evaluation module, and a cognitive intervention module. In the operation learning module, participants were taught how to wear the 3D VR helmets and operate VR handles to interact with the virtual supermarket during 3 separate 10- to 15-minute sessions. Multiple exercises were used to help the participants adapt to the virtual environment. In the cognitive evaluation and cognitive intervention modules, the participants were presented with a list of 3-12 familiar virtual images and tags of common items (such as oranges or toothpaste) that they were asked to memorize within a minute and a half (Figure 2). After memorizing the list, the participants engaged in a number sorting game for 20 seconds (Figure 3) before entering the supermarket to buy the items on the memorized list. Then, participants were asked to locate the counter and pay in RMB bills, as shown in Figure 4. The final screen in the game confirmed that the payment was completed, and a report listing the quantities of products purchased, nonshopping list items, and the total time needed for completion was displayed. The participant's task completion

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in the cognitive assessment module was set as the initial difficulty level in their cognitive training. The CVSM included 12 levels of difficulty according to memory quantity, delay time, calculation difficulty, and interval retrieval times. After completing 3 shopping sessions that included a maximum of 1 error each, the participant could increase his or her level of difficulty. Participants were instructed to train 3 times per week over a 5-week period and to complete 3 training sessions on each training day, with each session lasting 20-30 minutes. The entire cognitive training program ranges from simple to complex, involving training in multiple cognitive domains such as memory, attention, executive function, and calculation ability.

Figure 2. The shopping list of the Chinese virtual supermarket system.



Figure 3. The number sorting game of the Chinese virtual supermarket system.

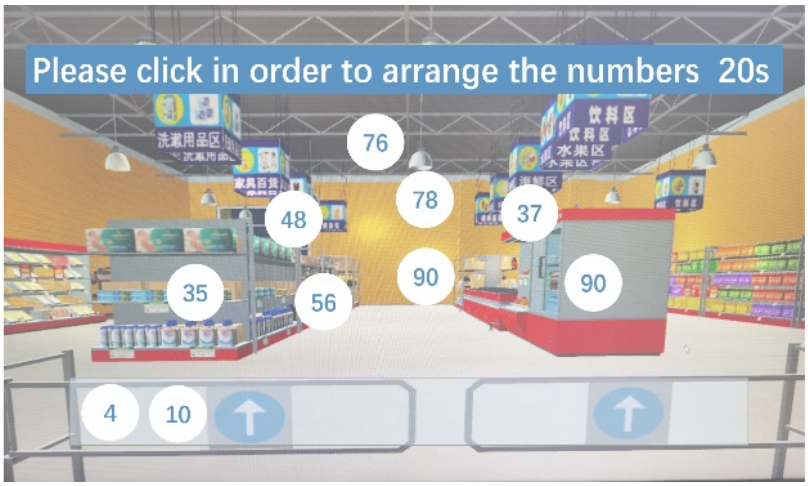
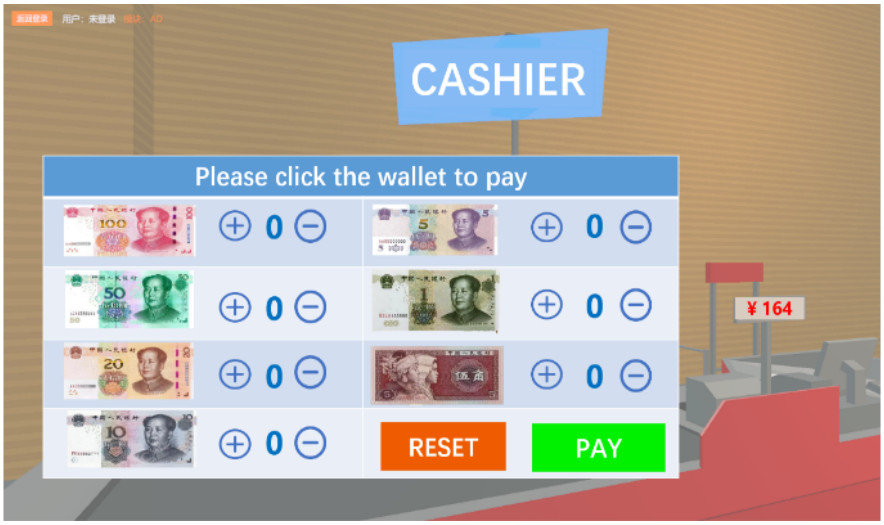


Figure 4. The payment interface of the Chinese virtual supermarket system.



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Instruments to Measure Outcomes

A pretest-posttest study design was used to evaluate the effects of the VR-based cognitive intervention using the CVSM system in older adults with MCI and MD. Various measurements were obtained to evaluate feasibility and effectiveness of the IVR intervention. Demographic characteristics such as age, sex, and years of education were recorded during the initial evaluation. Trained psychologists assessed the participants.

Feasibility

Feasibility was assessed as the incidence and severity of cybersickness symptoms and participant satisfaction based on the answers provided in a questionnaire conducted after the intervention. The questionnaire was developed specifically for this study.

Severity of Cybersickness Symptoms

All participants were assessed for the severity of IVR by using the Simulator Sickness Questionnaire, which consists of 16 items regarding 3 factors: nausea (sweating, difficulty concentrating, or stomach awareness), oculomotor disturbance (headache, eyestrain, or blurred vision), and disorientation (head fullness, dizziness with eyes opened or closed, or vertigo). The severity of symptoms was categorized as none, mild, moderate, or severe. The Simulator Sickness Questionnaire score was calculated as the sum of the scores of the 16 items multiplied by 3.74, and it ranged from 0 to 179.52 [34].

Incidence of Cybersickness Symptoms

The incidence of cybersickness symptoms was calculated.

Satisfaction

The satisfaction questionnaire was used to assess the views and opinions of the participants regarding the intervention. Items were rated on a 4-point Likert scale (4=strongly agree, 3=agree, 2=neutral, and 1=poor). The total score ranged from 8 to 32, with higher scores indicating higher satisfaction. The causes of patient satisfaction were further investigated via open interviews.

Effectiveness

In this pilot study, the neuropsychological evaluation included several commonly used measures of cognitive function, depression, and perceived stress.

Cognitive Function

Global cognition was measured using the MMSE and MoCA, which have both been shown to have high test-retest reliability and be sensitive to changes in people with MD and MCI. MMSE and MoCA are respectively composed of 30 cognitive domain-related problems such as attention, language, word recall, time, and place positioning. The higher the score, the higher the cognitive level [35,36]. The effects of the treatments on memory function, executive function, and attention were assessed using the Auditory Verbal Learning Test (AVLT), the Shape Trail Test (STT), and the Symbol Digit Modalities Test (SDMT), respectively. In this study, the AVLT will be used to evaluate language learning and memory function, which includes 3 tests: immediate recall, short-term delayed recall, and long-term delayed recall [37]. The score of AVLT in this study is the sum of the 3 test scores. The higher the total recall score, the better the memory function. The STT was developed by Agnes Chan from the Chinese University of Hong Kong to evaluate executive function, and it consists of 2 components. The STT-A consists of 25 consecutive numbers—from 1 to 25. The STT-B was modified as 25 numbers enclosed in 13 circles (from 1 to 13) and 12 squares (from 1 to 12). Taking the sum of completion time as the scoring standard, the shorter the time, the better the executive function [38].The SDMT is used to assess the tester's ability of attention, learning, conversion, and involves a substitution task using a coding key with 9 different abstract symbols, each paired with a numeral. Below the key, a series of these symbols was presented and the participant was asked to write down the corresponding number for each symbol. Participants need to complete as many of 115 items as they could in 90 seconds. The number of correct substitutions within this time was recorded as their score [39].

Depression

The Geriatric Depression Scale (GDS) is a self-report evaluation. The scale comprises 30 items: 10 items confirm depression if the answers are negative, while the remaining 20 items confirm depression if the answers are positive. Normal scores range from 0 to 10; a score of 11-20 indicates mild depression and 21-30 indicates moderate and severe depression [40].

Perceived Stress

The Chinese Perceived Stress Scale (PSS) is a scale for assessing individual stress. The scale mainly includes 14 self-assessment items: The 4th to 7th, 9th to 10th, and 13th items are used reverse score. The 1st to 3rd, 8th, 11th to 12th, and 14th items adopt positive scoring. The score of Chinese PSS equals total score minus 14. A higher score indicates that psychological pressure is higher, which is harmful to the physical and mental health [41].

Statistical Analysis

Baseline data are presented using mean and standard deviation. Student *t* test and Wilcoxon signed rank test were used to analyze the results to evaluate the effect of the VR cognitive intervention in patients with MCI and MD. The *P* value was corrected by false discovery rate to reduce the risk of type I error. In order to determine the effective size of the results, the effect size calculator (Cohen *d*) for *t*test was used. The data were analyzed according to the intention-to-treat principle. Missing data were replaced with the individual's available data at baseline or were obtained by phone. All statistical analyses were conducted using the SPSS software (version 22.0; IBM Corp). Statistical significance was set at $P<.05$.

Results

Participant Characteristics

A total of 52 older adults showed interest in participating in this pilot study and were screened for eligibility; 17 participated in the upgrading and transformation of the CVSM system in the preparation stage and 35 agreed to participate in the feasibility study. Four participants (1 with MD and 3 with MCI) were unable to complete the study owing to physical limitations. Therefore, 18 participants with MCI (12 females and 6 males; mean age 82.94 [SD 6.44] years; mean years of education 11.0

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[SD 3.97] years) and 13 participants with MD (10 females and 3 males; mean age 85.7 [SD 4.67] years; mean years of education 11.23 [SD 4.71] years) finally completed all courses of VR-based cognitive training as planned and were included in the final analysis. There were no significant differences between the MCI and MD groups at baseline with the exception of cognitive function (Table 1).

Table 1. Participants' baseline characteristics (N=31).

Characteristic	MCI[a] (n=18)	MD[b] (n=13)	*P* value
Sociodemographic data			
Age (years), mean (SD)	82.94 (6.44)	85.76 (4.67)	.19
Female, n (%)	12 (67)	10 (77)	.83
Education (years), mean (SD)	11.00 (3.97)	11.23 (4.71)	.88
Cognitive function, mean (SD)			
MoCA-CS[c]	21.56 (3.31)	13.92 (4.68)	<.001
MMSE[d]	26.06 (2.99)	18.54 (5.73)	<.001
AVLT[e]	38.11 (10.76)	25.38 (10.12)	.002
STT[f]	352.72 (132.79)	523.23 (307.71)	.04
SDMT[g]	21.83 (11.04)	12.85 (9.56)	.03
Psychosocial measures, mean (SD)			
PSS[h]	14.56 (12.05)	19.23 (15.28)	.35
GDS[i]	5.11 (4.23)	5.00 (4.63)	.95

[a]MCI: mild cognitive impairment.

[b]MD: mild dementia.

[c]MoCA-CS: Chinese-Changsha version of the Montreal Cognitive Assessment Scale.

[d]MMSE: Mini-Mental State Examination.

[e]AVLT: Auditory Verbal Learning Test.

[f]STT: Shape Trail Test.

[g]SDMT: Symbol Digit Modalities Test.

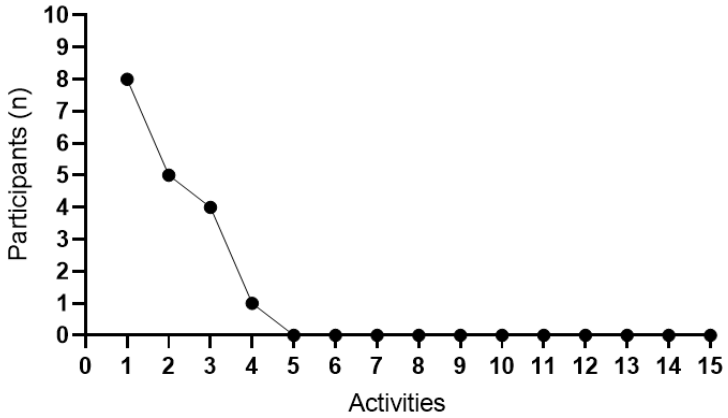
[h]PSS: Perceived Stress Scale.

[i]GDS: Geriatric Depression Scale.

Cybersickness Symptoms

Eight participants had mild cybersickness symptoms in the first 4 activities (range of scores: 3.74-11.22 points). After 3 consecutive activities, the probability of the development of simulator disease was significantly reduced (Figure 5). After the fifth intervention, there were no reports of simulator disease. No adverse events such as injuries, falls, or quarrels were reported during the IVR interventions.

Figure 5. Frequency of cybersickness symptoms.



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Effectiveness of the Intervention

Statistical analysis was performed using the SPSS version 22.0. For comparison of the continuity variables of normal distribution, Student *t* test was used (Table 2). Otherwise, Wilcoxon signed rank test was used (Table 3). In order to reduce the risk of type I error, the *P* value was corrected by false discovery rate. As seen in Table 2 and Table 3, there is a significant difference between average pretest and posttest results in both groups (q<0.05), except GDS and PSS. In order to calculate the effect size of the results, Cohen *d* has been used. The effect size of the MD group results is significantly higher compared with that of the MCI group in MoCA, SDMT, STT, AVLT, and GDS.

Table 2. Statistical analysis of preintervention and postintervention results of mild cognitive impairment and mild dementia groups by using Student *t* test and effect size calculation results with Cohen *d*.

Group, index	Preintervention, mean (SD)	Postintervention, mean (SD)	*t* value *(df)*	*P* value	q value	Cohen *d*
Mild dementia						
MoCA-CS[a]	13.92 (4.68)	21 (3.89)	–9.826 (12)	<.001	0.017	1.64
MMSE[b]	18.54 (5.74)	24.85 (5.74)	–7.697 (12)	<.001	0.017	1.09
SDMT[c]	12.85 (9.56)	17.31 (7.74)	–3.603 (12)	.004	0.009	0.51
PSS[d]	19.23 (15.28)	13.15 (10.95)	2.205 (12)	.048	0.056	0.45
Mild cognitive impairment						
MoCA-CS	21.56 (3.31)	25.67 (2.93)	–7.857 (17)	<.001	0.023	1.31
STT[e]	352.72 (132.79)	254 (66.18)	4.51 (17)	<.001	0.023	0.68
SDMT	21.83 (11.04)	27.22 (11.97)	–5.422 (17)	<.001	0.023	0.46

[a]MoCA-CS: Chinese-Changsha version of the Montreal Cognitive Assessment Scale.

[b]MMSE: Mini-Mental State Examination.

[c]SDMT: Symbol Digit Modalities Test.

[d]PSS: Perceived Stress Scale.

[e]STT: Shape Trail Test.

Table 3. Statistical analysis of preintervention and postintervention results of mild cognitive impairment and mild dementia groups by using Wilcoxon test and effect size calculation results with Cohen *d*.

Group, index	Preintervention, mean (SD)	Preintervention, median (min-max)	Postintervention, mean (SD)	Postintervention, median (min-max)	*Z* value	*P* value	*q* value	Cohen *d*
Mild dementia								
AVLT[a]	25.38 (10.12)	24 (8-50)	38.53 (8.63)	38 (28-57)	2.97	.003	0.010	1.39
STT[b]	523.23 (307.71)	394 (227-1246)	338.76 (112.30)	306 (204-591)	–3.04	.002	0.014	0.79
GDS[c]	5.00 (4.63)	4 (0-16)	3.38 (3.52)	3 (0-12)	1.42	.15	0.154	0.39
Mild cognitive impairment								
MMSE[d]	26.06 (2.99)	26.5 (16-29)	29.06 (0.72)	29 (28-30)	3.42	.001	0.003	1.37
AVLT	38.11 (10.76)	36 (14-64)	51.33 (8.28)	51.5 (32-68)	3.72	<.001	0.007	1.38
PSS[e]	14.56 (12.05)	8.5 (0-40)	9.11 (12.11)	3 (0-38)	2.18	.03	0.033	0.45
GDS	5.11 (5.24)	3.5 (0-20)	4.22 (6.31)	2 (0-24)	1.16	.25	0.245	0.15

[a]AVLT: Auditory Verbal Learning Test.

[b]STT: Shape Trail Test.

[c]GDS: Geriatric Depression Scale.

[d]MMSE: Mini-Mental State Examination.

[e]PSS: Perceived Stress Scale.

Satisfaction

The CVSM program received high user satisfaction ratings for all items (Table 4). All scores for cognitive intervention method/frequency, virtual environment, memory task, and interactive devices/modes were >3.50, indicating that the intervention was acceptable and positive. There were no complaints regarding the difficulty of the memory task. The

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visual and auditory supports (products, shopping lists, and hints) were reported to be clear and useful. The frequency of the intervention, comfort of the VR equipment, and difficulty of the operation received some neutral and poor ratings. One patient in the MCI group reported that the VR helmet was heavy, resulting in slight discomfort. Another patient in the MCI group reported that he did not like shopping in real life and was therefore neutral toward the VR supermarket scene. This patient also reported that the intervention was too frequent. Two patients in the MD group expressed concern about learning how to operate the IVR system, although they were able to complete the virtual shopping task with the guidance of the researchers.

Table 4. Participant satisfaction (N=31).

Items	Strongly agree, n (%)	Agree, n (%)	Neutral/poor, n (%)	Mean (SD)
Q1. Are you satisfied with the method of the IVR[a] intervention?	21 (68)	10 (32)	0 (0)	3.68 (0.47)
Q2. Are you satisfied with the frequency of the intervention?	23 (74)	7 (23)	1 (3)	3.71 (0.52)
Q3. Did you enjoy doing the shopping?	18 (58)	12 (39)	1 (3)	3.55 (0.56)
Q4. Did you recognize all the products in VR[b] supermarket?	31 (100)	0 (0)	0 (0)	4.00 (0)
Q5. Did you feel a sense of accomplishment after completing the shopping task?	17 (55)	14 (45)	0 (0)	3.55 (0.50)
Q6. Was it comfortable to wear the VR helmet?	25 (81)	5 (16)	1 (3)	3.77 (0.49)
Q7. Was it easy to learn VR handle operation?	26 (84)	3 (10)	2 (7)	3.74 (0.67)
Q8. Did you have a positive experience in using IVR?	25 (81)	6 (19)	0 (0)	3.81 (0.40)

[a]IVR: immersive virtual reality.

[b]VR: virtual reality.

Discussion

Principal Results

This study investigated the feasibility and effectiveness of a 5-week program for improving cognitive function in older adults with MCI and MD based on the increased use of IVR-based nonpharmacological interventions in the fields of cognitive impairment and geriatric preventive medicine. This is the first study to develop, implement, and evaluate the effects of an IVR-based cognitive training program in China. All participants who participated in the CVSM had improved executive function, attention, memory, and general cognitive function compared to baseline, which is consistent with the results of a meta-analysis of IVR-based cognitive training [42]. VR interventions are useful for patients with MCI or MD. Some studies [42,43] have reported limited positive effects in patients with MD and that the effects of VR were greater in patients with MCI than in patients with MD. However, in this study, the MD group had significantly greater improvement in general cognitive function than the MCI group. This difference in results may be due to the personalized difficulty setting of the CVSM system. An appropriate task difficulty setting and motivational incentives decrease the frustration of patients with MD when working on difficult tasks, enhancing the benefits of activated brain function [44]. Therefore, adjusting the appropriate task difficulty according to the basic cognitive level of patients with MD has a positive impact on improving the cognitive function of patients with MD.

The results of this study indicate that both groups had significantly improved perceived stress and depression after participating in the CVSM. VR has been observed to relieve anxiety and depression [45]. Some feasibility studies suggested that immersive virtual environment may promote the limited functioning of patients with cognitive impairment that affects communication, interaction, motivation, participation, and positive attitude toward others [46]. Therefore, the importance of virtual environment should be considered in cognitive training because the sense of existence in the virtual environment itself can enhance volitional motivation, allowing people to constantly deal with external stimuli and adapt to the changing environment in cognition [47]. There were few reports of mild dizziness during the early stages of the cognitive training period in this study, and simulator-related symptoms decreased as the number of cognitive training sessions increased. These results suggest that the CVSM is a feasible IVR system for older adults with MCI and MD. The low incidence of simulator disease in this study may be associated with the frequency and time of cognitive training programs. The neural mismatch model [48] indicates that unpleasant symptoms occur when the sensory information is inconsistent with the individual's past experiences. Therefore, older adults are prone to discomfort when they enter some VR environments. The use of adaptation training programs that last for several days and the gradual increase of time spent using the simulator during a single training session can help prevent the discomfort associated with the simulator [49].

Some intervention studies have reported high dropout rates of older adults in cognitive training based on technical support [43,50]. Cognitive training based on Immersive Virtual can be regarded as an effective method to enhance user participation, which contributes to the positive results of intervention [51]. However, older adults are less exposed to modern digital technology in their daily life. Therefore, not all can understand and accept it. In order to overcome this limitation, this study carried out many interesting lectures related to VR and

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experience activities in nursing homes during the recruitment of research objects, so as to increase older adults' understanding of virtual technology and shorten the “digital gap” between older adults and technology. The results of the satisfaction survey suggest that the participants in this study were highly engaged during the intervention and had a positive attitude toward IVR-based cognitive training. The majority of the participants were attracted to this novel cognitive training method.

Limitations

This study is not without limitations. First, our pretest and posttests were identical. Older adults received a total score for each pretest but were not notified which answers they got correct on the pretest. Nevertheless, if they remembered the questions in the pretest, the identical pretests and posttests may have exaggerated the posttest scores. Second, the sample size was small and the study did not include a control group and a long-term follow-up analysis. However, according to the Virtual Reality Clinical Outcomes Research Experts framework [52], researchers are required to conduct early testing with a focus on feasibility, acceptability, tolerability, and initial clinical effectiveness before a standardized randomized controlled trial can be started. Therefore, this study is beneficial as it reduces the risk of conducting a randomized controlled trial with an intervention that has not undergone thorough testing. The effects and mechanisms of IVR-based cognitive training on the cognitive performance of patients with MCI and MD should be studied using high-quality randomized controlled trials.

Conclusion

In conclusion, this pilot study validated the feasibility and effectiveness of IVR-based cognitive training by using a novel CVSM system in older adults with MCI and MD. The results of this study support the use of IVR-based cognitive training in this patient population.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AVLT: Auditory Verbal Learning Test
CVSM: Chinese virtual supermarket
GDS: Geriatric Depression Scale
IVR: immersive virtual reality
MCI: mild cognitive impairment
MD: mild dementia
MoCA: Montreal Cognitive Assessment Scale
MMSE: Mini-Mental State Examination
PSS: Perceived Stress Scale
SDMT: Symbol Digit Modalities Test
STT: Shape Trail Test
VR: virtual reality

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Original Paper

Virtual Reality Simulation Training for Cardiopulmonary Resuscitation After Cardiac Surgery: Face and Content Validity Study

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Abstract

Background: Cardiac arrest after cardiac surgery commonly has a reversible cause, where emergency resternotomy is often required for treatment, as recommended by international guidelines. We have developed a virtual reality (VR) simulation for training of cardiopulmonary resuscitation (CPR) and emergency resternotomy procedures after cardiac surgery, the Cardiopulmonary Resuscitation Virtual Reality Simulator (CPVR-sim). Two fictive clinical scenarios were used: one case of pulseless electrical activity (PEA) and a combined case of PEA and ventricular fibrillation. In this prospective study, we researched the face validity and content validity of the CPVR-sim.

Objective: We designed a prospective study to assess the feasibility and to establish the face and content validity of two clinical scenarios (shockable and nonshockable cardiac arrest) of the CPVR-sim partly divided into a group of novices and experts in performing CPR and emergency resternotomies in patients after cardiac surgery.

Methods: Clinicians (staff cardiothoracic surgeons, physicians, surgical residents, nurse practitioners, and medical students) participated in this study and performed two different scenarios, either PEA or combined PEA and ventricular fibrillation. All participants (N=41) performed a simulation and completed the questionnaire rating the simulator's usefulness, satisfaction, ease of use, effectiveness, and immersiveness to assess face validity and content validity.

Results: Responses toward face validity and content validity were predominantly positive in both groups. Most participants in the PEA scenario (n=26, 87%) felt actively involved in the simulation, and 23 (77%) participants felt in charge of the situation. The participants thought it was easy to learn how to interact with the software (n=24, 80%) and thought that the software responded adequately (n=21, 70%). All 15 (100%) expert participants preferred VR training as an addition to conventional training. Moreover, 13 (87%) of the expert participants would recommend VR training to other colleagues, and 14 (93%) of the expert participants thought the CPVR-sim was a useful method to train for infrequent post–cardiac surgery emergencies requiring CPR. Additionally, 10 (91%) of the participants thought it was easy to move in the VR environment, and that the CPVR-sim responded adequately in this scenario.

Conclusions: We developed a proof-of-concept VR simulation for CPR training with two scenarios of a patient after cardiac surgery, which participants found was immersive and useful. By proving the face validity and content validity of the CPVR-sim, we present the first step toward a cardiothoracic surgery VR training platform.

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(JMIR Serious Games 2022;10(1):e30456) doi:10.2196/30456

KEYWORDS

cardiac surgery; cardiopulmonary resuscitation; emergency resternotomy; virtual reality; simulation training; serious games; virtual reality simulation; digital health; medical training; virtual training

Introduction

Every year, around 2 million patients undergo cardiac surgery worldwide [1]. The incidence of cardiac arrest after cardiac surgery ranges between 0.7% to 8%, with a survival rate of approximately 50% [2-5]. This relatively high survival rate can be explained by a high incidence of reversible causes precipitating the arrest, such as ventricular fibrillation (VF; 25%-50%), cardiac tamponade, hypovolemia, and tension pneumothorax [2,4-6]. Notably, aside from VF, external massage is often ineffective in these cases because of reduced diastolic filling of the heart, resulting in inadequate tissue and brain perfusion [2]. In light of these findings, the Society of Thoracic Surgeons Taskforce on Resuscitation After Cardiac Surgery published an expert consensus in 2017 to provide guidelines for developing local protocols for cardiopulmonary resuscitation (CPR) after cardiac surgery [2]. As reported in the guidelines, early recognition of the clinical signs and symptoms is essential, indicating that emergency resternotomy is required [2,5]. The majority of postoperative cardiac surgery emergencies requiring CPR will involve reopening the sternum [2,5]. Several studies have shown that training and practicing based on a structured protocol improve the time to recognize the need for resternotomy and the time to reopen the thorax [2,7]. Early resternotomy reduces complications and improves outcomes for patients with cardiac tamponade, hypovolemia, or tension pneumothorax [2,7]. However, the paucity of cardiac arrest after cardiac surgery limits the possibilities of clinical training for clinicians [8]. CPR training allows clinical staff to acquire theoretical knowledge on the protocol, together with the ability to physically perform the steps described within the protocol [9]. This is commonly taught in instructor-led training sessions, requiring multiple team members and resources [2]. Moreover, these classroom sessions are currently restricted due to precautionary measures taken during the COVID-19 pandemic [10].

Simulation training enables training of multiple cases with unlimited practice (and possible errors) without compromising patient safety or the need for setting up training sessions [8]. Virtual reality (VR), with 360-degree scenarios, can recreate a fully immersive, interactive, and realistic scenario in which the user can repeatedly train without the need for other supplies or participants. Moreover, VR can be used in a multiuser setting, allowing different users to be present in the same scenario while physically distanced [11]. Multiple studies have shown that simulation training effectively improves knowledge, confidence, motivation, and satisfaction with the training versus standard training methodology [8,9,12,13].

Quantifying outcomes and the validity of simulations is a difficult task. It is essential that a VR simulator is valid in the sense that it resembles a realistic situation and reinforces the appropriate skills and knowledge [14]. This validity consists of several subtypes, including face validity and content validity. Face validity relates to the realism of a simulator, or in this case how well the simulation resembles real-world clinical practice [14,15]. This can be assessed informally by experts (referents) and nonexperts (novices/trainees) in the field [16-19]. Content validity judges the usefulness of the simulator as a training method that may be assessed by an evaluation of experts in the subject matter of the training [14-16,20]. The implementation of a new protocol and limited incidence of emergency resternotomies after cardiac surgery highlight the need to develop a high-fidelity training method that follows the expert consensus protocol for CPR and resternotomy for patients after cardiac surgery [2]. To facilitate medical staff training at our cardiothoracic surgery (CTS) department, we have developed a dedicated VR-based postcardiac surgery CPR simulation: Cardiopulmonary Resuscitation Virtual Reality Simulator (CPVR-sim). We designed a prospective study to assess the feasibility and to establish the face and content validity of CPVR-sim in a group of novices (eg, surgical residents, junior physicians, and nurse practitioners) and experts (eg, cardiothoracic surgeons and senior residents).

Methods

Simulator

The simulation was designed by a multidisciplinary team consisting of physicians, researchers, software developers, digital transformation experts, VR experts, and cardiothoracic surgeons from the CTS departments at Erasmus Medical Center (Rotterdam, the Netherlands), Zan Mitrev Clinic (Skopje, Republic of North Macedonia), and Distant Point LTD (Skopje, Republic of North Macedonia). Unreal Engine (Epic Games, Cary, North Carolina) software was used for software development. An Oculus Quest 2 (Oculus, Irvine, California) head-mounted display (HMD), in combination with two VR controllers and a high-performance laptop (MSI, New Taipei City, Taiwan), was used to run the CPVR-sim.

To study the feasibility of the CPVR-sim, we developed an immersive VR simulation resembling two CPR scenarios (both shockable and nonshockable cardiac arrest scenarios) after cardiac surgery, based on fictive patient cases (Multimedia Appendix 1). The patient scenarios recreated in the simulation were patients a few days after cardiac surgery through median sternotomy. These patients were found to be unresponsive on the surgical ward and determined to be in cardiac arrest and requiring CPR. In the first scenario, the cardiac arrest was caused by cardiac tamponade leading to pulseless electrical activity (PEA) where a resternotomy had to be performed to obtain the return of spontaneous circulation. The second scenario combined PEA and VF, and participants had to perform multiple actions, including external defibrillation, resternotomy, internal defibrillation, internal heart massage, and intracardiac medication administration.

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Before running the simulation, each participant was given a short briefing on the scenario, how to use the VR HMD, and how to interact with the controls and software to perform the CPVR-sim. When the simulation started, the user of the CPVR-sim was placed as a team leader of the CPR team. The team leader was able to assign tasks to the other participants in the simulation or was able to execute several tasks themself to manage the cardiac arrest situation. Figure 1 shows multiple screen captures of the team leader's view during the simulation. The team leader instructed the virtual colleagues by choosing between different menu options (Figure 1B) with the joystick on the controller. Additionally, a participant wearing the HMD and performing the simulation is shown (Figure 1D). The menu options were shuffled each time the simulation started, so the user did not know the order of the menu options beforehand. When the correct command was given, it was followed by visual and auditory feedback of the instruction. This means, for example, that when "Start Chest Compressions" was chosen at the correct moment, the virtual nurse confirmed the instruction and started chest compressions.

Figure 1. Screen captures of the Cardiopulmonary Resuscitation Virtual Reality Simulator (CPVR-sim) showing an overview with five virtual nurses in a patient room (A), the main menu (B), opening the incision with a virtual scalpel (C), performing the internal defibrillation (D), and a participant performing the simulation wearing the head-mounted display, with an in-screen screen capture of the CPVR-sim (E).



Study Participants

All participants work at the Erasmus MC in the Cardiothoracic Surgery Department as staff cardiothoracic surgeon, physician (including trainees in CTS), nurse practitioner, or medical student. To assess the content validity of the PEA scenario, participants were assigned to the novice or expert group. Staff cardiothoracic surgeons and certified CPR training instructors were categorized as expert, while the remaining participants were classed as novices (eg, junior physicians, nurse practitioners, surgical residents, and medical students). All participants completed written consent forms for their participation in this study. The research protocol was approved by the Erasmus Medical Center Medical Ethical Review Committee (MEC-2020-0989).

Questionnaire

To assess participant characteristics, face validity, and content validity, a questionnaire was developed, which included experience with emergency resternotomy, gaming, and VR, among other things. Subsequent questions were scored on a five-point Likert scale, ranging from 1 (fully disagree) to 5 (fully agree). The Likert scale questions were divided into the following categories: usefulness, satisfaction, ease of use [21], effectiveness, and immersiveness [12,22-24], as described in previous studies. Finally, the last part of the questionnaire consisted of open questions to assess the advantages and disadvantages of the simulation. The questionnaire can be found in File S1 in Multimedia Appendix 2. To determine face validity, we used questionnaire results on the ease of use, effectiveness, and immersiveness of all participants. To assess content validity, we looked at the results from the expert group that performed the PEA scenario regarding usefulness and satisfaction.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp). The chi-square test was used to perform statistical analyses of categorical data such as

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the participant characteristics. Continuous data are presented as medians with IQRs, and categorical data, including Likert scales, are presented as percentages.

Results

Participant Characteristics

All 41 participants performed the simulation and completed the questionnaire. Participants were divided into an expert and novice group to assess content and face validity of the PEA scenario. A total of 15 experts (staff cardiothoracic surgeons and certified CPR instructors) and 15 novices (physicians, residents, nurse practitioners, and medical students) were included in the PEA scenario. The median age of the expert group was 43 (IQR 38-55.5) years and of the novice group 30 (IQR 30-42.5) years (P<.001). Furthermore, the median work experience in CTS was 17 (IQR 9.5-26.5) years in the expert group and 1 (IQR 0.5-4.5) year in the novice group (P<.001). The participant characteristics are shown in Table 1.

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Table 1. Participant characteristics.

Characteristic	PEA[a] scenario, n (%)		Combined scenario (PEA + VF[b]), n (%)	Total (n=41), n (%)
	Experts (n=15)	Novices (n=15)	Experts + novices (n=11)	
Sex				
Male	12 (80)	10 (67)	5 (45)	27 (66)
Female	3 (20)	5 (33)	6 (55)	14 (34)
Profession				
Cardiothoracic surgeon	13 (87)	1 (7)	0 (0)	14 (34)
CTS[c] resident	1 (7)	4 (27)	0 (0)	5 (12)
CTS junior physician	0 (0)	6 (40)	6 (55)	12 (29)
CTS nurse practitioner	1 (7)	4 (27)	1 (9)	6 (15)
CTS medical student	0 (0)	0 (0)	4 (36)	4 (10)
Experience with post–cardiac surgery CPR[d]				
No experience	0 (0)	1 (7)	5 (45)	6 (15)
1-5 times	1 (7)	8 (53)	4 (36)	13 (32)
6-10 times	1 (7)	4 (27)	1 (9)	6 (15)
>10 times	13 (87)	2 (13)	1 (9)	16 (39)
Experience with emergency resternotomy				
No experience	0 (0)	5 (33)	6 (55)	11 (27)
1-5 times	4 (27)	9 (60)	4 (36)	17 (41)
6-10 times	1 (7)	1 (7)	1 (9)	3 (7)
>10 times	10 (67)	0 (0)	0 (0)	10 (24)
Experience with gaming console				
Never used a gaming console	2 (13)	2 (13)	1 (9)	5 (12)
Few times before	12 (80)	10 (67)	7 (64)	29 (71)
Regular basis	1 (7)	3 (20)	3 (27)	7 (17)
Experience with VR[e]				
Never had a VR experience	4 (27)	5 (33)	4 (36)	13 (32)
Few times before	8 (53)	7 (47)	7 (64)	22 (54)
Regular basis	3 (20)	2 (13)	0 (0)	5 (12)
VR expert	0 (0)	1 (7)	0 (0)	1 (2)
Experience with simulation training				
Never had simulation training	5 (33)	1 (7)	1 (9)	7 (17)
Multiple times	8 (53)	14 (93)	9 (82)	31 (76)
Certified trainer	2 (13)	0 (0)	1 (9)	3 (7)
Experience with digital training				
Never had digital training	5 (33)	7 (47)	2 (18)	14 (34)
Few times before	8 (53)	5 (33)	5 (45)	18 (44)
Multiple times before	2 (13)	3 (20)	4 (36)	9 (22)

[a]PEA: pulseless electrical activity.

[b]VF: ventricular fibrillation.

[c]CTS: cardiothoracic surgery.

[d]CPR: cardiopulmonary resuscitation.

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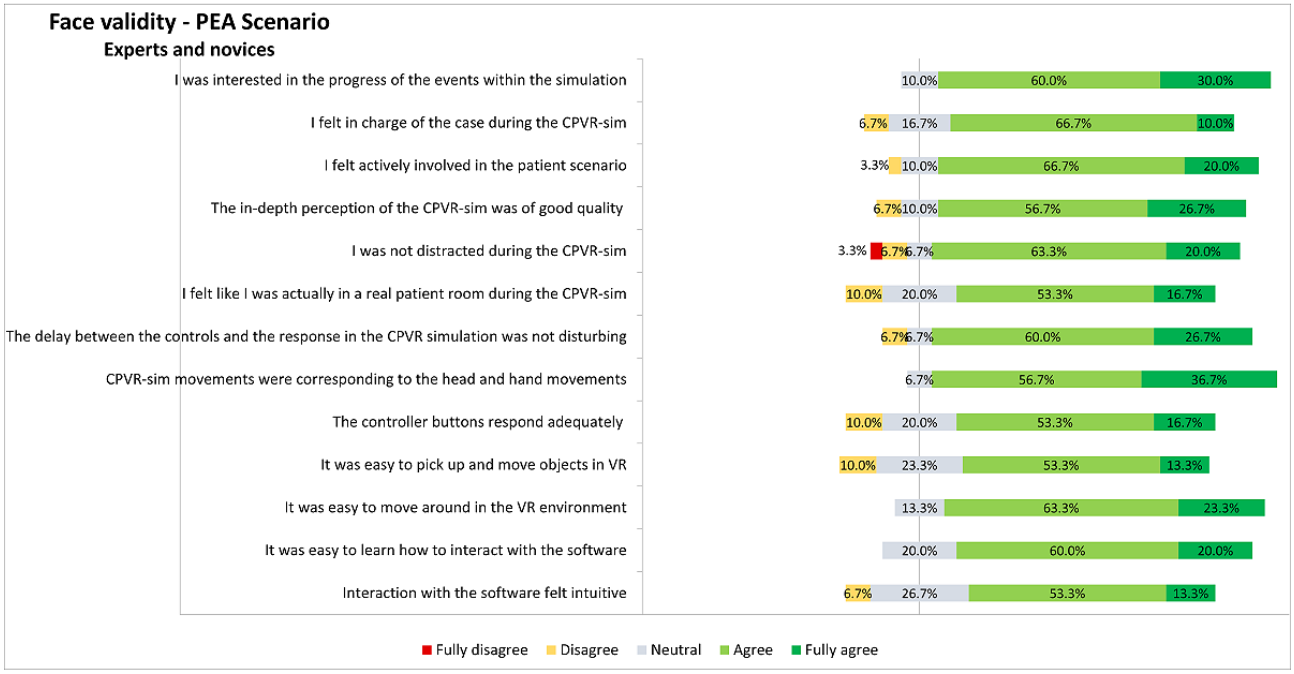
[e]VR: virtual reality.

Questionnaires

The face validity of both scenarios was assessed separately by analyzing the ease of use, effectiveness, and immersiveness questions in the questionnaires. The results of the PEA scenario are displayed in Figure 2. Most participants in the PEA scenario (n=26, 87%) felt actively involved, and 23 (77%) participants felt in charge of the situation, suggesting a predominant positive opinion regarding the face validity in both groups. The simulation software responded adequately and did not lag according to 21 (70%) of the participants, and 24 (80%) of the participants reported that it was easy to learn how to interact with the software. Notably, 12 (80%) of the novices in the PEA scenario said they learned a lot from the simulation, whereas only 7 (47%) experts reported the same. The results of the combined scenario are displayed in Figure 3. Additionally, 10 (91%) of the participants stated that it was easy to move around in the VR environment, and the same amount of people reported that the controller buttons responded adequately.

Subsequently, the content validity was assessed by analyzing the satisfaction and usefulness outcomes of the questionnaire of the expert group (n=15) who performed the PEA scenario (Figure 4).

Figure 2. Representation of the results on face validity–related questionnaires assessed from all (expert and novice) participants on the PEA scenario. Inconsistencies in the sum of percentages is due to the rounding of the percentages. CPVR-sim: Cardiopulmonary Resuscitation Virtual Reality Simulator; PEA: pulseless electrical activity; VR: virtual reality.



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Figure 3. Representation of the results on face validity–related questionnaires assessed from all (expert and novice) participants on the combined scenario. Inconsistencies in the sum of percentages is due to the rounding of the percentages. CPVR-sim: Cardiopulmonary Resuscitation Virtual Reality Simulator; VR: virtual reality.

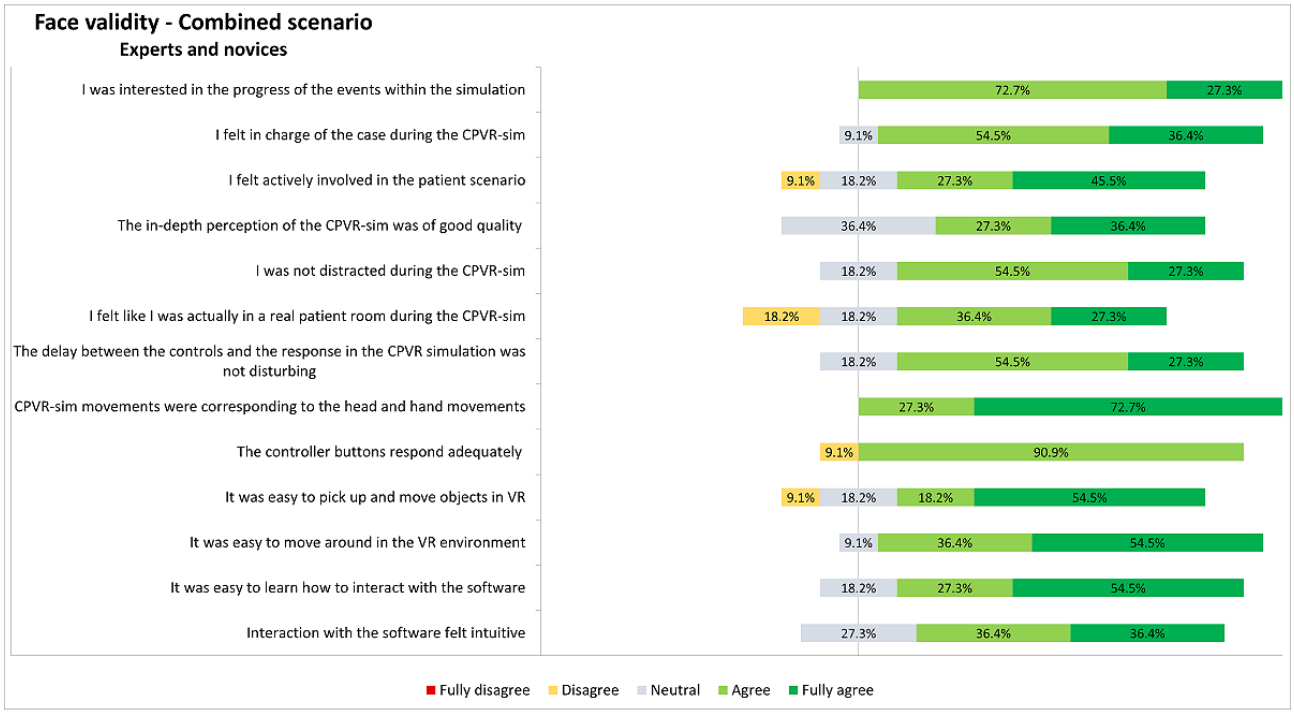
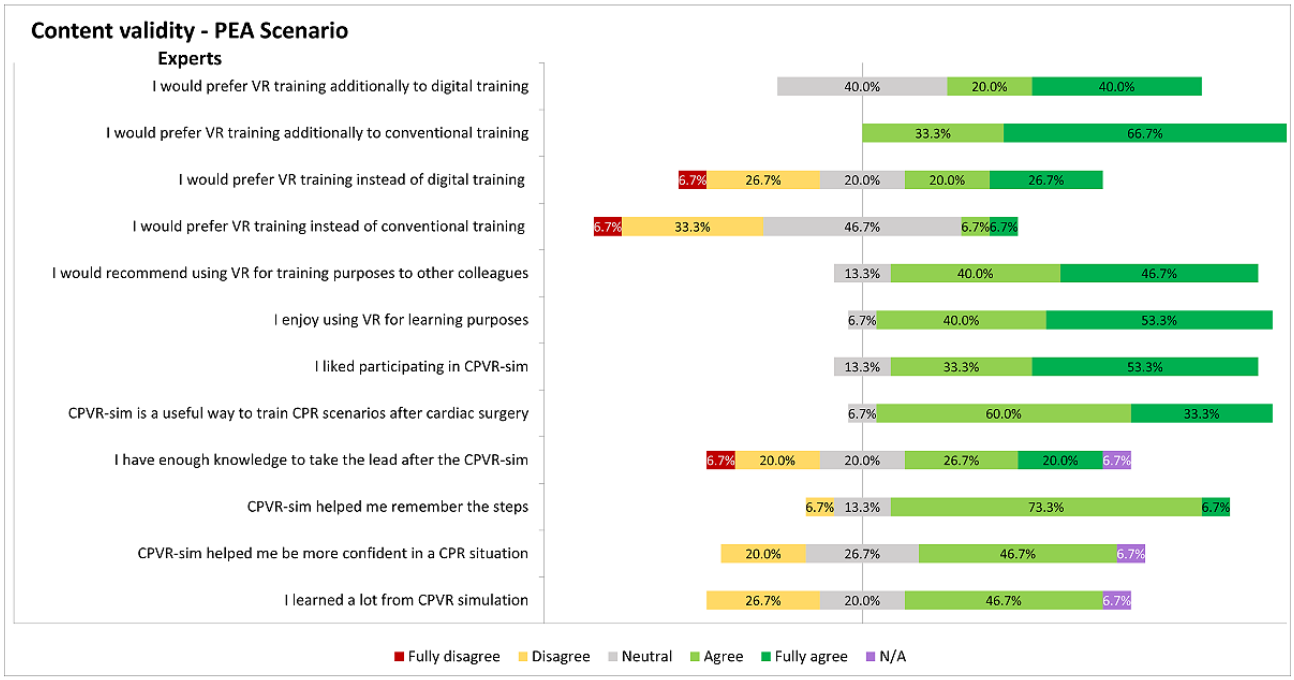


Figure 4. Representation of the results on content validity–based questionnaires of the PEA scenario, assessed from the expert participants. Inconsistencies in the sum of percentages is due to the rounding of the percentages. CPR: cardiopulmonary resuscitation; CPVR-sim: Cardiopulmonary Resuscitation Virtual Reality Simulator; N/A: not applicable; PEA: pulseless electrical activity; VR: virtual reality.



All expert participants in the PEA scenario (n=15, 100%) agreed that this VR training method is useful as a supplement to conventional training methods, and 9 (60%) participants agreed it was useful as a supplement to digital training. Notably, only 2 (14%) expert participants would prefer VR training instead of conventional training; however, 7 (47%) expert participants would prefer VR training instead of digital training. Conversely, 13 of 15 (87%) expert participants would recommend VR

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training to other colleagues, and most participants (n=14, 93%) reported that the CPVR-sim was a useful method to train infrequently occurring CPR cases after cardiac surgery (File S2 in Multimedia Appendix 2).

Finally, participants were asked for general advantages and disadvantages of the CPVR-sim. The most commonly reported advantages were the broad applicability of VR simulation in various CPR scenarios; the possibility of repetitive, personal, and quick practice sessions without being restricted by logistical challenges; and that the CPVR-sim is a beneficial method for step-by-step sequence training. Additionally, many participants felt it was a fun way of learning. The most important disadvantages of the current CPVR-sim version were the limited freedom of decision-making, lack of team training and interaction with a team, and the absence in the CPVR-sim of the pressure and hectic environment during such an emergency situation, which occasionally made it feel artificial. Results of the face and content validity questionnaire can be found in File S2 in Multimedia Appendix 2, and a complete overview of the advantages and disadvantages filled in by the participants can be found in File S3 in Multimedia Appendix 2.

Discussion

Principal Results

In this prospective study, we have designed and evaluated a VR simulation training platform with two different scenarios for post–cardiac surgery emergencies requiring CPR. To the best of our knowledge, this is the first time that such a VR simulation platform has been developed explicitly for use in a cardiac arrest scenario after cardiac surgery. Although future refinements of this concept are inevitable, we believe that the CPVR-sim will be a successful method that will help to overcome difficult challenges, including the infrequent incidence of resternotomy after cardiac surgery, accessibility, and costs of clinical training [25]. We observed that the expert and novice opinions were generally positive regarding the face validity and content validity. A significant majority of participants from both groups felt that VR simulations are a useful (supplementary) training method, as well as a high likelihood that they would recommend VR simulation training to other colleagues. Furthermore, in the CPVR-sim scenarios, the trainee was more actively involved in experiencing the virtual patient case, as compared with conventional digital training, listening to a presentation, or reading a protocol. This active involvement could be due to the elaborate simulation and multiple actions the user has to perform. This immersive and realistic VR environment facilitates memorizing stepwise procedures more efficiently [25]. Additionally, our results showed that frequent practice and increased exposure in the CPVR-sim is valuable since it refreshes the knowledge and gives the clinician more confidence in taking the lead in future situations, which is in line with previous studies [8,9,12,13]. This is especially important in infrequent CPR cases with emergency resternotomy, which occurs only a few times per year.

Another important feature of this VR training is the improved accessibility since the only requirements are an HMD and a computer, and there is no need to arrange a physical session. VR training has higher initial costs (eg, simulation development and purchase costs of the VR hardware) than conventional training. However, the increased accessibility of VR training results in more trainees being reached, spreading these initial costs over a larger group, compared with the relatively linear cost per trainee for conventional training. Therefore, the average cost per trainee would likely be lower in the long term for VR training than conventional training [26]. Moreover, purchasing and using VR hardware adds a new dimension and armature in training possibilities and other applications (ie, surgical planning) of a department, which can also lead to cost-efficiency. Finally, VR training facilitates the implementation of the new CPR protocol, enabling training for experts and novices alike who are not yet acquainted with the new protocol.

Limitations

In this simulation, only individual training was possible. It would be desirable to make the simulation available for multiple users at a time, enabling real-time interaction between team members [11]. By making the simulation available for multiple users at the same time, nontechnical skills such as communication and leadership can be trained with the team, which is important in CPR situations [27]. This would also enable learning from other trainees' mistakes. Multiplayer settings would additionally enable the trainee to view the CPR situation from different viewpoints and the possibility to review their own performance from an alternative perspective [25]. Another shortcoming of the CPVR-sim is that the simulation requires at least five different buttons to be pressed, which can be confusing for the trainee. The simulation would become more realistic and interactive when voice controls and haptic feedback such as hand or even body tracking are implemented to perform the actions within the simulation, instead of using the controllers as input in the simulation [28]. However, implementing voice control can be computationally and algorithmically challenging, as similar information can be said using a variety of different phraseology, and further research should be performed on the best interaction method within the VR environment [25-28].

Finally, a shortcoming in this simulation was the lack of pressure felt by participants and the absence of a hectic environment, characteristic of such an emergency situation. The virtual nurses stood still and walked calmly, and there was a lack of background noise. This could be improved in future development by adding stress components such as sounds or extra persons who are panicking [20]. Making the simulation more resembling the real-life situation might improve the success of VR training [25]. However, further research is needed to ensure such stress components do not compromise the educational value of the CPVR-sim.

Future Perspective

The most crucial next step in improving the simulation and increasing educational value is to extend the CPVR-sim with different roles in the CPR simulation, for example, for nurses. With this functionality, multiplayer scenarios will become possible, and a team can train together at the same time, ultimately creating a more realistic environment that will translate more directly into clinical practice. Furthermore, the

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simulation can be improved by adding more scenarios, asystole, and external pacing, for example.

In this study, we only assessed the content validity of the PEA scenario, but in future studies, the content must be validated for all different scenarios of the CPVR-sim. These face and content validity results support the use of the simulator as a training tool, but they are subjective measures of validity, and it is imperative to validate the simulation objectively. This can be perceived by determining the construct validity, concurrent validity, and predictive validity of the CPVR-sim [14,15,20]. Construct validity in a simulation is defined as the ability to distinguish objectively between different levels of experience [14,15,20]. In future research, this could be determined by testing a large number of users with various levels of experience in CPR and emergency resternotomy cases after cardiac surgery. Concurrent validity can determine the correlation between the VR simulation and existing evaluation tools [15,20]. Moreover, predictive validity is an even more powerful evidence method, which can be assessed by comparing the outcomes of the simulation with an established assessment method to assess the skills [15,20]. In further research, predictive validity could be determined by comparing the clinical staff's skills in a real-life simulation setting and CPVR-sim. These skills could be obtained by a structured skills assessment of both the skills in real life and within the VR simulation, determined by blinded experienced CPR trainers.

Conclusion

We have developed a proof-of-concept VR simulation of two CPR scenarios after cardiac surgery, which is immersive and useful, as stated by the expert and novice participants. Additional research is needed to further develop and validate the simulation platform, including multiple possible clinical scenarios; voice control; multiuser possibilities; and assessing the construct, concurrent, and predictive validity. However, we made a first step toward a CTS VR training platform, including multiple realistic and repetitive simulation training for the CTS department by proving the face validity and content validity of the CPVR-sim.

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We would like to thank Aleksandar Trifunovski, Ivo Matevski, Tomi Jurukovski, and Kristina Kerkez for their collaboration and development of the Cardiopulmonary Resuscitation Virtual Reality Simulator software. Finally, we would like to thank all participants for their time and effort to participate in this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary video of the cardiopulmonary resuscitation virtual reality simulator.
[MP4 File (MP4 Video), 103511 KB - games_v10i1e30456_app1.mp4]

Multimedia Appendix 2
Supplementary file.
[DOCX File , 43 KB - games_v10i1e30456_app2.docx]

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Abbreviations

CPR: cardiopulmonary resuscitation
CPVR-sim: Cardiopulmonary Resuscitation Virtual Reality Simulator
CTS: cardiothoracic surgery
HMD: head-mounted display
PEA: pulseless electrical activity
VF: ventricular fibrillation
VR: virtual reality

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Original Paper

Identifying Video Game Preferences Among Adults Interested in Quitting Smoking Cigarettes: Survey Study

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Abstract

Background: Smoking is the most prevalent cause of morbidity and mortality in the United States. Although most individuals who smoke express a desire to quit smoking, only a small percentage are successful. Serious games have become popular in health sectors as a potential avenue for delivering a scalable treatment that is both accessible and engaging for the smoking population. Several smoking cessation games have already been developed, but these games feature a broad range of gameplay elements and are not necessarily based on existing video game preferences in the general or smoking population.

Objective: To better inform treatment development, this study aims to evaluate video game genre preferences among treatment-seeking individuals who smoke (N=473).

Methods: Participants responded to a screening survey to enroll in a larger, serious game intervention for smoking cessation. During this screening survey, participants were asked to disclose their favorite video games, which resulted in 277 unique game titles. These titles were coded for genre categories based on publisher listings and game features. The genres were then analyzed for the frequency of reporting overall and across age groups.

Results: Action, Role-Playing, and Action-Adventure were the most reported genres among adults aged ≤34 years; Action, Action-Adventure, and Logic were the most reported genres among adults aged 35-44 years; and Logic and Action were the most reported genres among adults aged ≥45 years.

Conclusions: These data indicate that treatment-seeking individuals who smoke have different game preferences across age groups, and the data provide novel information to inform the development of future serious games targeting the smoking population that are tailored to the preferences of their age group.

Trial Registration: ClinicalTrials.gov NCT03929003; https://clinicaltrials.gov/ct2/show/NCT03929003

(JMIR Serious Games 2022;10(1):e30949) doi:10.2196/30949

KEYWORDS

genres; popular games; smoking cessation; video games; smartphone; mobile phone

Introduction

Background

More than 16 million adults in the United States are living with diseases related to cigarette smoking, and more than 480,000 deaths each year can be attributed to smoking-related causes [1]. The cost of direct medical care for conditions related to cigarette smoking is US $170 billion [2]. In 2018, more than half of adults in the United States (55.1%) who reported smoking had attempted to quit, but only 7.5% were successful [1,2], and quit rates remain low overall [3]. Given the substantial societal impact of cigarette smoking and the low success rates of those interested in quitting, there is a significant public health need

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to develop accessible and engaging methods of delivering smoking cessation interventions.

Serious games, or video games developed for purposes other than pure entertainment, have become popular in health sectors and may be one avenue for delivering a scalable treatment that is both accessible and engaging [4,5]. According to the Entertainment Software Association, 75% of households in the United States own a video game device, and 64% of adults play video games [6]. Several games have already been developed, targeting smoking cessation, such as *Cigbreak* [7], *Inspired* [8], *Tobstopp* [9], *QuitIt* [10], and *Quittr* [11], each of which uses different gameplay elements to facilitate smoking cessation. A recent review of 14 unique smoking prevention and cessation games not listed above found that of 7 smoking cessation game studies published, 5 had statistically significant positive results on smoking cessation outcomes—an indicator that serious games have a merit in smoking cessation research [12]. The review sought to identify common gameplay elements included in these games and found that the most frequently reported elements were rewards and punishment (eg, earning points for success and losing points for failure; n=32) and narrative and identity features (eg, the game follows a plot or story and the player uses an avatar to be integrated into the story; n=20) [12], but gameplay elements were inconsistently reported. In addition, of the published studies reviewed, the reasons participants may have dropped out or been unsuccessful were not reported, and it is possible that game genre or specific gameplay elements were an important factor. Derksen et al [12] suggested that the inconsistent reporting of gameplay elements makes it difficult to draw conclusions about each element and their combined impact on smoking cessation outcomes.

Publication bias may also limit the conclusions that can be made regarding the games that have already been developed but that were unsuccessful. There may also be more games in development or already commercially available that have not been studied empirically. As of 2017, there were 158 unique smoking cessation apps in the Apple App and Google Play stores; upon reviewing the 50 most popular apps, only 3 were supported by research [13]. There is also an array of mobile smoking cessation apps that use gamified elements (eg, diaries that provide feedback and rewards to users or games that seek to educate and distract individuals who smoke) that are available on the Google Play and Apple App stores but that have not undergone rigorous empirical testing. Thus, the number of evidence-based apps that are available to and approved by consumers and the ratio of evidence-based apps to nonevidence-based apps is lacking.

Objectives

It is useful to know that serious games can create positive outcomes for individuals interested in quitting smoking, but this knowledge alone is not as useful as understanding specific components of games that may contribute to their success. Cugelman [14] outlined 7 criteria for game suitability for specific populations. Among the criteria were (1) identifying who the users of the game will be, (2) understanding the context of those users, (3) determining the compatibility of the intervention with the users, (4) identifying the goals of the intervention, and (5) deciding on the behavioral strategies that will be used. Part of the *context* noted above includes identifying the types of games that users are already familiar with and enjoy playing. For example, a smoker who plays *Fruit Ninja* might be more responsive to *Cigbreak* over *QuitIt* because of *Cigbreak*'s use of action mechanics that are similar to *Fruit Ninja* compared with *QuitIt*'s reliance on role-play. In this manner, game genre preferences (such as Action and Role-Play) can provide important information regarding the types of gameplay features that might be suitable for specific populations.

There are a substantial number of studies on genre preferences comparing across population characteristics such as age, gender, personality traits, and symptoms of behavioral disorders [15-21]. However, if one is seeking basic data about genre preferences in the general population, the sources of this information are derived from market research and nonpeer-reviewed sources [22,23]. For researchers seeking to develop games specifically for smoking cessation, there are currently no data to verify whether general population preferences match the preferences of treatment-seeking individuals who smoke. This study aims to identify the genres of video games that are most widely endorsed by a general population of treatment-seeking adults who smoked. By doing so, this study aims to provide a basis for future detailed examination of the gameplay elements and features that are frequently used in these genres. In the *Discussion* section, we have provided examples of basic gameplay features of the most popular genres and how those features might be leveraged for smoking cessation games.

Methods

Recruitment and Participants

Data collection was approved by the institutional review board (ProG0520140170), which oversees the protection of human subjects in research, as part of a larger research study that involved developing and testing a video game–based smoking cessation intervention. The data presented here were collected as part of a screening for that larger study, and because personally identifiable information was not collected at that stage, a waiver of consent was approved by the institutional review board. Participants were recruited via advertisements on Craigslist, Facebook, and Google Ads. A variety of advertisements were used, each with slightly different text and images to appeal to different audiences who might be interested in quitting smoking (eg, some advertisements showed images of a video game along with text about quitting, some showed images of parents with their children to appeal to people who might want to quit for loved ones, and others showed pictures of money to appeal to people who might want to quit for financial reasons). Those interested in participating followed the link to a screening survey to report information about smoking history, age, prior experience with video games, desire to quit smoking, access to mobile devices, and contact information.

Participants (N=473) were asked to list their favorite video games. Games listed had to meet the definition of a game as specified by Tekinbaş and Zimmerman [24]—a system in which players engage in an artificial conflict, defined by rules, that

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results in a quantifiable outcome—and list the specific name of a game or franchise of games. Out of the raw number of responses (N=473), there were a total of 337 game-related responses. Following data cleaning, 60 entries were excluded from the final analyses due to being broad genres rather than specific games (eg, *fighting games* and *soccer*) or not meeting the game definition (eg, a coloring book app called *Chamy*). A total of 277 unique games were included in this analysis.

Procedure

Participants who answered the survey asked the open-ended question, "What is/are your favorite videogame(s)?" to determine prior experience with video games as well as questions about their smoking patterns (ie, number of cigarettes smoked per day and years spent smoking) and their age. Owing to the open-ended nature of the video game question, participants could list multiple games, allowing a greater representation of interests.

Each game was classified into genres identified by Adams [25]. The genres included Action, Action-Adventure, Adventure, Role-Playing, Simulation, Strategy, Sports, Massive Multiplayer Online (MMO), Party, Programming, Logic, Mobile, Trivia, and Board Games [25]. An additional category, Casino Games, was added because several participants reported playing casino and gambling games. Textbox 1 provides definitions of each category.

In total, 2 coders identified the genre of each individual game reported. Both coders searched for game titles using Google and, when available, used the genre reported by the publisher of the game. In the absence of publisher-identified genres, coders reviewed gameplay elements and store categorization to classify the game. The interobserver agreement was initially 77%. An additional coder who was not exposed to the previous coded list reconciled the 76 games that were scored differently between the primary coders. Reconciliation followed the same process described for the primary coders. The genre indicated by at least 2 of the 3 coders was selected as the official genre for the game and increased interobserver agreement to 99%. Participants' ages were paired with their genre preferences to analyze trends across age groups using descriptive statistics.

Age bins were selected to match the Centers for Disease Control and Prevention National Adult Tobacco Survey age categories (18-24, 25-34, 35-44, 45-54, 55-64, and ≥65 years [1,2]). Crosstabs analyses and a 2-tailed Fisher exact test were performed to determine whether there were trends in game genres by age, with α set to $P<.01$. Fisher exact tests were performed comparing smoking intensity with genre preference. Participants were classified by the number of self-reported cigarettes smoked per day as light (<1 to 5 cigarettes per day), moderate (6-10 cigarettes per day), or heavy (>11 cigarettes per day) [26,27].

Textbox 1. Video game genres and definitions (definitions are from a book by Adams [25]).

- **Action**: "Include physical challenges and require skills in hand-eye coordination to complete objectives, which include defeating opponents. (eg, *Call of Duty*)"
- **Action-Adventure**: "Involve components of both action (physical challenges, hand-eye coordination, opponent-based game play) and adventure elements (exploration, puzzle solving, relaxed time-constraints; eg, *Legend of Zelda*)."
- **Adventure**: "Focus on exploration of a story and environment through puzzles and interaction with other characters and the environment. There are no action challenges that require reflexes and these games do not demand the player use tactics and strategy to defeat an opponent. (eg, *Heavy Rain*)"
- **Role-Playing**: "Focus on growth of the player's character through challenges and story, wherein the players character begins weak and steadily gains more experience, strength and access to better weapons as the game progresses. There is typically a hierarchy of opponents to defeat as part of a quest. (eg, *Final Fantasy*)"
- **Simulation**: "Involve players building things (such as in management and construction games) and/or playing through a simulated experience of life in the environments they build. They do not typically involve exploration, conflict, or physical challenges. (eg, *The Sims*)"
- **Strategy**: "Require skillful thinking, strategy and tactics to achieve goals such as building dynasty's in a fantasy or real-world setting, or protecting a fortress from an invading force. (eg, *Civilization*)"
- **Sports**: "Simulate sports with players controlling a team or specific player, while another player or an artificial intelligence controls the opponents. (eg, *FIFA* series)"
- **Massive Multiplayer Online**: "An online multiplayer game that involves large numbers of online players in a virtual world. They can incorporate features of many different genres, and can be treated as a single or multiplayer experience. (eg, *World of Warcraft*)"
- **Casual, Mobile, Idle**: "Designed for short periods of play that can easily be entered and existed as needed. These can encompass a range of genre elements. Mobile refers to a game designed to be portable in nature (i.e., on a mobile phone). Idle games specifically feature a trivial task that a player accrues points over time for engaging in. (eg, *Angry Birds*)"
- **Party**: "Designed to support many players in a competition, but not on the same scale as an MMO. They include features such as racing and competition in small-groups. (eg, *Mario Party*)"
- **Logic**: "Require players to solve puzzles, navigate mazes, or match game images/tiles. Typically suited for casual play. (eg, *Candy Crush*)"
- **Casino**: "Prominently feature gambling elements such as slots and betting games, where the objective is to earn high points through risk. (eg, *Slots*)"
- **Board games**: "Classic board games such as chess, monopoly, or checkers that for which computerized version have been created."
- **Trivia**: "Focus on answering questions to obtain points. (eg, *Words with Friends*)"

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Results

Genres and Titles Reported

Participants were aged an average of 39 (SD 12.4; range 14-72) years, spent an average of 19.8 years smoking (SD 13.3; range 0-55 years), and smoked an average of 16.5 (SD 11.3; range 0-100) cigarettes per day. Table 1 shows the frequency with which different game genres were endorsed. Participants most often reported playing Action games (162/473, 34.2%), with titles such as *Call of Duty* and *Mario* being the most frequently endorsed. This was followed by Role-Playing (113/473, 23.9%), Action-Adventure (101/473, 21.4%), and Logic (79/473, 16.7%). Games identified as Action (57/277, 20.6%) had the most frequent variety of titles reported, followed by Role-Playing (51/277, 18.2%), Logic (43/277, 15.5%), Action-Adventure (35/277, 12.6%) and Strategy (30/277, 10.6%; Table 2).

The top 10 games and game series mentioned by participants were *Mario* (43/473, 9.1%), *Call of Duty* (29/473, 6.1%), *Candy Crush* (28/473, 5.9%), *Fallout* (26/473, 5.5%), *Grand Theft Auto* (26/473, 5.5%), *Final Fantasy* (24/473, 5.1%), *Skyrim* (20/473, 4.2%), *Red Dead* (13/473, 2.7%), *Borderlands* (11/473, 2.3%), and *Sims* (11/473, 2.3%). These games are in the genres of Action (*Mario*, *Call of Duty*, and *Grand Theft Auto*), Role-Play (*Fallout*, *Final Fantasy*, *Skyrim*, *Red Dead*, and *Borderlands*), Simulation (*Sims*), and Logic (*Candy Crush*). Of the top 10 games listed, 1 (10%) was a smartphone-based app game (*Candy Crush*), whereas 9 (90%) were console-based games requiring devices such as a PlayStation, Xbox, or computer to play, although several of the games could be played across multiple platforms.

Table 1. Genres of games endorsed by smokers (N=473).[a]

Genre	Participants, n (%)
Action	162 (34.2)
Role-Playing	113 (23.9)
Action-Adventure	101 (21.4)
Logic	79 (16.7)
Strategy	38 (8)
Sports	35 (7.4)
Simulation	28 (5.9)
Casino	24 (5.1)
Board or Card games	17 (3.6)
Massive Multiplayer Online	4 (0.8)
Adventure	3 (0.6)

[a]Due to participants often listing multiple games in different genres, the total in the figure exceeds the total number of participants in the study (N=473).

Table 2. Game titles reported by genre (n=277).[a]

Genre	Game titles reported, n (%)
Action	57 (20.6)
Role-Playing	51 (18.4)
Logic game	43 (15.5)
Action-Adventure	35 (12.6)
Strategy	30 (10.8)
Sports	19 (6.9)
Casino games	13 (4.7)
Simulation	13 (4.7)
Board or Card games	10 (3.6)
Adventure	3 (1.1)
Massive Multiplayer Online	3 (1.1)

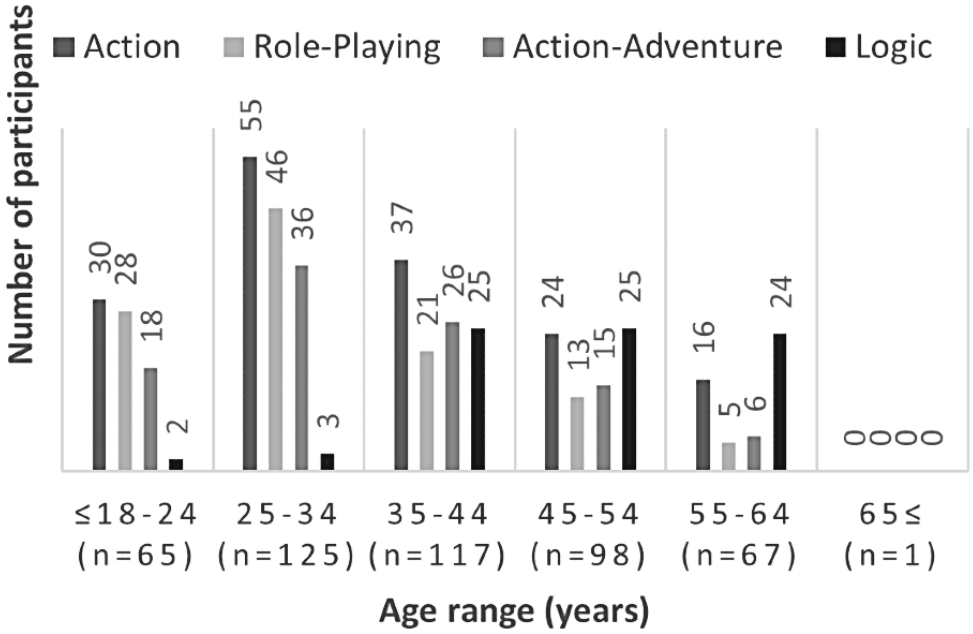
[a]Logic and Casino games were predominately mobile phone apps such as *Angry Birds* or *Slots*.

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Demographic Variables and Genre Preference

Action and Action-Adventure games were the most endorsed across age ranges <18 to 35 years (44%-46%), whereas Logic games were the least endorsed in this age range (2%-3%). Logic games were more frequently endorsed by older participants (aged 35-65 years; 21%-36%). Action games remained endorsed across these older age ranges as well, and it was the second most endorsed category among participants aged 45 to ≥65 years (24%-32%). Figure 1 shows a full distribution of genres endorsed by age. Using Fisher exact test, Action (P=.002), Action-Adventure (P=.008), Role-Playing (P<.001), and Logic (P<.001) genres were all significantly related with age. Genres not shown in Figure 1 (Strategy [P=.007], Board/Card games [P=.001], and Casino games [P<.001]) were also significantly related with age. Casino games were endorsed by 8.4% (24/283) of participants aged ≥35 years, and Board/Card games were endorsed by 5.6% (16/283) of the same age range. Strategy games were endorsed more frequently by participants in younger age groups, with 18.5% (7/39) of participants aged ≤18 to 24 years and 10.4% (13/125) of participants aged 25-34 years reporting games in these categories, whereas fewer endorsed strategy games across the 35-44 years (7/117, 5.9%), 45-54 years (5/98, 5.1%), and 55-64 years age ranges (1/67, 1.5%). There were no significant relationships by age for Adventure, Simulation, Sports, and MMO genres. Additional Fisher exact tests were performed to compare smoking intensity with genre preference. Participants were classified by the number of self-reported cigarettes smoked per day as light (<1 to 5 cigarettes per day), moderate (6-10 cigarettes per day), or heavy (>11 cigarettes per day) [26,27]. No significant relationship was found between smoking intensity and genre preference.

Figure 1. A bar graph depicting the raw number of times a genre was endorsed across age groups. Action, Action-Adventure, Role-Playing, and Logic were selected for this distribution because they were the four most frequently endorsed genres, overall. All 4 genres were significantly correlated with age with α (P<.01); Action (P=.002), Action-Adventure (P=.008), Role-Playing (P<.001), and Logic (P<.001).



Discussion

Principal Findings

Our results indicated that smoker video game genre preferences overlap with market information on genre preferences across the population in the United States [22,23]. Furthermore, these data support the existing literature regarding genre preferences that differ across age brackets, consistent with other information about video game preferences in older adults [20,28]. These findings can provide a starting point for researchers seeking to develop smoking cessation games by limiting the scope of *games* broadly defined to a short list of genres and their unique features.

Within each broad genre, there are several unique games with different features that may be more or less amenable to smoking cessation treatment. The Action games that were listed most often featured an avatar that the player used to solve puzzles, defeat enemies, and explore levels through physical challenges and hand-eye coordination [29]. For example, the *Mario* franchise includes a range of games that fall under Action, such as having the player scale platforms in the game world (*Super Mario 64*) to racing (*Mario Kart)* and fighting games (*Super Smash Bros*). Another top game noted by participants was *Call of Duty*, a first-person shooter action game that can be played in a multiplayer and internet-based format, where players shoot at specific targets to achieve an objective. The most common Action games that were listed were primarily single-player games, although some of the games could be played in multiplayer cooperative (ie, players working together with other players to achieve a common goal) and competitive (ie, players working against other players) modes to share the experience with others, either web-based or with a console. Action games use hand-eye coordination, require rapid decision-making, and focus on specific objectives [25]. Ideally, an action game designed to help people quit smoking would be developed so that it is not only a distraction from smoking but also incompatible with smoking (eg, requiring both hands, allowing little opportunity for breaks, and requiring a measure of smoking

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abstinence to proceed). *Cigbreak* uses a swiping mechanic to break cigarettes, and scores on this task move participants forward on a garden path [7]. The function of this in the game was cue exposure, showing participants images of cigarettes and theoretically reducing the salience of the cue, but may also have been effective because the task was incompatible with smoking. *Inspired* also used a swiping mechanic to sort in-game items rapidly and score points toward revitalizing a lush environment, and later iterations added an action element of defending a tree from invaders [8]. Swiping mechanics combined with the games' forced landscape mode (ie, holding a phone horizontally with 2 hands) were specifically implemented in *Inspired* to compete with smoking behavior by occupying the participants' hands with a game instead.

It is possible that Action games might also produce stress, and stress has been shown to serve as a smoking trigger for some individuals [30]; however, preliminary research suggests that the relationship between video games and increased cortisol levels is weak [31-33]. Thus, stress induced by video games may not meet the threshold to trigger cigarette cravings, but further research on the relationship between video games and stress is needed to determine how a high-stress action game might impact smoking. Furthermore, there is no current research evaluating whether video games can impact smoking withdrawal; therefore, video game–based smoking cessation interventions that target incompatible behavior may need to be combined with other evidence-based interventions that target nicotine withdrawal. Future research should evaluate the effects of serious games for smoking cessation on withdrawal and determine whether combining a video game–based intervention with other evidence-based strategies differentially impacts withdrawal and long-term treatment outcomes.

Role-Playing games were the second most popular genre endorsed by participants aged ≤35 years. This genre includes games within the *Fallout*, *Final Fantasy*, *Skyrim*, *Red Dead*, and *Borderlands* franchises. Role-Playing games typically feature the player as a character in the game world who grows and develops through game-based experiences. These games usually feature action elements (such as fighting, shooting, and enemy encounters) and involve the player in the game narrative [29]. For example, in *Fallout 4*, the player assumes control of a customizable character who embarks on a journey that will eventually reunite them with their child, as well as fulfilling other plotlines in a postapocalyptic world. To help with this task, players can equip themselves with various weapons, shop for status-boosting supplies in markets, or build a fortress among a myriad of other in-game choices. The strong narrative used in the Role-Playing genre could be harnessed in a game geared toward smoking cessation by connecting the narrative to smoking abstinence (eg, health of an avatar improves or worsens based on smoking status). One smoking cessation game that falls into the Role-Play genre is *QuitIt*, in which the players guide their character through a craving episode by choosing coping strategies [10]. Role-Playing games could also make access to game-based rewards contingent on abstinence (ie, weapons become unlocked with evidence of smoking abstinence). These game-based rewards hold value to players, as evidenced by the 2020 video game industry's all-time high revenue of US $60.4 billion, with the majority of that revenue being spent on digital content such as in-game currency, avatar accessories, weapons or tools, and *loot boxes* [34-36].

The Action-Adventure genre often incorporates a combination of features, including action, exploration, puzzles, and narrative, to engage players over the course of the game. For example, in the *Legend of Zelda* series, the player uses a character, Link, to explore the world and uncover story points. During this journey, the player can obtain weapons, armor, and other status-boosting items to customize their play style and ultimately inform their interpretation of how they envision Link. As with the Role-Playing games described previously, Action-Adventure games could harness the narrative and use game-based resources as incentives for meeting abstinence goals or for completing other nongame activities that would support abstinence. The narrative elements of both Role-Playing and Action-Adventure genres may be particularly well suited for promoting long-term engagement in a smoking cessation intervention because it has the potential to keep players engaged over extended periods.

Logic games, such as *Candy Crush*, *Angry Birds*, and *Gardenscapes*, were frequently endorsed by participants. These games feature puzzles with different rules and objectives, such as matching 3 or more of the same picture or object (*Candy Crush)* or determining the force, angle, and special power needed to knock down a structure (*Angry Birds*). These games use simple instructions and mechanics and are sometimes referred to as *casual* games because they are easy to learn and fast to play [37]. *Quittr* uses a logic game in the form of hidden objects in the app and another based on city building (simulation) [11]. *Bejeweled Blitz* is another game that falls within this category of *casual* logic games. One study found that most people played *Bejeweled Blitz* for social reasons, but they also reported that middle-aged adults played it as a form of stress relief, which could substitute cigarettes for people who smoke to manage their stress [38]. Older adults reported playing these games more frequently than other age groups, which is consistent with previous literature on the genre preferences of older adults [20,28]. Using casual logic games might be a successful strategy for distracting people during cravings. Casual gaming bouts last for approximately 6-15 minutes according to market research [39], which aligns closely with the duration of smoking cravings, which last for approximately 6-10 minutes [40]. Nicotine has been reported to increase sustained attention and result in faster response times [40-42], and deprivation from nicotine impairs these functions, leading to reports of worsening attention and working memory [43].

People also report playing casual puzzle games to improve cognitive performance [38]. For example, older adults report feeling as though their visuospatial skills and response times improve after playing casual games, but no explicit measures of attention and working memory were collected beyond self-report. For people who smoke to improve their focus and attention, Action and Logic games could potentially mediate the cognitive impairments experienced during a quit attempt. Further research is needed to determine whether different forms of serious games impact cognition during smoking cessation efforts. The relationship between Action games and increased cognitive performance is also supported. Individuals who play

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Action and Role-Playing games have been shown to outperform nongamers in attentionally demanding tasks [44], and attentional training through video games can improve performance on tasks [45].

Researchers should consider whether the target audience includes gamers who happen to smoke or nongamers who want to quit smoking using a video game intervention but would not play games otherwise. Most games identified in our survey could only be played on a computer or dedicated console, such as PlayStation or Xbox. Health games targeted for regular gamers might be more successful by devoting resources to console-based games. For example, an intervention designed to target players who chain smoke while playing could be console based and include features that would compete with smoking (eg, frequently requiring the use of both hands), making it incompatible or difficult to do while playing.

It should be noted that developing games can be a costly endeavor; some of the games endorsed by participants reported development budgets of US $40-$50 million (*Call of Duty*: *Modern Warfare 2* [46]). On the lower end of the spectrum, independent, smaller developers can expect to spend anywhere from US $50,000 to US $750,000 [47]. Researchers interested in developing health games targeting gamers would be better served to identify the mechanics these gamers enjoy rather than trying to compete with the graphics and complexity of big-budget games. Alternatively, if researchers are interested in leveraging the appeal of big-budget games for smoking cessation, it may be more useful to treat the game itself as a reward for smoking abstinence goals rather than attempting to recreate the gameplay and presentation. For instance, in the case of an individual who chain smokes while gaming, motion tracking software could be used to identify when the individual begins to smoke and pause the game until the individual confirms that appropriate behaviors have been engaged in (putting out the cigarette, disposing of it, or using a coping strategy such as nicotine gum). *Quittr* takes advantage of this model by offering players resources to help quit smoking and using games to distract participants from cravings [11]. Similarly, *Tobbstop* uses minigames to distract from cravings, and accessing these minigames and other smoking cessation resources in the app rewards the user with progress on beautifying their in-app island [9].

Casual mobile games could leverage the portability of mobile games, allowing for better access when an individual is experiencing a craving and in need of an immediate substitution. For example, an app was recently developed to help individuals who smoke access existing games during cravings, with individuals reporting that playing the games moderately helped them cope with cravings [48]. In addition, mobile games might eventually qualify as prescription digital therapeutics, increasing access to digital interventions through Food and Drug Administration authorization and insurance coverage [49].

A few limitations of the current data set are worth noting. First, future research should collect additional demographic information, such as gender and racial identity, to assess how gaming preferences may differ across demographics, similar to those found with age. Second, participants were asked to report their *favorite* games, which may have limited the range of games reported. In addition, because the question soliciting game titles was open ended, some reports were incomplete or incorrect (for instance, *Smash* was often reported instead of *Super Smash Bros*). Third, the researchers used the publisher-stated genre when available, which may not correspond with the definition of these genres by Adams [14]. Genres can be flexible, and games often use elements of different genres in one game, making them difficult to categorize. Fourth, all participants were recruited through social media or other web-based platforms. This biased sample may not be representative of all video game–playing, treatment-seeking individuals who smoke. Finally, these data were collected from July 2018 to September 2019, so the specific game titles might be different today; however, the game genres would likely remain similar. Future research on this topic would benefit from gathering information on specific features that participants like about the games they play to better aid in the development of gaming interventions for smoking cessation.

Conclusions

The findings of this study highlight the need for researchers to devote time and resources to understanding their target demographic before developing a game. Although there were some general themes and commonly listed game titles, those interests were shown to change with age. On the basis of these findings, researchers seeking to develop games for smoking cessation should leverage the popularity of Action games broadly speaking and Logic games in populations aged ≥36 years because of the popularity of this genre increasing with age. Participants endorsed games with narrative elements (as seen in the popularity of the Role-Play and Action-Adventure genres), suggesting that a game with an interesting story and character cast might maintain engagement and interest in the game among a large proportion of individuals. Finally, it may be possible to match the function for smoking (eg, attention) with the benefits of certain types of gameplay (eg, cognitive enhancement), which would be expected to improve outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

MMO: Massive Multiplayer Online

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Original Paper

Using Distance Communication for the User-Centered Development of a Smartphone-Based Serious Game for Children With Type 1 Diabetes: Participatory Design Approach

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Abstract

Background: The complications of type 1 diabetes (T1D) can be delayed or prevented in children with T1D who receive proper self-management education. Smartphone-based serious games are increasingly being used as an effective tool for teaching self-management. When developing a serious game, it is important that the development process be user-centered. Traditionally, different face-to-face methods have been used when children participate in the development process. However, face-to-face data collection is not always feasible. In such situations, distance communication can be used when developing a serious game.

Objective: The objective of this study is to develop a user-centered smartphone-based serious game that teaches self-management focused on carbohydrate intake in children aged 8-14 years with T1D using distance communication in both the development and evaluation of the game.

Methods: The development and evaluation of a smartphone-based serious game prototype was inspired by the Lean principles, and a user-centered approach was applied. The development process included 1 expert interview and design workshops with children with T1D. On the basis of the interview and design workshop results, a serious game prototype was developed using Microsoft PowerPoint. The evaluation of the serious game prototype included an interview with a dietitian and a playtest with children with T1D. All data were collected using distance communication.

Results: A user-centered smartphone-based serious game prototype was developed and evaluated. The expert interview with the dietitian formed the basis for the learning outcomes in the game. Four children and their parents contributed to the preferences, needs, requirements, and ideas for selected parts of the game design. The dietitian evaluated the prototype positively and validated its content and accuracy. The serious game prototype was well-received by the children and their parents during the playtest. The serious game prototype was perceived as a useful and engaging way to learn. However, the difficulty level was not appropriate, and the information was too basic for participants who had been diagnosed over a year ago. The use of digital communication platforms did not cause any problems.

Conclusions: The smartphone-based serious game prototype has the potential to be a useful and attractive tool for teaching disease self-management. The use of distance communication proved to be a useful approach in the development of a serious game.

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KEYWORDS

type 1 diabetes; children; serious game; distance communication; user-centered approach; evaluation; playtest; mobile phone

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Introduction

Background

Type 1 diabetes (T1D) is one of the most common chronic diseases diagnosed in children aged <15 years [1-3]. More than half a million children are affected by T1D worldwide [3]. It is estimated that the incidence of T1D among children aged <15 years is increasing in many countries. The annual increase is estimated to be approximately 3% [3].

Children with T1D constitute a vulnerable health demographic [4]. Living with T1D is intrusive and requires a high degree of self-management to achieve glycemic control [3,5,6]. Self-management refers to tasks that an individual must undertake to control the disease and minimize the risk of short- and long-term complications [7,8]. Proper T1D self-management is complex and requires monitoring multiple daily blood glucose levels, controlling and counting carbohydrates, controlling physical activity, and managing insulin doses using multiple daily insulin injections [2,3,9,10]. Consequently, every time children with T1D play sports or eat food, they must consider how these activities will affect their blood glucose levels [2]. Self-management is further complicated by the unknown carbohydrate content of food served outside the home [11].

Owing to the complexity of self-management, children rarely manage their care alone. Parents most often play a key role and are responsible for managing T1D in children [2,11,12]. In carbohydrate counting, parents have a great responsibility, as this is particularly difficult for the child [11].

Despite help from parents, many children with T1D are unable to manage T1D or attain glycemic control [2,13]. Less than 8% of children with T1D (aged 6-12 years) and less than 7.5% of adolescents with T1D (aged 13-19 years) have optimal glycemic control [14]. Crucial factors include incomplete knowledge and understanding of treatment regimens and future health risks [10] and not following the prescribed diet [15].

Studies have indicated that it is crucial to teach children self-management and involve them in their own care from an early age to improve glycemic control [1,2,9,11,12]. Preadolescent children (aged 8-14 years) are a prime target group for developing self-management skills and understanding the effects of diet, physical activity, and insulin [14]. Teaching self-management involves facilitating and implementing the knowledge, skills, and abilities necessary for self-management [16]. In particular, knowledge of carbohydrates (eg, content and types) is essential because the amount of carbohydrates in each meal is directly related to the increase in blood glucose level and hence the dosage of insulin [17]. This knowledge can improve glycemic control, thereby reducing the risk of complications [18].

Serious games are increasingly used as tools in health education [19-22]. Serious games are digital games in which game mechanisms and characteristics are used in nongame contexts [23], such as education and health care. Children with T1D have been shown to benefit from serious games designed to teach self-management [24-26]. Serious games are effective in promoting and transferring knowledge and developing self-management skills [27-30]. These games stimulate problem-solving, reflection, and hypothesis testing [19,21,24,25]. Moreover, improvements in short- and long-term memory have been proven [31]. Serious games are an effective educational tool in T1D because they are particularly engaging and appealing [20,32], which is important because children need the motivation to learn [33].

Serious games have been developed for children with T1D to teach self-management [14,29]. However, such serious games are not available in the Danish language or adapted to Danish standards and practices for self-management education. It seems that the development of a Danish T1D serious game focusing on carbohydrates would be beneficial for teaching self-management in preadolescent children (aged 8-14 years). Recently, serious games for T1D have been dominantly developed as smartphone-based apps owing to their ubiquity [14]. A smartphone is part of everyday life for most children and adolescents [26]. In total, 95% of US teens had a smartphone in 2018 [34], whereas 93% of children aged 8-15 years in the United Kingdom owned a smartphone in 2019 [35]. In 2014, around 95% of all Danish children (aged 12-14 years) had a smartphone [36]. Therefore, when developing a new serious game, smartphones appear to be an appropriate platform.

When developing a serious game for children with T1D, it is crucial to involve children with T1D in the process to arrive at an appropriate final product [5,37-40]. When the end user participates in the development process and the findings are translated into product design, the likelihood that the indented target group will engage with the final product is increased [38-42].

Children have frequently participated in the design and development of serious games [4,11,40,43,44]. Traditionally, participation has been implemented using different face-to-face methods, including semistructured interviews, participatory design workshops, and co-design sessions [4,11,43]. However, face-to-face interaction and data collection are not always possible. During the spring of 2020, the COVID-19 pandemic changed our ability to interact in person, making face-to-face data collection impossible because of restrictions. Therefore, there is a need for alternative methods to maintain social distancing in the context of COVID-19 [45].

Distance communication can be defined as synchronous communication between geographically separated participants, enabled by devices such as a telephone or computer [46]. Distance communication has previously been used to collect and analyze research data successfully [47,48]. For instance, telephone interviews have been shown to be as productive, reliable, and efficient as face-to-face interviews [49-51]. Fox et al [47] conducted synchronous web-based focus groups with young people. They suggested that the web-based environment increased disclosure related to sensitive issues and positively impacted group dynamics and the researcher-participant relationship compared with face-to-face focus groups [47]. Furthermore, video chat using Skype (Microsoft Corp) has been demonstrated to work well as a viable, alternative data collection tool for qualitative research. The use of video also counteracts the challenges of using telephones. The video allows the

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facilitator and participant to use nonverbal cues and prompts (eg, smiling and nodding) [48].

Objectives

To the best of our knowledge, distance communication has not been used to conduct user-centered workshops with children. Hence, the aim of this study is to develop a user-centered smartphone-based serious game that teaches self-management to children with T1D aged 8-14 years using distance communication in both the development and evaluation of the game. This paper describes the development process, participatory design outcomes, and evaluation of the prototype. The smartphone-based serious game prototype is focused on carbohydrates, as this has been highlighted as an essential element of self-management in T1D [17,18].

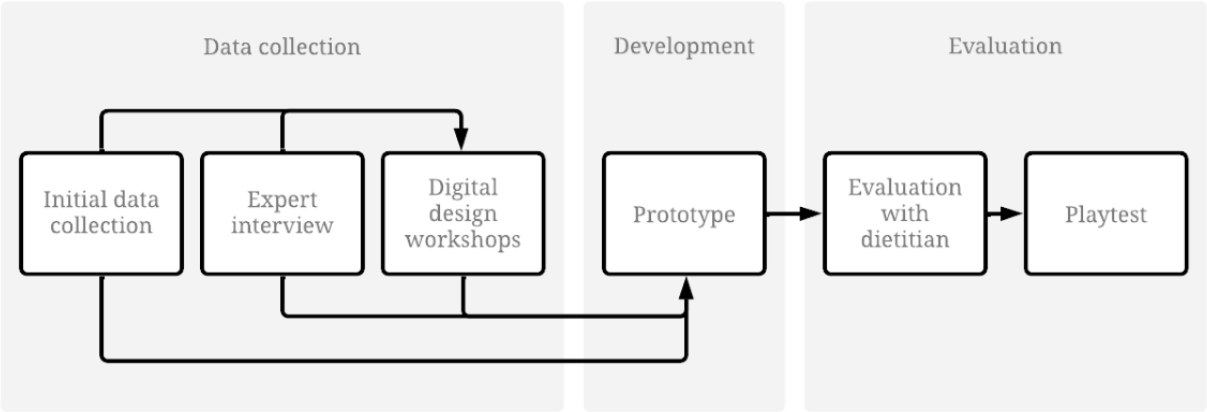
Methods

Development Process

A smartphone-based serious game prototype for children with T1D was developed and evaluated at Aalborg University, Denmark, from December 2019 to June 2020. The development and evaluation process was inspired by the Lean principles [41] and previously published studies [4,52-55]. Both the Lean principles and previously published studies focused on rapid prototyping, turning ideas into a prototype that is then evaluated, iterated, and refined based on feedback from the end user [4,41,52-55]. A user-centered approach was applied, where the needs and ideas of the user (children with T1D) were addressed and the perspectives of multiple stakeholders, including children with T1D, their parents, and health care professionals, were taken into account.

The development process included initial data collection, 1 expert interview, and 4 digital design workshops. Afterward, the serious game prototype was evaluated in 2 steps, including an evaluation with a dietitian and a playtest (Figure 1).

Figure 1. Development process for the prototype.



Initial Data Collection

Before this study, a systematic scoping review was conducted to identify game mechanisms that contribute to teaching self-management. The systematic scoping review has been described in detail by Nørlev et al [29] and published elsewhere. The findings from this review were used to develop a serious game prototype. Moreover, basic information about T1D and self-management, including diet, carbohydrates [3,17,56], and serious game design and development [1,31,57-64], were collected.

Expert Interview

An expert interview was conducted with a dietitian with >20 years of experience in educating children with T1D. The interview aimed to determine the essential knowledge about diet and carbohydrates that a child with T1D needed for self-management.

An expert interview was conducted on March 12, 2020, using FaceTime (Apple, Inc). A semistructured questionnaire consisting of open-ended questions was used (Multimedia Appendix 1). The interviews were audio-recorded and later transcribed. The transcribed data were analyzed thematically, inspired by Malterud [65]. Initial coding attached labels and themes to text segments, which appeared to indicate important information related to the research question. For each label and theme, the text segments were compiled into text that captured the essence of each theme. The transcribed materials were compared with the emerging themes. The findings were validated with participants. The first 3 authors (JN, CD, and KS) conducted the analysis.

Digital Design Workshops

Overview

Four digital design workshops were conducted in April 2020. The aim was to explore the preferences, needs, requirements, and ideas for selected parts of the game design. The digital design workshop was tested in a pilot with a child aged 8 years and without T1D before data collection to determine the timeframe and intelligibility.

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Participants

The participants (n=4; Table 1) were recruited via social media from the Danish Diabetes Association's family network. The participants were asked to send an email to the authors if they wanted to participate. All eligible participants who responded within the deadline and met the inclusion criteria were enrolled in this study. The inclusion criteria were as follows: (1) be diagnosed with T1D; (2) be aged 8-14 years; (3) be able to speak and understand Danish or English; (4) have access to Skype, Microsoft Teams (Microsoft Corp), FaceTime, or similar app; and (5) have access to a printer. The parents were asked to be present during the digital design workshop.

Table 1. Participant characteristics—digital design workshop (n=4).

Participant number	Age (years)	Sex	T1D[a] duration (years)
1	11	Male	5
2	10	Female	1
3	11	Male	3.5
4	14	Female	4

[a]T1D: type 1 diabetes.

Tasks and Artifacts

The digital design workshops consisted of the following three tasks: (1) suggestions for food, (2) avatars, and (3) rewards (Table 2). The tasks were based on the results of expert interviews and a systematic scoping review [29]. Visual tangible artifacts were developed for all 3 tasks (Table 2) to support cooperation by facilitating and stimulating participation, reflection, and imagination [66]. To clarify that the serious game prototype should be developed as a smartphone game, the children received a smartphone template, which they were asked to sketch on for all 3 tasks. For the second and third tasks, the participants received pictures and a description of the narrative that was decided for the game. These visual tangible artifacts were sent by email to the participants 24 hours before the digital design workshop. Participants were asked to print these artifacts.

Table 2. Tasks and artifacts in the digital design workshops.

Task number	Description	Artifacts	Purpose
1	Suggestions for food: sketch suggestions for food that causes blood glucose levels to rise fast and food that keep blood glucose levels stable	• Smartphone template	Gain insight into relevant food to include in a game for children with T1D[a] aged 8-14 years
2	Avatars: sketch what an avatar in a T1D game should look like	• Smartphone template • Description and pictures of the narrative	Obtain design ideas
3	Rewards: sketch the preferred rewards	• Smartphone template • Description and pictures of the narrative	Obtain design ideas

[a]T1D: type 1 diabetes.

Procedure

Digital design workshops were held using FaceTime. All 4 children participated once, individually, for a duration ranging from 60 minutes to 90 minutes. All 4 digital design workshops were managed by a facilitator. The facilitator introduced the first task. The child was then asked to draw the answer. When the child had finished, the facilitator asked the child to describe the drawing. The facilitator asked questions to validate and clarify the child's thoughts and intentions with the drawing while taking notes. If the child made any comments while drawing, the facilitator also took notes. This procedure was repeated for the last 2 tasks. During the entire digital design workshop, the facilitator was able to see and communicate with the children and parents through FaceTime. The child could ask the facilitator for help at any time.

Data and Analysis

The digital design workshops were recorded (audio and video), transcribed by the authors afterward, and supplemented with the facilitator's notes. The participants and their parents were asked to take a photo of their drawings from each of the 3 tasks and send them via email. This provided 3 types of data (Table 3). The photos and transcribed materials formed the core data for the analysis, whereas the notes added context and framing.

For each of the 3 tasks, the drawings, transcribed recordings, and facilitators' notes from the digital design workshops were compared to classify the objects in the drawings. The first 3 authors (JN, CD, and KS) identified and labeled common features across the drawings, as well as unique features for each drawing individually. The findings were noted in a matrix and discussed by the authors until an agreement was reached. A summary of the findings from each of the 3 tasks was provided. Afterward, the findings were compared with transcribed recordings to validate the authors' interpretations.

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Table 3. Types of data from the digital design workshops.

Type	Description	Status
Photos of drawings	Photos of the drawings made during the 3 tasks	Core data
Recordings	Transcribed recordings of all 4 digital design workshops	Core data
Facilitator's notes	Notes written down during and after each digital design workshop	Contextualizing data

Development of the Smartphone-Based Serious Game Prototype

A smartphone-based serious game prototype was developed as a hi-fi prototype using Microsoft PowerPoint (Microsoft Corp). The serious game prototype contained effects, including animations and sounds, to make it feel like a real game. Before the development, a requirements specification was performed, as well as a plan for the user interface.

Evaluation

The serious game prototype was evaluated in the following two steps: an evaluation by a dietitian and playtests with children with T1D.

Step 1: Evaluation With Dietitian

A dietitian evaluated the serious game prototype. This evaluation aimed to validate the content and accuracy of the serious game prototype, including the evidence base, health information, and learning materials. Before the evaluation, screen captures of the serious game prototype were e-mailed to the dietitian. The evaluation was conducted via phone. Each screen capture of the serious game prototype was reviewed individually, and the dietitian was asked to comment on each screen. The evaluation was audio-recorded, and notes were taken. All comments were reviewed and incorporated into the serious game prototype before the second step of the evaluation.

Step 2: Playtest

Overview

The serious game prototype was evaluated through a playtest to explore whether it engendered the experience for which it was designed. The playtest could find problems early and help confirm whether the game was suitable for the intended audience [67]. The playtest was designed to answer several key questions (Textbox 1).

Textbox 1. Key questions in the playtest.

Main question

- Is the game engaging and appropriate for children with type 1 diabetes (T1D) aged 8-14 years?

Supplementary questions

- Are all 4 mini games appealing?
- Is the level of difficulty in the mini games appropriate?
- Do the children with T1D believe they learn something from the game?
- Are the children with T1D bored, confused, or frustrated when playing?
- How can the game be improved?

Participants

Children and parents from the digital design workshops were invited via email to evaluate the serious game prototype through a playtest. Two children and their parents participated in the study. The children were girls, aged 10 and 14 years. The serious game prototype was e-mailed to the children and parents immediately before the playtest.

Procedure

Before the evaluation, a protocol for the playtest was provided. The playtests were conducted using FaceTime. Both children participated once, individually. Each child had 1 parent present during the playtest. Two authors (JN and KS) conducted the playtest. The child and the parent received an oral explanation. Both the child and parent were encouraged to vocalize their thoughts and reactions while the child played the game. The child was guided to play all 4 minigames. After finishing 1 minigame, the facilitator asked follow-up questions if needed. The playtest was completed through a postgame follow-up interview with the child and parent. A script was used for the open-ended follow-up questions.

Data and Analysis

The playtest sessions were audio- and video-recorded and directly observed. The recordings were then transcribed. The data were analyzed and coded based on key questions. During the initial coding, labels and themes were attached to text segments that appeared to indicate important information in relation to the key questions. Labels and themes and the belonging text segments were entered into a matrix and discussed until an agreement was reached. A summary was written for each label and theme to capture the essence of each theme. The first 3 authors (JN, CD, and KS) participated in the analysis and coding.

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Ethical Considerations

Participants were invited to participate through written information on social media (digital design workshops) or email (expert interviews and evaluations). After enrollment in the study, all participants (children, parents, and dietitians) received written information. Verbal information was provided before data collection by the facilitator to the participants, who had the opportunity to ask questions. All the participants were informed that they had the right to withdraw their consent at any stage. All data collection was performed after the participants had accepted and signed an informed consent form. The parents were asked to be present during the digital design workshop and evaluation. Only authors and facilitators directly involved in data collection were present in the room during the data collection. No ethical approval was sought for this human factors study, as this was determined to be unnecessary according to guidelines outlined by the Danish National Committee on Health Research Ethics.

Results

Results From the Expert Interview

The expert interview mapped the essential knowledge about diet and carbohydrates that a child with T1D needed to learn to self-manage. Three educational themes emerged: carbohydrate counting, types of carbohydrates, and tips and tricks (Textbox 2). These themes were implemented in the serious game prototype.

Textbox 2. Themes identified from the expert interview.

Carbohydrate counting

- Counting and assessing carbohydrate content in a meal
- The link between the amount of carbohydrates, blood glucose level and the required dose of insulin

Types of carbohydrates

- Fast and slow carbohydrates
- Food items containing fast and slow carbohydrates
- How the different types of carbohydrates affect blood glucose levels

Tips and tricks

- How to make carbohydrate counting easier

Results From the Digital Design Workshops

Overview

The digital design workshops provided preferences, requirements, and design ideas for the selected parts of the game. The children were engaged and focused during the digital design workshops. They expressed their thoughts and elaborated on what they had drawn and why.

Task 1: Suggestions for Food

All 4 children provided several suggestions for different types of food (Figure 2; Table 4). Candy, soda with sugar, and white bread appeared in most drawings to illustrate the cause of the rapid increase in blood glucose levels. All 4 children drew rye bread or wholegrain bread as a food type that maintained stable blood glucose levels.

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Figure 2. Example drawings from the digital design workshops' task 1: suggestions of food (candy [lollipop], rye bread, carrots, and soda with sugar).



Table 4. Task 1: suggestions for food and the number of occurrences across the 4 drawings.

	Occurrences (n=4), n (%)
Food that causes a fast increase in blood glucose levels	
Candy (lollipops, marshmallows, candy bars, candy floss, or wine gum)	4 (100)
Soda (with sugar)	3 (75)
White bread	3 (75)
Cookies	2 (50)
Sugary breakfast cereal	2 (50)
Syrup or honey	1 (25)
Pasta (white)	1 (25)
Food that keeps blood glucose levels stable	
Rye bread or wholegrain bread	4 (100)
Vegetables (carrots, cucumber, cauliflower, cabbage, or avocado)	4 (100)
Oats (and porridge)	2 (50)
Water or tea	2 (50)
Natural yogurt	1 (25)
Eggs	1 (25)

Task 2: Avatars

An avatar was illustrated as a human in 3 drawings and as a cartoon character in 2 drawings. Of the 4 children, 2 (50%) preferred several avatars to choose from, whereas the other 2 (50%) children only drew 1 avatar. Of the 4 children, 3 (75%) children wanted to name the avatar themselves and 2 (50%) children appreciated being able to customize the avatar. Furthermore, all the children said that the avatar should be diagnosed with T1D and be nice (Figure 3).

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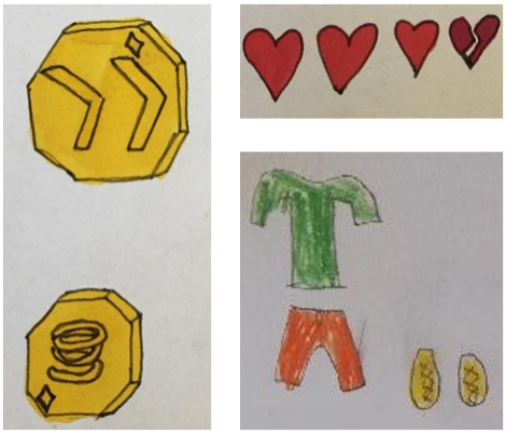
Figure 3. Example drawings from the digital design workshops' task 2: suggestions for the avatars. From the left: eggs with arms and legs; a human; and different suggestions including a unicorn, dolphin, ghost, human, and cupcake.



Task 3: Rewards

Several suggestions for the types of rewards emerged in the drawings, including points, coins, superpowers, accessories for the avatar, keys and tokens, tools, and extra lives or chances (Figure 4). Of the 4 children, 2 (50%) children thought that the points should be accumulated and used to place the player on a high score list. Of the 4 children, 1 (25%) child stated that both points and coins should be used to buy things and advantages in the game. Superpowers, keys and tokens, and tools should unlock or provide different benefits to the game. According to the children, rewards should be earned when completing a level or task, when making a correct choice in the game, and according to their performance. Of the 4 children, 1 (25%) child said that rewards should be given at random intervals when playing and 1 (25%) child expressed that earned rewards should be lost when making an incorrect choice.

Figure 4. Example drawings from the digital design workshops' task 3: suggestions for rewards (coins, extra lives, and accessories [clothes]).



Presentation of the Smartphone-Based Serious Game Prototype

The smartphone-based serious game prototype revolved around T1D self-management and specifically intended to teach children with T1D about carbohydrates and their effects. Textbox 3 lists the learning objectives and outcomes for the prototype.

The following seven game mechanisms were included in the serious game prototype: (1) narrative context, (2) feedback, (3) avatar, (4) simulation, (5) goals, (6) levels, and (7) social interactions.

Textbox 3. Learning objectives and outcomes.

Learning objectives and outcomes of the serious game prototype

- The child should be able to differentiate between different types of carbohydrates.
- The child should understand how different types of carbohydrates affect their blood glucose level.
- The child should be able to react to high and low blood glucose levels.

When the game begins, the player must choose and name an avatar. The avatar then presents the story behind the game through speech bubbles. The avatar reports that it is diagnosed with T1D and lives inside the human body, where it must

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explore the impact of different types of carbohydrates in 4 different minigames. The player's mission is to make correct decisions about carbohydrates to help the avatar control its blood glucose levels and prevent health consequences (hypoglycemia and hyperglycemia).

After familiarizing the player with the narrative context, the main menu appears (Figure 5), and the avatar demonstrates the main features. The avatar shows the blood glucose meter at the top of the screen as an imprint of its current blood glucose level throughout the 4 minigames (Figure 6). The blood glucose meter provides the player with feedback on their performance. If the player makes the correct choice, the blood glucose level will remain or return to normal (the green zone in the middle of the meter). If the player makes an incorrect choice, the blood glucose level will drop (left side of the meter) or become too high (right side of the meter), depending on the choice made. If the blood glucose level becomes too low or too high, the avatar's facial expression changes, resulting in symptoms of hypoglycemia or hyperglycemia.

There were 4 different minigames in the serious game prototype. The first minigame is *Activities*, which is a simulation game. *Activities* teaches the player about the relationship among food (carbohydrates), blood glucose level, and physical activities and how different types of food can affect the blood glucose level after physical activities. *Activities* simulates different physical activities (eg, football) that affect the blood glucose level. The avatar points out how the player should help it choose the correct food to maintain normal blood glucose levels (green zone). The choice affects the blood glucose level and the avatar will indicate whether the choice was correct or incorrect.

The second minigame is *Quiz*, which is a quiz game. The *Quiz* aims to teach the player about the different types of carbohydrates and how they influence the blood glucose level. All questions were about carbohydrates and blood glucose levels. The avatar points out how the player must drag and drop the correct food item on the avatar to answer the question. This level contains 10 questions in total. If all 10 questions are answered correctly, a new level begins. The game ends when the player provides an incorrect answer. This level must then be repeated.

The third minigame is *It's raining carbohydrates*, which is an arcade game. It aims to teach the player to identify foods containing different types of carbohydrates. The avatar introduces the game and instructs the player to choose one of three challenges: *fast carbohydrates*, *slow carbohydrates*, or *blood glucose level*. If the child chooses *fast carbohydrates* or *slow carbohydrates*, they must catch the type chosen (either fast or slow) when it falls in the stomach and make other types and things pass by. At the blood glucose level, the player must catch the right food or insulin based on the current blood glucose level seen on the blood glucose meter to maintain the blood glucose level within the normal zone. The player must touch the correct food and insulin before passing the stomach. The game ends when the player catches an incorrect item or when a correct item is not caught.

The fourth minigame is the *Obstacle Course*, which is an action-adventure game. The aim of the *Obstacle Course* is to teach the child about different types of carbohydrates. The player has to help the avatar through the course to complete it. Along the way, there are several obstacles to overcome, for example, avoiding villains and fast carbohydrates, which slows down the avatar. Several items help the avatar, including different medals that give the avatar superpowers to jump higher and operate faster.

In all 4 minigames, the player could win or lose points, depending on the performance. The points are accumulated and used to place the player on a high score list. All 4 minigames contain several levels. These levels become increasingly difficult and complex to complete. Throughout the serious game prototype, the avatar provides informative feedback for correct and incorrect answers.

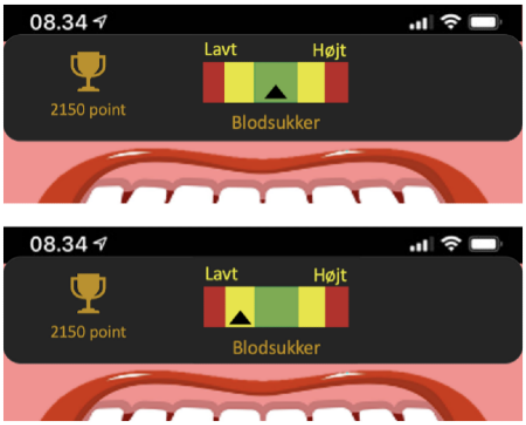
In addition to the 4 minigames, the serious game prototype contains a shop and a chat. In the shop, the player could buy different items to customize the avatar. In the chat, the player could communicate with other players. The chat consists of context-sensitive predefined dialogues to reduce the risk of bullying and foul language. The player must touch the message they wanted to send and a speech bubble with the message appears in the chat field.

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Figure 5. The main menu.



Figure 6. The blood glucose meter.



Results From the Evaluation

Results From the Evaluation With the Dietitian

In general, the feedback from the dietitian was positive and mostly pertained to the inaccurate terminology and language used. However, a few evidence-based and learning material issues were apparent, including misleading or confusing food items that could be interpreted in multiple ways, potentially causing some children to provide an incorrect answer.

The dietitian made suggestions for other response options in accordance with recommendations for a T1D diet. For instance, the dietitian recommends that children with T1D always consume juice or grape sugar if they experience a drop in their blood glucose levels.

Results From the Playtest

The idea of playing a game to learn about self-management was well-received by the children and their parents. In general, the serious game prototype was perceived as a useful and enjoyable way to learn within the limits of what is possible with an early prototype. Laughter, excitement, and curiosity were observed among the children. Furthermore, the children and their parents thought that they were able to learn about T1D self-management from the game and felt an increase in motivation to learn. The interactivity was more motivating than in the traditional materials they had previously used. In particular, instant feedback, including the glucometer and the avatar's symptoms, was appreciated. Both children and parents found it easier to understand how, when, and why the blood glucose level was influenced, and they found it easier to recognize high and low blood glucose symptoms.

The children and parents appreciated that the game contained different minigames, as they thought it would appeal to the children and make the game more exciting and engaging. The quiz was particularly appealing.

The evaluation showed that the level of difficulty was not appropriate and that the information was too basic. The game was too easy, and the participants knew most of the answers.

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Consequently, the game became boring quickly. Both children and parents found the game suitable for newly diagnosed children or children with limited knowledge. The game would benefit from more complex tasks and knowledge to become a meaningful and helpful tool for children who have been diagnosed for a longer time or those with more knowledge. It was proposed that the player should be able to choose the time of diagnosis so that the game's level of difficulty could be adjusted accordingly. Furthermore, it could be difficult to identify food items from drawings that sometimes confused children.

The children liked that they could choose from several different avatars. The chat also earned a positive feedback. The children and their parents appreciated the social elements and liked connecting with other children with T1D. Children's opinions on the predefined dialogue were more diverse. The oldest child felt that it was an obstacle and wanted to be able to write messages freely, whereas the youngest child liked it. Both the children and their parents liked that the serious game prototype had a multiplayer mode. The children suggested a feature in which they could invite a friend to compete in a minigame.

Discussion

Principal Findings

This study describes the development and evaluation of a user-centered smartphone-based serious game prototype for children with T1D using distance communication. This study found that it is possible to develop a user-centered serious game prototype using distance communication. The serious game prototype revolves around T1D self management and focuses on teaching children with T1D about carbohydrates and their effects on blood glucose levels, highlighted as an essential element of self-management [17,18]. The serious game prototype consisted of 4 minigames. The results indicate that the serious game prototype has the potential to be a useful and attractive tool to teach self-management focused on carbohydrates to newly diagnosed children with T1D that may help prevent development of T1D-related complications. Furthermore, this study implies that the developed serious game prototype does not engage children who have been diagnosed over a year ago and the results show other options to consider for this group.

For a serious game to be successful and to provide learning, players must actively use it. Enjoyment and motivation are important criteria for learning and improving one's skills. A child who does not enjoy an activity is unlikely to engage long enough to reap any benefits [30,33]. Minigames have been successfully used to teach self-management previously [18,30,43,68-70]. The present serious game prototype allows players to engage in 4 types of minigames. The minigames were appreciated by the children with T1D and their parents because the minigames made the serious game prototype more engaging. These findings are in accordance with past research, which concluded that children aged 7-12 years are more likely to accept simpler games [71]. Minigames are particularly relevant for children as they quickly become bored [14]. However, in the evaluation, the serious game prototype was considered boring because the minigames were too basic and easy for children with T1D. It was suggested that the serious game prototype was more appropriate for newly diagnosed children or for children with limited knowledge. This suggestion is in line with Pescare et al [72], who found that a serious game mainly devoted to distinguishing complex carbohydrates from simple carbohydrates could be more effective for children who were newly diagnosed with T1D than for children who had been diagnosed for a longer period. Therefore, adding new and more complex tasks and challenging content to the serious game prototype may help improve the longevity of play and make the game meaningful and helpful for children who have been diagnosed for a longer time and have already been taught the basics of carbohydrates [73]. In addition, the ability to tailor and customize information has been shown to make serious games more relevant to the user and increase their use [74]. DeSmet et al [75] reported that games are best tailored to both sociodemographic information (eg, age and gender) and behavioral change needs (eg, knowledge and motivation). Tailored and customized information can be considered in future versions of serious games.

Several self-management games for T1D incorporate personal data, including real blood glucose measurement data [14,71]. Holtz et al [76] demonstrated that gamifying personal data is associated with improved glycemic control, quality of life, and diabetes behavior. Personal data enhances the educational effect by making the player understand how their decisions and actions affect the subsequent gameplay and heighten the player's intrinsic motivation to play a self-management game, resulting in improved self-management [14]. Therefore, adding the child's data may be beneficial for serious game prototypes.

The children and parents highlighted instant feedback as it was found to promote an understanding of the relationship between actions and consequences. This feedback is similar to other studies that have demonstrated that serious games containing instant feedback and simulations effectively promote self-management [30,72]. Moreover, feedback on actions in the game contributes to experimental learning [14] by allowing players to observe how their choices enhance or hinder the desired outcome [77].

Chat and social interaction were positively evaluated. Consistent with other research, children emphasized the enjoyment of social interaction [11,12,71]. Although fun is the primary reason children play games, social interaction has been reported as the second reason to play games [77]. Peer support and socializing with others in the same situation are crucial for coping with T1D [70]. In addition, studies indicate that parental involvement in a serious game is beneficial and may play a key role in positive outcomes because parents have a strong influence on their child's behavior [78]. Past research has demonstrated that cooperation games are comparatively better than competition games for learning outcomes [33,79] and multiplayer games lead to greater enjoyment, longer engagement, and a lower dropout rate than individual games [80].

In this study, a distance communication–based, user-centered approach was applied. Children frequently participate in user-centered development and evaluation of serious games

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[44]. However, unlike the distance communication approach used in this study, user-centered methods traditionally consist of face-to-face interactions [4,6,11,43]. Internet and videoconference tools are increasingly popular methods of gathering qualitative data, such as focus groups or synchronous interviews by using Skype [81,82], and have become the most feasible alternative to face-to-face data collection [82]. Videoconferencing provides synchronous interaction between the researcher and participants and allows participants to be in a familiar environment, making them more comfortable [82]. The comfort of the participants is particularly important when children participate in research [81,82]. Collecting data using virtual methods makes it possible to include geographically remote participants [81]. Therefore, the number of potential participants can be increased. In this study, distance communication allowed the authors to include participants from different regions in Denmark, which probably increased the number of participants. Most children were accustomed to using a computer and engaging in video conferencing, and all participants in this study had experience with digital tools. Therefore, as expected, distance communication may not have had a significant impact on the results. This minimal impact is in line with Lo Iacono et al [48], who concluded that remote technologies such as Skype and FaceTime offer new opportunities for researchers and work well as a data collection tool.

Study Limitations

This study has some limitations. The small sample size and limited variation within the participant pool for each stage of the serious game design process are the major limitations of this study. The participants are presumably not representative of all Danish children with T1D aged 8-14 years, and the small sample size probably prevents the transferability and generalizability of findings to wider or other contexts. Therefore, a larger sample size is preferable. The literature states that 5 users are considered sufficient to test a prototype [83]. This must be considered in the conclusion. However, the development of the serious game prototype was inspired by the Lean principles, which focus on an iterative process consisting of gathering feedback early in the process and making improvements to the prototype accordingly [41]. Therefore, the serious game prototype developed in this study is a good starting point for future versions of a serious game for newly diagnosed children with T1D. In the future, the serious game prototype must be adjusted according to the results of the playtest and tested multiple times until users are satisfied. Furthermore, a future version of the prototype must be tested to determine whether the serious game prototype is effective in teaching self-management.

Conclusions

This study suggests that distance communication can be an approach to allow children to participate remotely in the development process of a user-centered serious game prototype. The digital design workshops helped ensure that the serious game prototype met the user's needs and preferences. These findings indicate that the developed serious game prototype has the potential to be a useful and attractive tool for teaching self-management suitable for newly diagnosed children or children with limited knowledge. The serious game prototype was perceived as a useful and engaging way to learn about self-management within the limits of what is possible with an early prototype and small sample size. In the future, the serious game prototype must be refined according to the results of the playtest and further evaluated to determine whether it is effective in teaching self-management.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide for the expert interview.
[DOCX File , 17 KB - games_v10i1e33955_app1.docx]

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Abbreviations

T1D: type 1 diabetes

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Original Paper

Teaching Students About Plagiarism Using a Serious Game (Plagi-Warfare): Design and Evaluation Study

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Abstract

Background: Educational games have been proven to support the teaching of various concepts across disciplines. Plagiarism is a major problem among undergraduate and postgraduate students at universities.

Objective: In this paper, we propose a game called Plagi-Warfare that attempts to teach students about plagiarism.

Methods: To do this at a level that is beyond quizzes, we proposed a game storyline and mechanics that allow the player (or student) to play as a mafia member or a detective. This either demonstrated their knowledge by plagiarizing within the game as a mafia member or catching plagiarists within the game as a detective. The game plays out in a 3D environment representing the major libraries of the University of Johannesburg, South Africa. In total, 30 students were selected to evaluate the game.

Results: Evaluation of the game mechanics and storyline showed that the student gamers enjoyed the game and learned about plagiarism.

Conclusions: In this paper, we presented a new educational game that teaches students about plagiarism by using a new crime story and an immersive 3D gaming environment representing the libraries of the University of Johannesburg.

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KEYWORDS

serious games; educational games; plagiarism; library games; game mechanics; education; teaching

Introduction

Plagiarism is the reuse of another person's ideas, work, or words as one's own, without sufficient credit being given to the original creator [1]. Reasons people plagiarize are that the benefits outweigh the drawbacks, while a student's motivation to plagiarize could be the goal of good grades and the ability to measure up with their peers [2]. Another noteworthy reason is that with the flood of online information, several researchers have noted that students are more likely to ignore the ethics behind plagiarizing [3].

Beyond concerns in the student realm is a slight, less rampant concern with academics who also plagiarize in their own academic writings [4]. This is because certain research institutions offer financial incentives/subsidies (sponsored by the government of the country) for research outputs, making academics in such institutions more desperate to produce more research [4]. Although most academics do not plagiarize, they sometimes look the other way when their students do. One, because of the concerned modules [5], and sometimes because of the stressful red tape that goes into reporting these transgressions to the institution, as this leads to many meetings and validation processes [6,7]. If students are trained well, and taught what is and is not plagiarism, they often avoid it [8,9].

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Many of the incidences reported are attributed to ignorance on the part of the student, the incapability to write original content, the pressure on postgraduate students to publish, or simply the lack of realization and understanding of what is implied by plagiarism [8]. In this paper, we propose a game called Plagi-Warfare (a video exhibition of Plagi-Warfare has been created earlier [10]) that attempts to teach students about plagiarism.

A number of software tools or technological solutions have been proposed to assist in the fight against plagiarism. Popular paid tools (such as those listed in Tripathi et al [11]) include Turnitin, CopyCatch Gold, and EVE2: Essay Verification Engine, while some free online tools include Dupli Checker, Copyleaks, and PaperRater. Particularly, games have also been created to engage students or players with plagiarism educational contents. Here, we briefly mention 3 of these games. The first is Goblin Threat [12]. Goblin Threat is played by finding and clicking on goblins, who ask questions about different aspects of plagiarism. Sound and engaging design are used to keep the players' attention. The second is Cheats and Geeks [13], a board game where players race against a rival to display their research. Players are enticed by a chance to move faster by committing wrongdoings. Finally, Planet in Peril [14] is a game where the player navigates through a 3D campus environment and learns about plagiarism through exchange with aliens. There are several opportunities to improve existing educational games for teaching plagiarism or other subjects/contents. First, it is helpful to look at the limitations of existing games and attempt to address those limitations in creating more effective games for teaching a topic such as plagiarism. Some of such limitations are as follows:

- Some of these games are especially relating to students in certain academic fields [14]. This makes the audience restricted. A game that will teach students about plagiarism should be playable by students who are not gamers.
- According to Broussard [14], many educational games are not engaging enough to allow players to select their own in-game visual representations (or avatars), stating that this could improve the player's compassion for their virtual self.
- Kazimoglu et al [15] raised a similar concern about games not having multiple gameplay paths, forcing the player to make similar choices every time, hence leading to boredom for the player.
- As far as we know, no library plagiarism game takes place in a virtual environment that its students are familiar with, within the context of South African university libraries.
- The levels of complexity of gameplay are not well defined (and mostly absent) in these educational or plagiarism-teaching games [16].
- Due to the static nature of the contents of plagiarism and the challenge of presenting this content using the vehicle of games, previous games lack the replayability factor—gamers quickly get used to what challenges pop up in the game and where—leading to boredom after a few iterations of playing the game [17-19].
- The storyline of some of the previous games is mostly unrelatable to the students, for example, having aliens on campus in the game Planet in Peril [14]. We have evidence to show that games having realistic stories are more relatable to students [20].

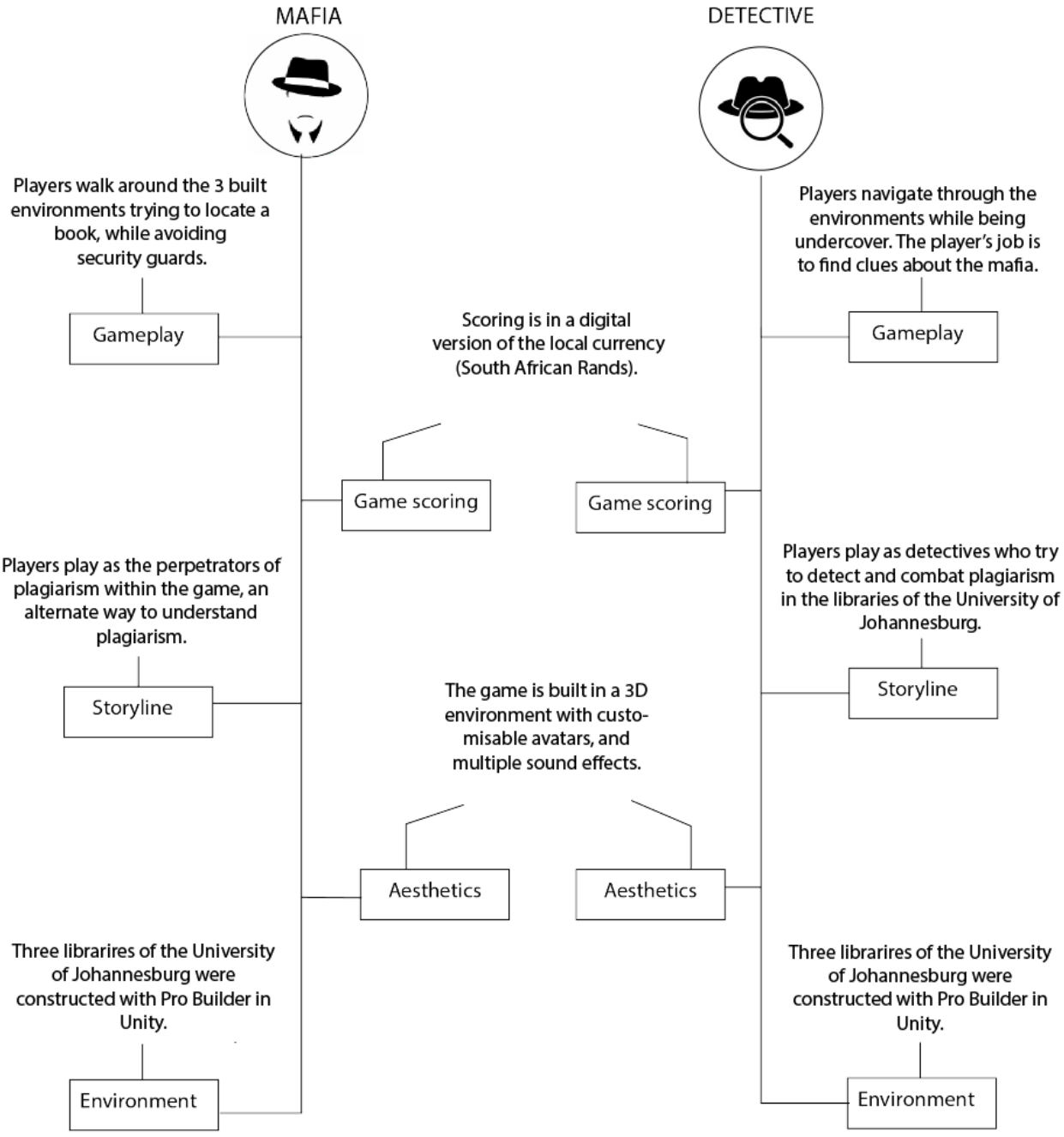
This paper is organized as follows. The Methods section presents the game design and algorithms for the new game that teaches plagiarism, Plagi-Warfare, as well as the technologies used in the implementation of Plagi-Warfare. Discussed in the Results section is an evaluation on the feedback on Plagi-Warfare. The Discussion section presents the background of the work and an analysis of related works, with the gap that is addressed in this work. Finally, we present the conclusions of this work and future works.

Methods

In this section, we present aspects of the game design of Plagi-Warfare. We start with the writing of the game's story, followed by the description of the world where the story takes place. We end it with the description of the content of the game (plagiarism lessons, quizzes, or facts), levels of the game, scoring in the game, the technological/software design of the system for the game, and the follow of the game. Figure 1 shows the Plagi-Warfare game components.

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Figure 1. Plagi-Warfare game components.



Story Development

Here, we present the background story of Plagi-Warfare. In Plagi-Warfare, the player is able to choose whether to play as the bad guy or the good guy, that is, as a *mafia member* or a *detective*. The story of the mafia is that the player is an expelled student who is back to assist students in plagiarizing. The player joins the *plagiarism cartel* as a low-ranking member, completing tasks sent to their virtual phone and avoiding getting caught by detectives. The detective mode allows the player to be hired to investigate plagiarism cases within the library. The player walks around the library, questioning students about their work and assignments, to find more out about the plagiarism mafia. The students found guilty are questioned further and informed about the consequences of their actions. The player then uses what they have found to take down the plagiarism mafia.

World Design

In this section, we describe the design of the game world or environment. The environments in Plagi-Warfare were built using Unity Game Engine; it plays out in 3D gaming environments that are modeled after the libraries of the University of Johannesburg, South Africa. The libraries used in the gaming environment include the Auckland Park Bunting Road (APB) campus, the Kingsway Avenue (Auckland Park Kingsway [APK]) campus, and the Doornfontein (DFC) campus libraries. In Plagi-Warfare, there are 27 scenes: 4 of the scenes are used to assist the player to sign into/up for the game; 5 of the scenes are for the navigation for each mode of gameplay

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(resulting in 10 scenes for the mafia and detective modes)—that is, used to create pages for the user to access the leaderboard, options, profile, level selection, and level failed message; 7 scenes are for quizzes or game challenges; and 6 scenes are library environments, 3 for each game mode, representing the 3 libraries of the university.

Content Design

The content of Plagi-Warfare are the questions or challenges in the game. The questions that constitute challenges in the game were supplied by the librarians at the University of Johannesburg. These challenges are meant to test the players' knowledge about plagiarism through scenario-based questions. The questions are composed with Boolean responses (true or false), identifying the best answer from multiple answers and identifying odd answers, word responses, and short text responses. To make sure that Plagi-Warfare is replayable, we used the seed questions/challenges to create an algorithm for the procedural generation of similar instances of the same questions, allowing the questions to be presented in a slightly different way every time. This has been proven to keep the interest of players in the game [21,22].

Level Design

There are 6 levels in Plagi-Warfare. In the mafia role and in the detective role, there are 3 levels. The mafia levels are divided into 2 types of activities: The first type of activity involves the players exploring the gaming environment (which are virtual libraries) with the controllers and engaging in maneuverings, such as avoiding patrolling detectives (because the detectives are on the lookout for mafia members), while trying to locate hidden objects, such as books. The second type of activity is where the knowledge of the player about plagiarism is tested using scenarios or quizzes. The detective levels are divided into 2 types of activities: The first type of activity requires the player to roam the virtual environment and speak to student nonplayer characters (NPCs) to find potential mafia members. The second type of activity is to interrogate suspicious student NPCs with the use of a quiz. Players have to determine whether the student NPCs' answers are correct or incorrect. The hardware required to play Plagi-Warfare is a desktop or a personal computer with an attached mouse and keyboard.

The following mechanics are used to control the level of difficulty in Plagi-Warfare:

- Each time a level is loaded, the mission objective's location is randomized. This forces the player to search through the whole environment, still having the risk of being caught by detective NPCs.
- The detectives' alert proximity increases as the levels progress, which increases the chances of the player getting caught.
- There is an increase in the difficulty or complexity of questions used in the quizzes.
- The number of questions asked increases in the game as the level increases.

The average range of completion time for each level of Plagi-Warfare is 5-10 minutes.

Scoring Design

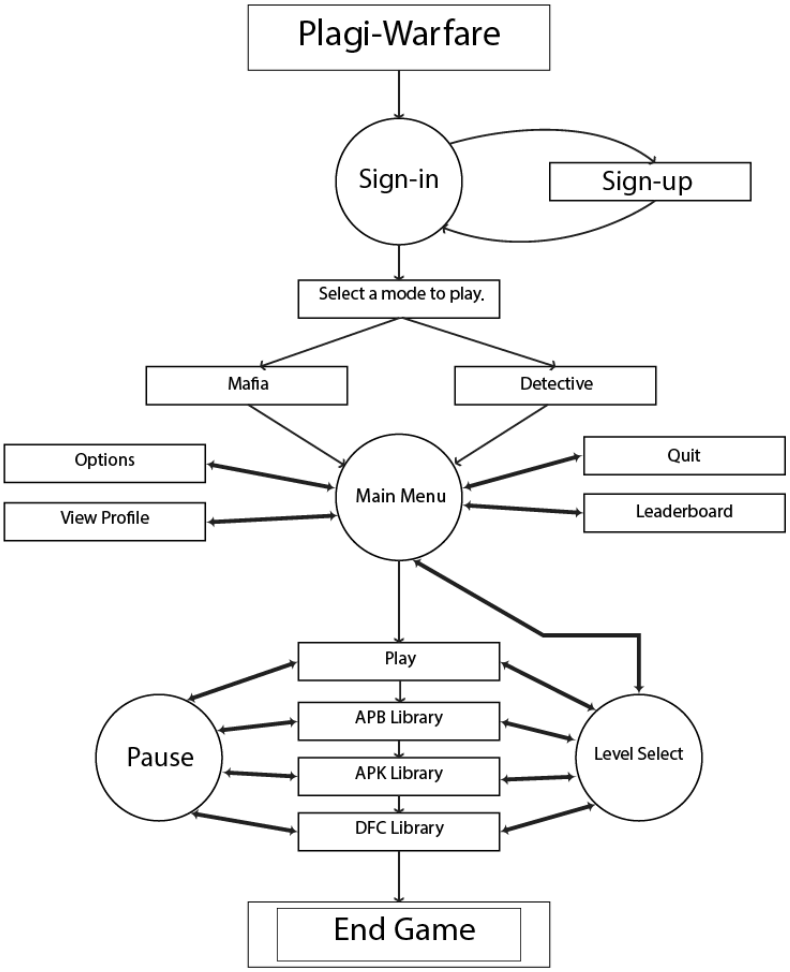
Plagi-Warfare is scored in South African Rands (symbolically noted as ZAR or simply R). Players are allocated virtual money for completing levels of the game. For each question answered correctly, a player gets R250 ($16.38). If a player answers 6 correct questions in a level, they are given R1500 ($98.27) for that level. Players are expected to gain bragging rights from their net worth in the game. For a player to proceed, they have to answer 80% of a level's questions. There is a leaderboard in the game that shows the top players and their respective net worth.

Game Flow Design

The flow of play in Plagi-Warfare is illustrated in Figure 2. The player starts by signing in (or signs up if the player is new to the game), and they select the desired mode of play, detective or mafia member. The player is then presented with menu options to access the leaderboard and game options (where they can select avatars to represent themselves), view their profile, or select a level to play. When all levels are completed for the selected mode, the game halts—"End Game."

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Figure 2. Plagi-Warfare game flow design. APB: Auckland Park Bunting Road; APK: Auckland Park Kingsway; DFC: Doornfontein.



Design of Players' Feedback

We selected 30 participants from the University of Johannesburg across different backgrounds, all having good exposure to games and a good knowledge of what plagiarism is. The following are the questions from the survey:

- How likely would you play the game? (1, unlikely; 10, extremely likely)
- Would you recommend the game to someone else to play?
- Do you think this game can help in educating students about plagiarism?
- What would you enjoy about this game?
- What would you improve about the game?

Implementation, Results, and Evaluation

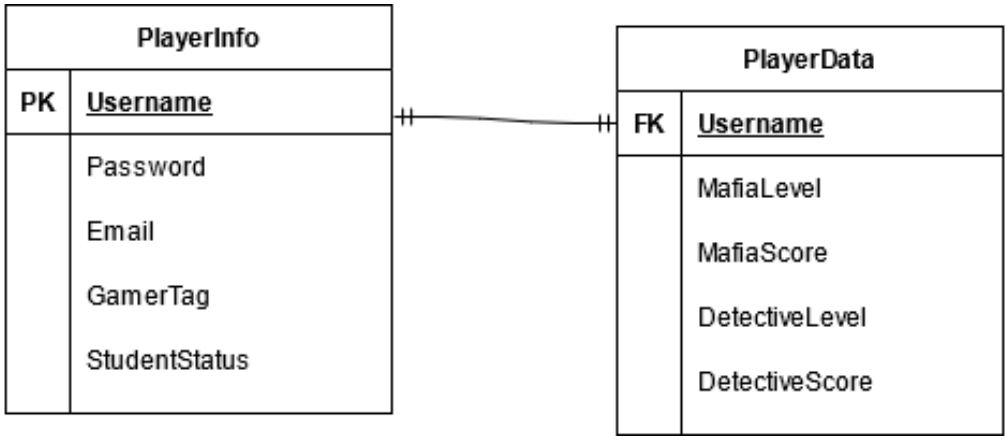
Here, we present the technologies used for the implementation of Plagi-Warfare, a description of some important algorithms designed to perform certain tasks (such as procedural content generation of variants of plagiarism quizzes), results in the form of screenshots from the finished game, and an evaluation showing the opinion of players of this game.

Systems Design, Tools, and Resources

Plagi-Warfare was created using the Unity Game Engine, alongside the Microsoft Visual Studio Integrated Development Environment (IDE). We also used some asset libraries, such as Unity Asset Store, Turbosquid, and Cgtrader (used for both 3D models and 3D graphics) and Mixamo (used for character animation and generation). The database is hosted on PhpMyAdmin, which holds 2 tables, PlayerInfo and PlayerData. PlayerInfo holds the account information of the player—that is, username, email, password, gamer tag, and student status. PlayerData holds the game data of the player—that is, current level and scores for each respective game mode. PlayerInfo has a mandatory one-to-one relationship with PlayerData. A simple entity-relationship (E-R) model that describes these tables and their relationship is shown in Figure 3. The E-R model is a tool used by analysts to visualize data stored in a database [23].

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Figure 3. Plagi-Warfare database design.



Algorithms

Here, we present a few algorithms that were designed to perform specific operations in the game. Algorithm 1.1 (Textbox 1) takes a set of 20 predefined locations from design time and a book object that needs to be placed in the game scene. The algorithm computes a random location for the placement of the book and returns this location to other parts of the game.

Other algorithms include the following:

- Content generation algorithm: An algorithm that takes a library quiz designed by a librarian and automatically generates variations of the quiz, thereby maximizing the replayability of the game.
- Field-of-view (FoV) algorithm: During the mafia gameplay, there are detectives patrolling the environments to attempt to catch the player. This algorithm sets an invisible radius around each detective with a set degree range and length. Should the player enter this area, a caught screen is triggered, causing the player to have to restart the level.
- Transferring NPCs: In the detective side, when the player is in range of the NPC's box collider, this algorithm is triggered. The player is given an option on whether they want to take the NPC to the interrogation room by pressing the E key. Once this event is triggered, 3 different locations are checked. If the first location is not filled, then the NPC is moved to that position. Once all 3 locations are filled, this algorithm does not run. When the player is in close proximity to a student NPC, they are given an option to take the student NPC to the interrogation room.
- Selective shuffling: This algorithm selects random quizzes from the repository of generated quizzes, given that the player has not previously been presented with the actual instance of the quiz problem.
- Updating levels in the database: This algorithm saves the player's current state (level of play, current score, etc) in the database.
- Answer submission: This algorithm validates the player's answer with respect to the predefined model answer of the plagiarism quiz. Scores are awarded as a result.

Textbox 1. Algorithm 1.1.

Algorithm 1.1: Shuffling spawn locations of objects

Data: LocationsXYZ [20], BookObject

Result: Book Location

```
    begin
    instance_location ← LocationsXYZ(getRandom[1,20]);
    Book_Loc ← Transform (BookObject, instance_location);
    return Book_Loc
end
```

Results

Screenshots From Plagi-Warfare

Here, we showcase a few screenshots from Plagi-Warfare. In Figure 4(a), the bookshelves at the APB campus library are shown. Figure 4(b) shows a conversation scene between the player and the NPC. The entrance of 1 of the environments is shown in Figure 4(c). Figure 4(d) shows 1 of the book spawn locations during a game session. The NPC interrogation is shown in Figure 4(e). In Figure 4(f), we show the detective's introduction scene. Figure 5 presents a view of the APB library from upstairs and the different way points of the NPCs. Each color represents a different NPC path. More results (a recorded video of the game during play) are published online.

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Figure 4. Screenshots of both gameplay and behind the scenes of environments. APK: Auckland Park Kingsway; NPC: nonplayer character.



Figure 4 (a) Bookshelves



Figure 4 (b) NPC Interaction

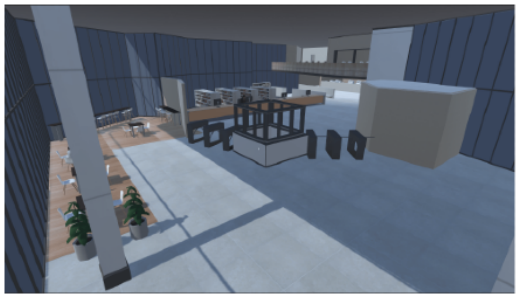


Figure 4 (c) Entrance of APK

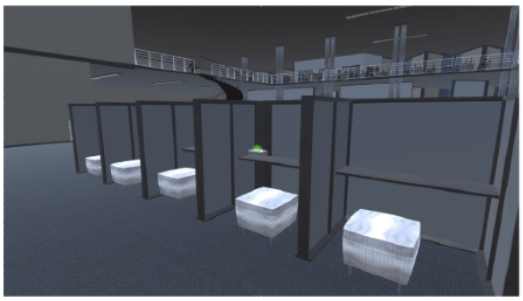


Figure 4 (d) Book Spawn

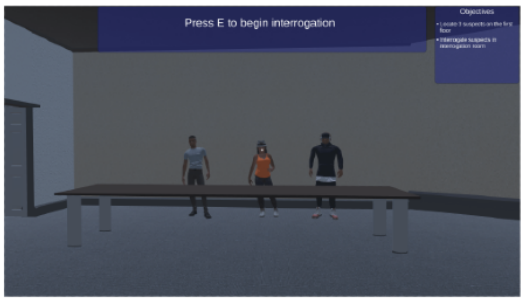
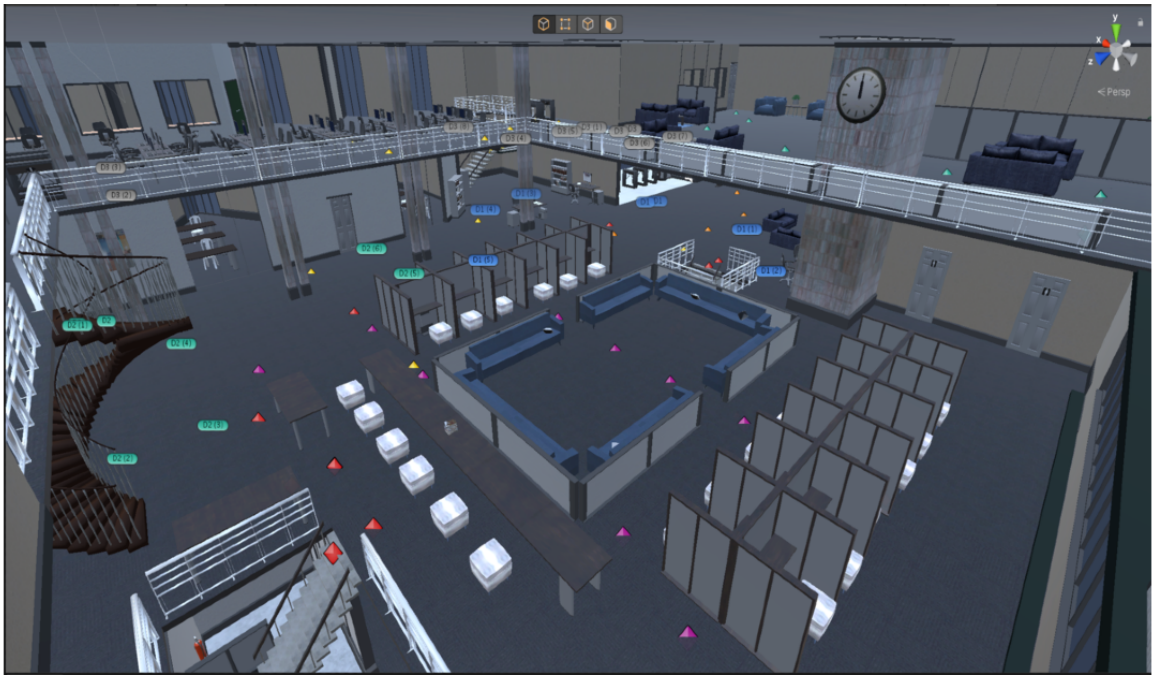


Figure 4 (e) Detective Interrogation



Figure 4 (f) Begin interrogation

Figure 5. Library at APB campus, illustrating the different NPC waypoints. APB: Auckland Park Bunting Road; NPC: nonplayer character.

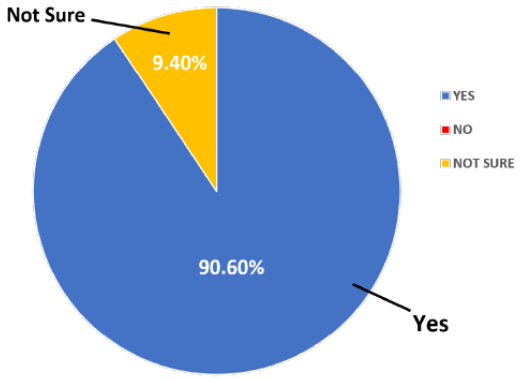


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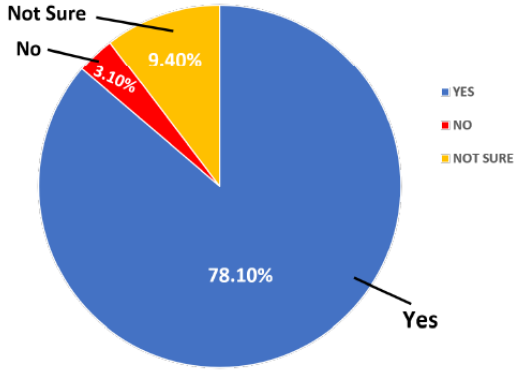
Game Evaluation

In this section, we present the result of an evaluation conducted to gather the opinions of players. The results from the evaluation are shown in Figure 6(a) and Figure 6(b). The results show that the majority (27/30, 90%) of the players found the game educational and believed that they could learn about plagiarism from the game, while a small number stated that they were not sure—there was no negative stance on this question. In addition, 1 (3%) player said that they would not recommend the game, while 23 (77%) said they would, and the remaining (6, 20%) were not sure. This is a high recommendation rate.

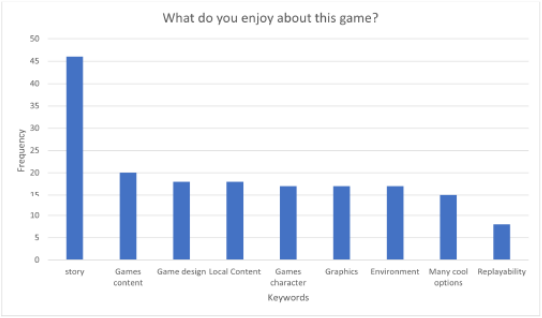
Figure 6. Evaluation of Plagi-Warfare. NPC: nonplayer character.



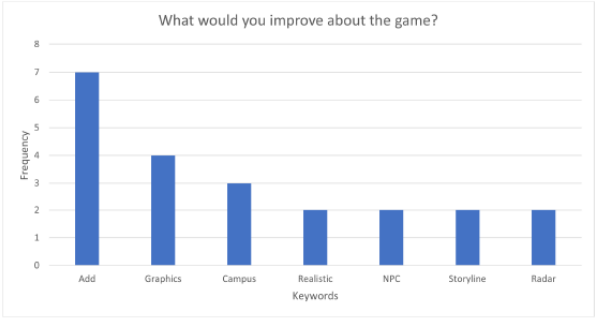
(a) Can you learn about plagiarism from this game?



(b) Would you recommend this game?



(c) What do you enjoy about this game?



(d) What would you improve about this game?

We also allowed the players to respond to 2 questions in free text: what they enjoyed about the game and how they think Plagi-Warfare can be improved. As seen in Figure 6(c), notable keywords that our participants repeatedly used are “story,” “game content,” and game design”; after inspecting the actual text of responses, we confirmed that this directly translates to the fact that our players loved the story, the learning that takes place, and the look and feel of the game. Other keywords were “local content” (implying that they know the library and they enjoyed that). There was little attention given to the replayability of the game—this is understandable as it only becomes important after players play for a longer time. The last question that players had to answer was whether they had other ways of improving the game. Here, many keywords came up in the responses, implying that there is no one aspect of the game that is majorly deficient. However, notable suggestions (when we eliminate obvious keywords) included “realistic” and “add/adding” (suggesting the addition of more features). These responses are good for a first launch of Plagi-Warfare and encourages a number of possible upgrades.

Discussion

Principal Findings

The role of serious games in the learning domain is rapidly growing. This paper explored the development of effective serious games with regard to plagiarism. We hope readers will obtain a general understanding of how to create an effective serious game to combat plagiarism.

The players found the gameplay and storyline quite engaging. This is important as serious games need to find a balance between entertainment and education in order to create an effective learning environment [24].

We explained how to develop a game that is both enjoyable and educational by demonstrating functional mechanics.

This is critical since players are less likely to learn from it if they dislike playing the game [19]. Serious games must therefore be enjoyable in order for learning to take place.

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Serious Games in the Learning Domain

In this paper, we leveraged the usefulness of serious games in the learning domain—that is, educational games—and explored new stories, gameplay, and game mechanics to present plagiarism as content in an immersive library gaming 3D environment. This resulted in a video game that we named Plagi-Warfare. In Plagi-Warfare, players can assume 2 different roles: as a mafia member or as a detective. As a mafia member, they make cash from plagiarizing for other students, and as a detective, they try to catch an NPC who is playing as a mafia member. Hence, the major contributions of this paper are as follows:

- We proposed a new game story and designed new game mechanics for student players to get into an immersive gaming environment and get rewarded by either detecting plagiarism scenarios (as detectives) or play the role of a mafia member to commit plagiarism within the game—another way of clearly acknowledging what plagiarism is.
- We created a game that gets played out in a 3D environment, representing the university library of our home university—the University of Johannesburg.
- We used new algorithms to create procedurally generated questions that are variations of typical plagiarism-related questions, ensuring replayability of the game.
- We proposed several algorithms for the implementation of this game and named this game Plagi-Warfare.
- We evaluated this game by asking students to play the game and assess its effectiveness.

What Is Plagiarism?

The main concept of plagiarism is presenting or using someone else's work or ideas as your own work, not citing or giving credit to the person whose idea you are using [25]. There are 2 types of plagiarism, intentional and unintentional [26]. Intentional plagiarism is when the person knows the concept of plagiarism and has the writing and academic knowledge to prevent/avoid plagiarism by correctly citing the sources but still makes the conscious decision to copy [27]. Unintentional plagiarism is more common; this is when the person who is copying has little to no understanding of the concept, has a lack of writing skills regarding citing, and a lack of knowledge about avoiding plagiarism [28].

Plagiarism Due to Students' Lack of Information

Unintentional plagiarism can be caused by a lack of knowledge about plagiarism [29-31]. According to Baker-Gardner et al [28], a possible determinant of whether students will plagiarize can be the students' awareness of the plagiarism policy of the university. When plagiarism policies are clear and precise, there will be caution in trying to plagiarize as students will be aware that consequences exist [32]. Once plagiarism policies are known to not be compromised, the students will be more careful when writing in order to make sure that they do not plagiarize [28]. Another problem associated with ignorance and plagiarism is the thin line between general knowledge and authorship [33]. Being able to differentiate between common knowledge and someone's ideas is important for students in order to avoid plagiarizing [33,34].

Although universities often provide information about plagiarism on their websites and from their libraries, we still have cases of plagiarism among students [35]. There may be documentation on plagiarism; however, students are faced with the challenge of having to read so much, so it is often difficult to identify what is significant, let alone comprehend and internalize that critical information [36]. According to the study conducted by Obeid et al [37], when students were exposed to a plagiarism intervention session (students who were exposed to plagiarism lessons), they were proven to plagiarize less in comparison to those who were in the control group (students who did not attend the plagiarism lessons). This signaled that the intervention was an efficient method of reducing plagiarism among research course students.

Serious Games in Teaching: Educational Games

Serious games are significantly important in education and in improving the willingness of students to learn [38,39]. More satisfaction and enjoyment of the game lead to an enhanced level of interest in the subject matter for the player [40,41]. It has been shown that:

- Having a well-designed educational game and learning methods that are progressive has been a huge instrument in educational support [42].
- A test to see whether a game would improve the knowledge of the player was proven to be effective [43-45].
- Knowledge can be improved through observation and experimentation in the gaming environment [46-48].

One challenge with educational games is that the immersive part of these games is mostly missing [49,50], making these games boring. It is therefore important to find a balance between the difficulty of the game and the enjoyment of the player. Different individuals learn in different ways; hence, it is best to cater for as many learning styles as possible [51]. We know from the literature that when you combine learning activities with immersive media, it is proven to have great outcomes, sometimes even better than those in both nonimmersive and in-person circumstances [52]. Educational games have to solve this conundrum of being educational and fun/immersive in order to successfully induce learning [53,54]. An attempt to introduce balanced fun and learning was presented by Ade-Ibijola and Aruleba [24]. This motivates the creation of immersive educational games, such as the one presented in this paper—Plagi-Warfare.

Problem Statement and Motivation

Higher education institutions around the world have a significant problem with plagiarism [55,56]. Resources, such as the internet, have contributed to an increase in plagiarism [57]. This problem became more prevalent during the 2020 COVID-19 pandemic, where all assessments were conducted online [58], leading to the emancipation of many proctoring systems [59]. There is also a concern that in most cases, students are not informed of universities' policy on plagiarism [60]. Gullifer et al [61] stated that the amount of information students have to consume on

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admission to institutions is usually too much, leading to less attention on the topic of plagiarism.

Several attempts have been made to educate students about plagiarism using games [12-14]—most of these games are designed with stories, mechanics, and gameplay that the students do not find interesting or realistic [62]. This is the problem addressed in this paper—to create a more realistic story, mechanics, and gameplay in delivering an immersive educational game for teaching students about plagiarism. This we have done in a new game—Plagi-Warfare. In the following section, we discuss related works, in particular existing educational games for teaching plagiarism and other library-created games.

Related Works and Gaps

In this section, we present related works, specifically serious games in education or educational games for teaching plagiarism and games used by libraries around the world to teach specific subjects or topics.

Existing Plagiarism Educational Games

Table 1 describes 4 educational games that are specifically designed to train/inform the player about plagiarism, and Table 2 lists existing library games worldwide.

Table 1. Existing plagiarism educational games.

Game name	Similarity to Plagi-Warfare
Cheats and Geeks [63]	Designed in the style of a dice board game, the game places the player in the role of a graduate student who has to publish a paper for a competition. The player must complete pop quizzes about plagiarism before being able to complete the challenges in the game.
Frenetic Filing [63]	A retro-style-designed game in which the player needs to solve as many processed plagiarism cases before a set time elapses. The game rewards the player with virtual sneakers and coffee that assist in speeding up the player's review of cases.
Murky Misconduct [63]	Murky Misconduct is a crime detective game where the player engages as a plagiarism investigator. They are tasked with tracking down potential perpetrators by comparing academic papers and finally prosecuting the players. Players are educated on the complex ethics issues and consequences of plagiarism.
Goblin Threat [12]	This game is designed as a clicking game, where the player must find hidden goblins, which ask the player questions related to plagiarism. Game content covers how to cite sources, types of plagiarism with their repercussions, and the variations between plagiarism and paraphrasing.

Table 2. Existing library games around the world.

Game name	Description of library game	University/college library	Educational content
Nightmare on Vine Street	In this game, the player is secured inside the library around evening time and must satisfy zombies with assets found in the library to get away [14,64].	University of Tennessee at Chattanooga, USA	The game improves the information literacy of students.
Within Range	In this game, the player has to place books according to the call number before the allocated time is up [14,64,65].	Carnegie Mellon University, USA	Library staff learns how to store books.
Defense of Hidgeon	At the beginning of this game, students are instructed to start library research while navigating, looking, and finding assets. During the game, students have to go to distinctive libraries and search web for answers [64,66].	University of Michigan, USA	Students learn how to conduct research using library resources.
Secret Agents in the Library	The player assumes the role of a secret agent in this online game. The objective of the game is to protect the library from an invader by answering questions as well as fetching assets from within the library [14].	Lycoming College, USA	The game improves the information literacy of students, and students learn how to access the library website.
It's Alive	Here, the player acts as a crazy scientist endeavoring to obtain body parts to build an animal, and to obtain these body parts, the player has to correctly respond to a sequence of questions [14,65].	Lycoming College, USA	Players are able to find out about biology research methods.
Get a Clue	Students have to solve a crime by visiting assigned areas and getting rid of suspects and library resources in the game [64].	Utah Valley University, USA	Students are able to navigate around the university library.
LibraryCraft	Students can visit various pages of the library website. Students need to find a book in their catalogue and use the author's name as a password to show that they have completed the task [14,67].	Utah Valley University, USA	Students find out about the library resource/assets and how to manage research.

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Gaps

Although there have been attempts by different game developers and researchers to create educational games for teaching students what plagiarism is, the following issues are yet to be addressed:

- Story and gaming environment: For this, we proposed a 2-sided storyline that allows a student to play as a good guy or a bad guy, detecting plagiarism or plagiarizing and escaping being caught, respectively, within the game.
- Replayability: To the best of our knowledge, none of the existing games has the ability to present the player with new problems every time they play. We have written new algorithms for this task.
- First local solution: As far as we can tell, no South African university has an educational game for teaching plagiarism.

These issues are addressed in the design of Plagi-Warfare, discussed in the Methods section, covering the design aspects of Plagi-Warfare, such as the game flow, story development, and other design considerations.

Future Work

We are currently busy digitizing several topics offered by the university's library to make them more attractive to students. Educational games are at the center of this digitization; hence, we anticipate more work in this space in the future. In the future, we will also open up the evaluation of Plagi-Warfare to the entire student population of our university. Given that we have over 40,000 students, we hope to gain more insights into what we can improve about this game.

Conclusion

In this paper, we presented a new educational game that teaches students about plagiarism by using a new crime story and an immersive 3D gaming environment representing the university libraries of the University of Johannesburg. To do this, we allowed players to play as either a mafia member or a detective and supplied them with procedurally generated quizzes that ensure that the game remains replayable. We demonstrated the first version of the game and presented the evaluation of the game. The responses from the students show that the game can be used to learn about plagiarism and that they would recommend it to others. Plagi-Warfare addresses a major gap in South Africa, as there is no such game in any South African university, and worldwide with its unique storyline and its environment that allow the global community to experience our libraries at the University of Johannesburg. Given the increasing appeal of video games among digital natives, the use of an immersive game about plagiarism is expected to give more students the motivation and eagerness to learn about plagiarism.

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Conflicts of Interest

None declared.

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Abbreviations

APB: Auckland Park Bunting Road
APK: Auckland Park Kingsway
DFC: Doornfontein
E-R: entity-relationship
FoV: field of view
IDE: Integrated Development Environment
NPC: nonplayer character

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Original Paper

A Serious Game (Immunitates) About Immunization: Development and Validation Study

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Abstract

Background: Vaccination is a fundamental part of all levels—local to worldwide—of public health, and it can be considered one of humanity's greatest achievements in the control and elimination of infectious diseases. Teaching immunization and vaccination can be monotonous and tiring. It is necessary to develop new approaches for teaching these themes in nursing school.

Objective: We aimed to develop and validate a serious game about immunization and vaccination for Brazilian nursing students.

Methods: We developed a quiz-type game, Immunitates, using design and educational theoretical models and Brazilian National Health Guidelines. The game's heuristics and content were evaluated with 2 different instruments by a team of experts. A sample of nursing students evaluated the validity of the game's heuristics only. We calculated the content validity index (CVI) for each evaluation.

Results: The study included 49 experts and 15 nursing students. All evaluations demonstrated high internal consistency (Cronbach $\alpha \geq .86$). The game's heuristics (experts: CVI 0.75-1.0; students: CVI 0.67-1.0) and the game's contents demonstrated validity (experts: CVI 0.73-1.0). Participants identified some specific areas for improvement in the next version.

Conclusions: The serious game appears to be valid. It is intended as a support tool for nursing students in the teaching–learning process and as a tool for continuing education for nurses.

(JMIR Serious Games 2022;10(1):e30738) doi:10.2196/30738

KEYWORDS

educational technology; immunization; nursing education; validation; methodological study; vaccination; public health; nursing students; teaching; education; support tool; continuing education

Introduction

Vaccination, a fundamental part of public health, is one of humanity's greatest achievements in the control and elimination of infectious diseases [1]. The benefits of vaccines have been proven; in the last few decades, as an example, smallpox was eradicated through immunization [2]. Vaccines have saved lives; reduced the incidence of polio by 99% in the world; and reduced diseases, disabilities resulting from diseases, and deaths caused by diphtheria, tetanus, and whooping cough [2].

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Immunization of the population can decrease the transmission of infectious diseases, in turn decreasing hospitalizations, public expenditures on health care, and population mortality, which may increase the life expectancy of a population. Immunization will always be a necessary health action. Each year, 130 million babies are born [3], and they all have the right to receive protection against vaccine-preventable diseases.

In Brazil, it is necessary to abide by the recommended vaccination schedule [4] for children to be considered immunized. Thus, it is important that those responsible for a child are knowledgeable about the importance of vaccination—why the entire population must take the recommended vaccines—and that myths are debunked and explained.

Therefore, it is important that health professionals, especially nurses, have theoretical knowledge that offers a foundation and security to organize and promote health education. In this sense, nursing students must learn enough to provide health education to their future patients. Furthermore, in Brazil, nursing duties in primary care include administering vaccinations and managing everything related to them to ensure the safety of the immunobiological materials, and consequently, that of the patient [5].

In Brazil, the theoretical topics related to vaccination are mostly found in manuals and ordinances—technical texts that can be long, boring, and unappealing—resulting in dense and exhaustive reading for the student. We believe the use of a different methodology (serious games) in the teaching–learning process will help teachers to stimulate learning in the classroom and students to reinforce and review their knowledge on immunization. By using new methodologies, teaching can be more dynamic and the pattern of traditional vertical teaching, wherein the teacher demonstrates and the student repeats, can be broken [6]. Breaking this pattern of traditional education is important given the profile of the current generation of students—they are no longer just listeners but critical protagonists in the process of building knowledge [7,8].

The use of educational technologies in nursing has gradually increased over the years in Finland [9] and in other regions (Norway, other European countries, Asia, and Brazil [10]). To the best of our knowledge, there are no digital serious games related to vaccination in Brazil that are specifically for nursing students and nurses. We aimed to develop serious game about vaccine-preventable diseases and immunization and validate the game's contents and heuristics.

Methods

Game Development

Framework

As a theoretical frame of reference for the creation and development of the game, we used the Elemental Tetrad (Story, Aesthetics, Mechanics, Technology) [11] and the first 3 levels (Remembering, Understanding, and Applying) of the Revised Bloom's Taxonomy [12], as they have been commonly used in studies [13-16] that addressed the development of educational health technologies.

The contents of the game (a database with questions, answers, and feedback) were based on the Brazilian Ministry of Health's Manual of Rules and Procedures for Vaccination [17].

Story

In the game *Immunitates* (Figure 1), the player assumes the role of nurse in the vaccination room and answers questions on immunization. When the players correctly answers a sufficient number of questions, their nurse avatar is promoted. The aim is to reach the last level of the game when the nurse reaches the role of Minister of Health.

Feedback on each question is immediate, thus maintaining the user's motivation and engagement in the game [18].

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Figure 1. Welcome screen.



Aesthetics

The player is asked to choose a female or male avatar (Figure 2), which changes job positions as the player advances to the next levels.

Figure 2. Avatar selection screen.

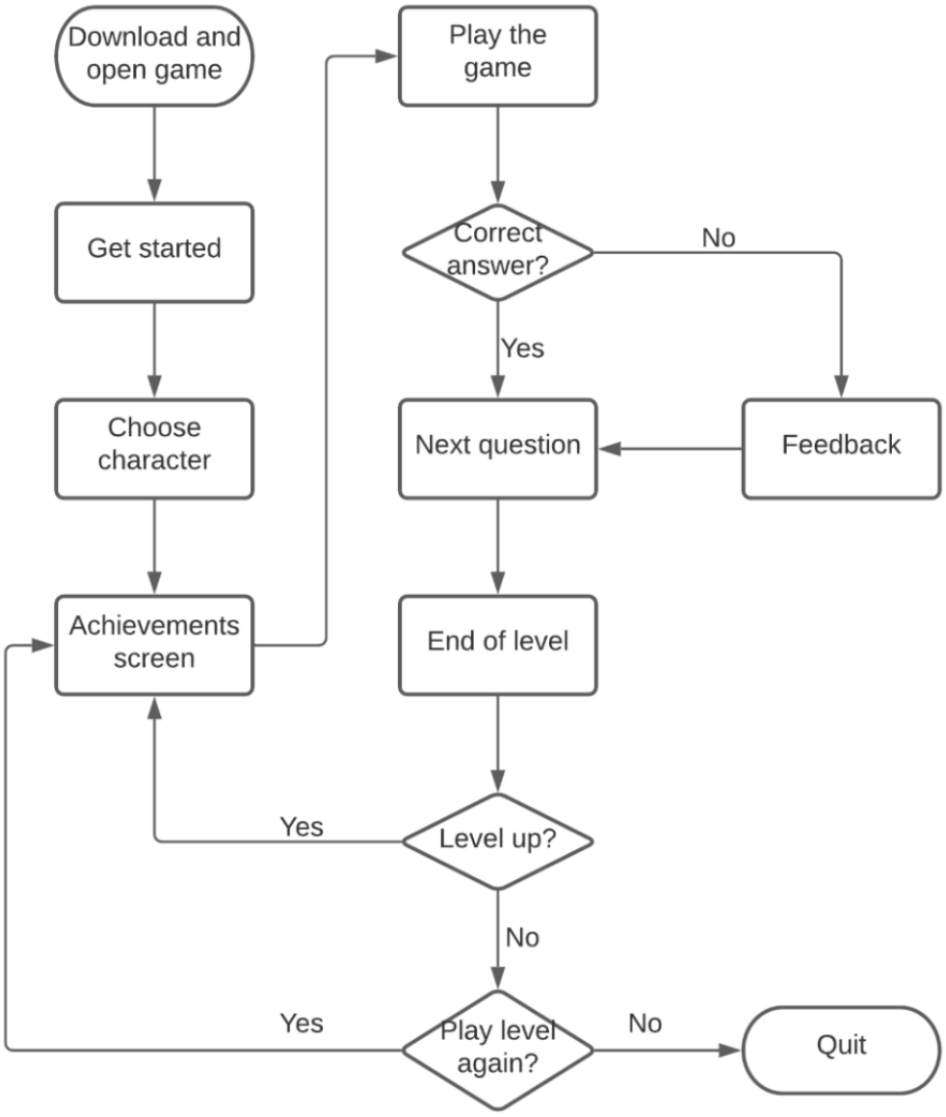


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Mechanics

The game has a quiz format, and players progress by levels (Figures 3-5), which are unlocked as the player answers questions correctly. The game has 7 levels, each corresponding to a job position that the nurse avatar achieves (Figure 6). Each level has a bank of questions, from which a specific number of questions are randomly chosen (Table 1). For example, level 1 has a bank of 5 questions, and each time the player accesses the level, 3 of the 5 questions are chosen. The player must correctly answer at least 1 question for the next level to be unlocked. If the user does not correctly answer the minimum number of questions, they fail the level but can immediately play it again.

Figure 3. Immunitates flowchart.



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Figure 4. Screen explaining the game's story.



Figure 5. Achievements screen.



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Figure 6. Female and male avatars.



Table 1. Game levels.

Level	Questions in database, n	Questions played, n	Correctly answered questions to progress to the next level, n
1 Immunization room nurse	5	3	1
2 Nurse manager of the Basic Health Unit	7	5	2
3 Director of the Basic Health Unit	9	6	3
4 Director of Health Surveillance	11	7	3
5 Health secretary	13	8	4
6 Director of the National Immunization Program	15	9	4
7 Health minister	20	10	5

The question database for the entire game consists of 80 questions. For each question, there are 3 options, with only 1 correct option (Figure 7), and text is automatically displayed to explain the correct answer, as automatic rationale feedback, if the player selects the incorrect option (Figure 8). Questions written with direct and simple wording and that require players to remember information were considered easy questions. Questions that require complex clinical reasoning were considered difficult and are presented later on in the game. For better visualization of the question and answer texts, questions could be up to 150 characters long, while each answer and feedback could be up to 120 characters.

Throughout the game, the player listens to a theme song (which can be muted on the achievements screen). The player also has the option to reset the game on the information screen (not pictured), this action restarts the game completely and all progress is lost.

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Figure 7. Correct answer screen.

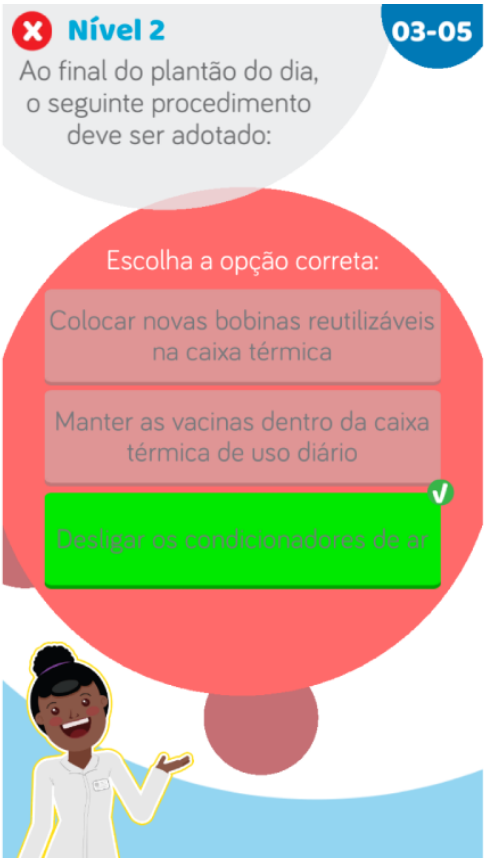


Figure 8. Incorrect answer screen with feedback.



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Technology

The game was programmed in January 2019 using C++ and JavaScript for mobile phones with Android and iOS operating systems; the game is available in Portuguese for free from the Google Play Store and the Apple App Store.

Game Validation

This study was undertaken with 2 different independent samples: (1) experts in nursing education technologies, nursing games, or immunization and (2) nursing students.

Experts

Inclusion criteria for experts were adapted from an existing model [19] that is widely used in Brazil to select experts for validation studies [20]. It was a mandatory criterion to have a Bachelor of Science degree in Nursing. An additional criterion was having specialized knowledge, clinical practice, or authorship in areas related to immunization, technology, or health education.

We actively searched 90 public nursing colleges in Brazil for nursing professors who had a history of researching nursing education technologies, nursing games, or immunization. We contacted 983 professors by email, inviting them to validate the game's heuristics and content. The email had 2 different links: one to download the game, and the other to provide demographic information (age, gender, time working as a nurse, and additional degrees or certifications) to indicate that they accepted to be part of the study. Participants received a second email with links to heuristics and content evaluation forms.

Students

Inclusion criteria for students were being an undergraduate nursing student enrolled at University of Brasília Ceilândia College in the discipline *Comprehensive Care for Women and Children's Health* at the time of data collection. In this discipline, students learn about the Brazilian vaccination calendar and immunization, and students were invited, during a class, to take part in this study. Students who agreed to participate were sent an email with 3 links: one to download the game, one to provide demographic information (age and gender), and a third to validate the game's heuristics only.

Ethics

The study was conducted in accordance with the Helsinki Declaration and Resolution 466/2012 [21] of the National Health Council (Brazil). The study was approved by the Research Ethics Committee of Ceilândia College, University of Brasília (CAAE 08595019.2.0000.8093).

Evaluations

Game heuristics were evaluated by both experts and nursing students using *Avaliação Heurística para Jogos Educacionais Digitais* (AHJED, *Heuristic Evaluation for Digital Educational Games*) [22]), which has 8 dimensions—interface, playability, multimedia, artificial intelligence, game's story, educational elements, contents, and educational agent—evaluated on a Likert scale (Multimedia Appendix 1).

Game contents were evaluated by experts using an instrument [23] with 3 dimension—objectives, structure and presentation, and relevance (Multimedia Appendix 2) and by omitting items about functionalities that were neither present nor intended to be present in the game.

Participants also had the option to leave comments about their experience playing the game and suggestions about what could be improved in the next version.

Analysis

Statistical analysis was performed using SPSS software (version 22; IBM Corp).

The content validity index (CVI) is widely used in the field of health [24-26] and is used to assess the proportion of agreement for an item of an instrument [27]. The index was calculated in 2 ways: For the game heuristics evaluation, the number of *agree* and *strongly agree* responses were summed and divided by the total number of responses. For the game content evaluation, the number of *adequate* and *totally adequate* were summed and divided by the total number of responses. Items with CVI≥0.80 would remain as they are, whereas items with CVI<0.80 should be changed for the next version of the game.

We also calculated Cronbach α [28], a statistical measure that estimates the internal reliability of a questionnaire, for each evaluation (experts' AHJED, students' AHJED, and experts' content). Cronbach α≥.70 was deemed acceptable [29].

Results

Of those invited, 184 nursing professors provided demographic information in response to the first email, but only 49 completed the game validation and met inclusion criteria; therefore, 49 experts took part in this study. Of the 49 experts, 43 experts (88%) were female, and 6 (12%) experts were male. Experts ranged from 28 to 63 years old (mean 44.04 years old), with time working as a nurse ranging from 3 to 40 years. Of 48 students enrolled in the discipline, 15 took part in the study. Of the 15 students, 14 (93%) students were female, and 1 (7%) student was male. Students ranged from 20 to 28 years old (mean 22.13 years old).

Overall, the CVI ranged from 0.77 to 0.97. For heuristics, the CVI ranged from 0.75 to 1 in the expert group and 0.67 to 1 in the student group. Cronbach α was always greater than 0.86 (Table 2; Multimedia Appendix 3).

For content, the CVI ranged from 0.73 to 1, overall ranging from 0.88 to 0.93 (Table 3). Cronbach α was always greater than 0.89. Detailed results can be seen on the original tables in the supplementary files (Multimedia Appendix 4).

Participant comments were translated from Portuguese to English by the authors of this study. Not all participants chose to leave a comment. Both experts and students left suggestions related to the content, aesthetics, and their experiences playing the game (Table 4).

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Table 2. Evaluation results for Immunitates heuristics.

Dimension	Experts (n=49)		Students (n=15)	
	Cronbach α	Content validity index	Cronbach α	Content validity index
Interface	.87	0.90	.88	0.93
Playability	.87	0.88	.88	0.94
Multimedia	.87	0.87	.88	0.97
Artificial intelligence	.87	0.90	.88	0.89
Game's story	.86	0.90	.88	0.93
Educational elements	.86	0.90	.88	0.87
Contents	.87	0.83	.88	0.77
Educational agent	.87	0.86	.87	0.76

Table 3. Evaluation results for Immunitates content.

Dimension	Experts (n=49)		Students (n=15)	
	Cronbach α	Content validity index	Cronbach α	Content validity index
Objectives of the content	.90	0.88	—[a]	—
Structure and presentation of the content	.90	0.90	—	—
Relevance of the content	.89	0.93	—	—

[a]Only experts evaluated the content.

Table 4. Comments and suggestions from experts and nursing students.

Participant	Comment
Expert 2	"I suggest including more in-depth questions on the topic, to stimulate research and interest in the continuity of the game."
Expert 4	"I believe that the feedback when we make mistakes should come with a suggestion for reading."
Expert 7	"I suggest you remove the circles that are moving around, it takes your attention and makes it tiring."
Expert 10	"Suggestion: enable a 'learn more' hyperlink; the player will be able to download the vaccination calendar, vaccination manuals and be redirected to the Ministry of Health webpage."
Expert 15	"The font size for some questions is a little small. I suggest keeping the same size, if possible."
Expert 25	"You should improve the options for questions and answers, making them shorter and easier to understand."
Expert 27	"I felt the need for more complex questions, which would need clinical reasoning."
Expert 28	"I suggest the themes to be worked on levels of complexity."
Expert 49	"I really liked the game."
Student 7	"The way the game approaches the subject is very good and helped me a lot."
Student 11	"I believe the game should show a small screen with information on the topic when we answered a question wrong."
Student 12	"Very good game."
Student 15	"I wish there were more levels."

Discussion

The results present evidence of validity and suggest that the game can be used by both nurses and nursing students alike, as the game was tested and well accepted by them. We noticed that digital serious games about vaccination have up until now been developed for children [30,31].

Evaluations demonstrated high internal consistency (Cronbach α≥.86) [32]. Although most items within the evaluated heuristics were greater than 0.80, a few—level of difficulty (students: CVI 0.73), partition of the content (students: CVI 0.67), player's performance (students: CVI 0.67), and aesthetics of the game (experts: CVI 0.75; students: CVI 0.67)—did not reach this stipulated number; these features will be reworked for the next version of the game based on suggestions:

> *I suggest including more in-depth questions on the topic, to stimulate research and interest in the continuity of the game.* [Expert 2]

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> *I suggest you remove the circles that are moving around, it takes your attention and makes it tiring.* [Expert 7]
>
> *The font size for some questions is a little small. I suggest keeping the same size, if possible.* [Expert 15]
>
> *I wish there were more levels.* [Student 15]

For content, CVI≥0.88. Still, for some items in groups 1 and 2, CVI values were below expectations. Experts suggested that the content did not instigate change in behavior and attitude (CVI 0.73),

> *I felt the need for more complex questions, which would need clinical reasoning,* [Expert 27]

and that the messages were not clear or objective (CVI 0.78):

> *You should improve the options for questions and answers, making them shorter and easier to understand.* [Expert 25]
>
> *I suggest the themes to be worked on levels of complexity.* [Expert 28]

The content will also be reworked for the next version of the game.

The validation of educational technologies has been widely used in Brazil [23-25,33], and worldwide, in countries such as the United Kingdom [34], Canada [35], Italy [36], and Germany [37].

According to Korhonen [38], playability should not be the main objective of a game, although it is necessary for a positive experience, as good playability positively affects the user experience. Our results confirm this, since both experts (CVI 0.87) and students (CVI 0.88) indicated playability was acceptable, and expert and student participants commented on their good experience and how they liked the game:

> *Very good game.* [Student 12]
>
> *I really liked the game.* [Expert 49]

Content is perhaps the most important part of an educational tool. From participants' suggestions, it was clear that both experts and students would have liked to have an external link that could provide theoretical support as a way to further their knowledge.

Expert 2 suggested including more in-depth questions to stimulate research and interest in the player, which corroborates the findings of a previous study [39], namely, that the difficulty of a game can affect player motivation. The game must have challenging elements but still leave the player confident enough to overcome them. Experts 27 and 28 also commented on the need for more complex questions that would need clinical reasoning, but expert 25 thought that the questions should be simpler, shorter, and easier to understand.

However, players may have different skills; what is classified as difficult, a player may perceive to be very easy or very difficult, which can lead players to feeling frustrated or even bored, which decreases their motivation and engagement with a game [40].

It is also true that technology-specific problems can arise when using educational technologies, such as issues downloading or installing and log-in, audio, and video-related problems. Students can find this method of teaching to be unengaging or they may simply not find the time to study using these new tools [41].

During the COVID-19 pandemic, when teachers and students worldwide had to stay at home, a new challenge arose in health care education. Somehow training in a field that is traditionally taught with a hands-on approach had to continue in alternative manners. During the first wave, educators began to utilize new educational technologies to continue teaching. The impact of these technologies in the field of health care education is unique because educators must continue training future professionals who will soon be working in-person at hospitals amid the pandemic, despite social distancing [42]. Although many educators have had to improvise and quickly learn how to use these new technologies during the COVID-19 pandemic, the use of technology in the teaching–learning process should be driven by pedagogical needs and goals and not by technological pressures [43].

When elements of gamification, such as points, achievements, and levels, are incorporated into the undergraduate teaching–learning process, there is a positive effect on student motivation and performance [44]. Motivation is the state in which the individual feels moved to do something. According to the Self-Determination Theory, motivation is separated into levels (from a little to a lot of motivation) and orientation (intrinsic and extrinsic motivation). In extrinsic motivation, the individual seeks reward or escapes punishment, whereas intrinsic motivation refers to pleasure to do or an inherent personal satisfaction [45]. Harandi [46] highlights that when students are motivated to learn, they are likely to be involved; when they are involved, they are more likely to achieve educational goals.

There were a few limitations in this study. The budget available for the construction of the game did not allow for all intended features to be included in this version. Suggestions made by the participants were documented so that, in the future, they can be implemented.

The number of students who participated was small, which can alter the results of the evaluation of educational technology. Students who had already completed the discipline *Comprehensive Care for Women and Children's Health* were not included, even though they already had the necessary knowledge to validate the game, because these students were engaged in course work outside the university, and we had difficulty contacting them.

In future studies, we intend to test the effectiveness of the game by comparing knowledge acquisition from class only compared with that from the combination of class and playing the game to determine if this game is useful in helping nursing students. We also intend to test graduate nurses' satisfaction with the game and knowledge acquisition from the game to determine if it is useful to this target audience. With these results, we would be able to categorically affirm that the game is useful to both nurses and nursing students.

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Immunitates presents evidence of validity, even though some areas of the game require improvement. Immunitates is designed to be a support tool for nursing students (ie, not to replace face-to-face class instruction) and to be a tool for continuing education for nurses.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Instrument for heuristic validation.
[DOCX File , 16 KB - games_v10i1e30738_app1.docx]

Multimedia Appendix 2
Instrument for content validation.
[DOCX File , 14 KB - games_v10i1e30738_app2.docx]

Multimedia Appendix 3
Heuristic validation results.
[DOCX File , 22 KB - games_v10i1e30738_app3.docx]

Multimedia Appendix 4
Content validation results.
[DOCX File , 15 KB - games_v10i1e30738_app4.docx]

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Abbreviations

AHJED: Avaliação Heurística para Jogos Educacionais Digitais (Heuristic Evaluation for Digital Educational Games)
CVI: content validity index

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Original Paper

Feasibility, Enjoyment, and Language Comprehension Impact of a Tablet- and GameFlow-Based Story-Listening Game for Kindergarteners: Methodological and Mixed Methods Study

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Abstract

Background: Enjoyment plays a key role in the success and feasibility of serious gaming interventions. Unenjoyable games will not be played, and in the case of serious gaming, learning will not occur. Therefore, a so-called GameFlow model has been developed, which intends to guide (serious) game developers in the process of creating and evaluating enjoyment in digital (serious) games. Regarding language learning, a variety of serious games targeting specific language components exist in the market, albeit often without available assessments of enjoyment or feasibility.

Objective: This study evaluates the enjoyment and feasibility of a tablet-based, serious story-listening game for kindergarteners, developed based on the principles of the GameFlow model. This study also preliminarily explores the possibility of using the game to foster language comprehension.

Methods: Within the framework of a broader preventive reading intervention, 91 kindergarteners aged 5 years with a cognitive risk for dyslexia were asked to play the story game for 12 weeks, 6 days per week, either combined with a tablet-based phonics intervention or control games. The story game involved listening to and rating stories and responding to content-related questions. Game enjoyment was assessed through postintervention questionnaires, a GameFlow-based evaluation, and in-game story rating data. Feasibility was determined based on in-game general question response accuracy (QRA), reflecting the difficulty level, attrition rate, and final game exposure and training duration. Moreover, to investigate whether game enjoyment and difficulty influenced feasibility, final game exposure and training duration were predicted based on the in-game initial story ratings and initial QRA. Possible growth in language comprehension was explored by analyzing in-game QRA as a function of the game phase and baseline language skills.

Results: Eventually, data from 82 participants were analyzed. The questionnaire and in-game data suggested an overall enjoyable game experience. However, the GameFlow-based evaluation implied room for game design improvement. The general QRA confirmed a well-adapted level of difficulty for the target sample. Moreover, despite the overall attrition rate of 39% (32/82), 90% (74/82) of the participants still completed 80% of the game, albeit with a large variation in training days. Higher initial QRA significantly increased game exposure (β=.35; *P*<.001), and lower initial story ratings significantly slackened the training duration (β=−0.16; *P*=.003). In-game QRA was positively predicted by game phase (β=1.44; *P*=.004), baseline listening comprehension (β=1.56; *P*=.002), and vocabulary (β=.16; *P*=.01), with larger QRA growth over game phases in children with lower baseline listening comprehension skills (β=−0.08; *P*=.04).

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Conclusions: Generally, the story game seemed enjoyable and feasible. However, the GameFlow model evaluation and predictive relationships imply room for further game design improvements. Furthermore, our results cautiously suggest the potential of the game to foster language comprehension; however, future randomized controlled trials should further elucidate the impact on language comprehension.

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KEYWORDS

serious gaming; language comprehension; enjoyment; feasibility; GameFlow

Introduction

Background

Over the past 2 decades, there has been a major increase in the development of serious digital games for children with special educational needs [1,2]. This clear trend presumably relates to the popularity and motivational aspects of noneducational digital games and the increasing exposure to technological devices in children's current daily lives [3]. Within the field of education, serious digital games are described as games for electronic devices with certain game rules and player outcomes, which aim to entertain but pursue at least one additional learning objective (eg, fostering mathematics, language, or reading) [2,4]. To obtain the desired educational impact from such games, children are often required to engage in interventions on a recurrent basis and for a considerable amount of time. Hence, game enjoyment, which triggers gameplay and increases the feasibility of maintaining playing [5,6], is key to the success of serious gaming interventions [7]. Thus, when evaluating serious games, it is of high relevance to assess not only the educational efficacy of interest but also the related aspects of game enjoyment and feasibility [2]. This study will address the enjoyment and feasibility of a newly designed serious story-listening game suitable for children aged 5 years. In addition, given the focus of the game on story listening, this study aims to preliminarily investigate its potential to train language comprehension [8].

Language comprehension is the process of interpreting spoken language input [9]. It involves speech processing at the basic auditory level, derivation of word meaning, knowledge of syntactic and morphological structures, and the integration of information within a broader language context [10]. Language comprehension creates opportunities for verbal communication in daily life and lays the foundations for reading comprehension long before receiving reading instruction [11,12]. Hence, unsurprisingly, language comprehension is a well-known precursor to academic achievement [8,13,14], employment [14,15], and social participation [14,16]. Individual differences in language comprehension already exist at an early age and remain relatively stable over time [17]. Hence, dramatically, without remediation, young children with poor comprehension are more likely to lag behind their peers throughout their entire development [17].

Problems with language comprehension are apparent in a high proportion of children with developmental language disorders (DLDs) [18]. DLD is characterized by severe problems with expressive and/or receptive language development in the absence of a clear-cut neural, cognitive, or auditory cause, affecting communication in daily life [19]. Remarkably, children diagnosed with DLD who experience comprehension deficits more often have persistent language problems [18], respond less well to interventions, and require more extensive support than children with DLD who exhibit language deficits in the expressive domain only [20]. In addition to DLD, lower comprehension skills have also been observed in second language learners [21], children in low socioeconomic status environments [22], children with hearing impairments [23], and children diagnosed with developmental dyslexia [24,25].

Language comprehension deficiencies benefit from interventions early in childhood [14]. Indeed, a recent systematic scoping review by Tarvainen et al [18] revealed that comprehension in young children is effectively tackled by (1) guidance in parent-child or clinician-child communication strategies or (2) by targeting receptive and expressive language aspects, such as vocabulary, morphology, and inferential language. Moreover, in young children aged <6 years, implicit therapy techniques, in which the child is exposed to optimal language without explicitly explaining certain rules, are preferred over explicit instructional approaches [26]. An example of a rather implicit approach concerns the method of storybook listening.

Given the evidence of storybook listening for fostering several language comprehension components in young children (eg, receptive vocabulary, morphosyntax, and narrative comprehension [27-29]), both in physical [30-33] or digital settings [34,35], to the best of our knowledge, no study has ever embedded the story listening method in a serious gaming context. Digital games often offer stimulating audiovisual game worlds and appealing rewards [36,37]. Given these motivational aspects [38,39], serious gaming is already widely applied in educational, psychological, and medical contexts [40-44], including the field of language learning (eg, game-based interventions specifically targeting vocabulary [45]). However, when designing a commercial serious digital game, detailed knowledge of game enjoyment is of crucial relevance. A digital game that is not experienced as fun will not be played [5], and consequently, in the case of serious gaming, learning will not occur. Hence, when evaluating serious games, both the aspects of enjoyment and educational impact must be considered [2]. However, despite its high relevance, the factor of enjoyment is hardly ever evaluated in existing serious games because of the lack of proper frameworks. To clarify the concept of game enjoyment as well as to facilitate its evaluation, Sweetser and Wyeth [5] proposed a summarizing framework—the GameFlow model—which is based on extensive gaming literature and the general theory of flow [46]. The model intends to guide serious game developers in the process of creating and improving games

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that are both educational and enjoyable [6]. More specifically, the GameFlow model [5] proposes eight interrelated gaming elements that are important for attaining overall game enjoyment: (1) concentration, (2) challenge, (3) player skills, (4) control, (5) clear end or intermediate goals, (6) feedback, (7) immersion, and (8) social interaction. The concentration principle states that a game becomes enjoyable when a player is able to concentrate on the game itself without being constantly distracted by surrounding background factors such as game and volume settings. The challenge principle argues that to enjoy a game, it must be sufficiently challenging. The player's skills principle reasons that a game should provide opportunities to improve playing skills at a pace that is adjusted to the capacities of the individual player. The control principle asserts that players must experience a feeling of control over their actions, decisions, the appearance of their avatars and strategies, and the game world. The fifth clear end or intermediate goal principle states that a game must inform the player of clear end or intermediate goals from the start. The principle of feedback emphasizes the importance of appropriate feedback on game progress or errors at appropriate times. The immersion principle states that players must be completely absorbed by the game world. Finally, the social interaction principle underlines the relevance of social interactions during gameplay. To successfully embed each GameFlow element in a digital game, the GameFlow model [5] proposes a set of predefined implementation criteria for each element. For example, one of the criteria to attain the concentration principle states that game developers should not add irrelevant game tasks on top of the main learning task (refer to the study by Sweetser and Wyeth [5] for a full overview of the elements and their corresponding criteria). When evaluating games based on these GameFlow criteria, Sweetser and Wyeth [5] were able to successfully distinguish between low- and high-rated games. Thus, the validity of the GameFlow model in evaluating enjoyment in digital games is warranted.

Objectives

This study addresses the enjoyment and feasibility of a newly developed serious tablet- and game-based story-listening intervention (henceforth, story game), for which the GameFlow model served as a guideline in the design process. Moreover, given the focus of the game on story listening, which is a frequently used method of increasing young children's language comprehension [8], its potential to foster language comprehension will also be preliminarily investigated. The story game was originally developed to enhance basic auditory speech processing by modifying the recorded speech signals of stories with a so-called envelope enhancement (EE) algorithm [47-51] and, as such, boost phonology and reading in kindergarteners at cognitive risk for dyslexia. The EE algorithm automatically detects and amplifies important rhythmic acoustic cues of the speech envelope (ie, onset rise times), which are considered important for phonological skill (and potentially reading) development [52,53]. The story game was implemented in a broader preventive reading intervention aiming to (1) evaluate the efficacy of a tablet-based phonics intervention specifically targeting reading and phonology—GraphoGame Flemish (GG-FL) [54,55]—and (2) investigate the possible educational boosting effect of the EE story game on top of GG-FL, which will be addressed in a future study. Story game enjoyment will be evaluated in three ways based on (1) postintervention child and parental questionnaires, (2) fulfillment of the GameFlow criteria, and (3) in-game data indicative of game enjoyment. Feasibility will be addressed by analyzing the difficulty level of the game, attrition rate, and individuals' final game exposure and training duration, together with their corresponding gaming profiles. Language comprehension growth will be addressed by exploring the accuracy of in-game story content-related questions as a function of game progress and baseline language subskills important for overall language comprehension (eg baseline vocabulary, morphological awareness, and listening comprehension [27-29]). Thus, we will test the hypothesis of whether language comprehension improves when progressing through the game while controlling for baseline language skills and also whether children with lower baseline language skills show larger growth potentials.

Methods

Participants and Ethics Approval

Following a school-based screening of 1225 children in the third year of kindergarten, 149 (12.16%) children aged 5 years (n=119, 79.9% children with and n=30, 20.1% children without an elevated cognitive risk for dyslexia) were enrolled in a game-based preventive reading intervention study (trial registration number S60962; assigned by the Clinical Trial Center of Universitair Ziekenhuis Leuven, Belgium). For the completed checklist on CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth; version 1.6.1), consider Multimedia Appendix 1. A cognitive risk for dyslexia was assigned when a child scored above the 10th percentile on a nonverbal reasoning test [56] and below percentile 30 on minimally 2 out of 3 assessments of robust reading predictors (ie, letter knowledge [57], phonological awareness [57,58], and rapid automatized naming [59]). Typically developing children scored above percentile 40 on all reading precursors and were matched to the risk sample based on nonverbal reasoning ability, school environment, and gender. Consider the studies by Van Herck et al [49], Vanden Bempt et al [55], and Verwimp et al [60] for a more detailed description of the screening tasks, procedures, and participant selection. All the selected participants were in their third year of kindergarten, Flemish monolingual Dutch speaking, born in 2013, and had a schooling period of minimally 20 months. None of the selected children reported an additional behavioral or familial risk of attention deficit hyperactivity disorder, language or articulatory problems, severe hearing impairments, or neurological deficits. Furthermore, as Flemish schools only provide reading instructions from the first grade onward, all participants were considered to be prereading. This so-called prereading phase was also confirmed by a unanimous floor effect on a preintervention reading test [55]. Signed informed consent was obtained from all participants, and the study was approved by the medical ethical committee of Universitair Ziekenhuis Leuven, KU Leuven (Katholieke Universiteit Leuven; approval number B322201836276).

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Study Design and Procedure

Of the 149 children in the entire intervention study sample, 91(61.1%) at-risk children were asked to play the story game. Within the framework of the reading intervention study, these 91 children were randomly assigned to 1 of 3 experimental groups. The first group (GG-FL EE group; 31/91, 34%) played the story game with envelope-enhanced stories and combined it with a phonics-based GG-FL intervention [54]. For technical details of the EE algorithm, refer to the study by Van Herck et al [49]. The second group received the same intervention as the first, with the only difference being that no EE was applied to the stories in the story game (GG-FL nonenhanced group; 31/91, 34%). The third group also played the nonenhanced story game and combined it with tablet-based commercial Lego Duplo-, and Playmobil applications (henceforth active control [AC] games), which did not train any reading-related skills (AC nonenhanced group; 29/91, 32%). The intervention lasted 12 weeks/84 days in total and took place in the second semester of the last and third year of kindergarten. Of the 149 children, the remaining 28 (18.8%) at-risk and 30 (20.1%) non–at-risk children served as the at-risk passive control and the typically developing control group of the reading intervention study, respectively, and did not receive any type of digital gaming intervention. As this study mainly focuses on story game feasibility and enjoyment, the last 2 control groups, who did not play the story game, will not be discussed any further in this research paper. Before the intervention period, all the necessary games, including the story game, were installed on 91 tablets (Samsung Galaxy E9.6). All story sound levels of the story game were calibrated to be played at 60 dB-A over ATH-m20x headphones using speech-weighted noise that was constructed based on an average spectrum of the different storytellers [61]. Then, a variety of cognitive linguistic tasks, including baseline language skills (listening comprehension, receptive vocabulary, and morphological awareness), were individually assessed in all participants at school in a quiet test room. After this baseline test phase, the 91 at-risk children who were assigned to 1 of the 3 intervention groups received a tablet, a corresponding calibrated headphone, and a manual for parents with instructions to start the tablet intervention at home. With the support of a reward calendar with stickers, they were instructed to combine story game sessions with 15-minute GG-FL or AC sessions for 6 days per week over 12 weeks. This equaled 72 gaming sessions for both GG-FL or AC and the story game. After the intervention, the parents and children received a questionnaire to assess their motivation, enjoyment, and engagement during the intervention period.

Story Game Intervention

Overall Game Description

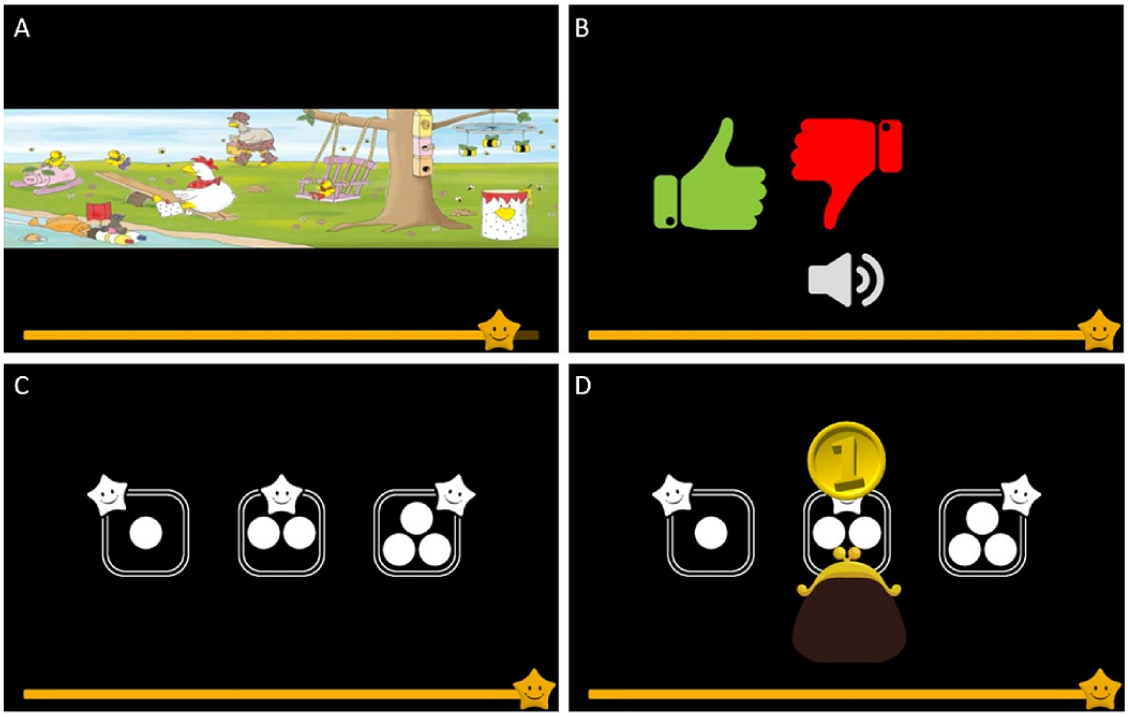
The tablet-based story game application was developed in Unity 3D [62] and programmed entirely using the C# scripting language. For an overview of the rationale, developmental design-related decisions, stories, and programming details of the game, refer to the technical story game development guide (Multimedia Appendix 2 [5,47-53,58,62-79]). The story game provided 72 gaming sessions, each of which mainly comprised listening to 1 long (eg, approximately 10 minutes) or 2 short (eg, twice approximately 5 minutes) stories accompanied by story illustrations. Game settings prevented children from playing ≥1 session every 24 hours. The 72 sessions were categorized into 18 play phases of 4 grouped sessions containing 4 (longer) to 8 (shorter) stories from the same book series and author. In total, 87 stories from 14 different book series were implemented in the game. Generally, the game contained three main game modes: (1) the main intervention task environment, which involved actual story listening, story rating, and responding to content-related questions; (2) the virtual hub world, in which players consulted their game progress on a map; and (3) an avatar customization system, where players could buy accessories for their game avatars or buy new avatars. Most of the artwork in the game, such as 3D models, textures, and animations that were used to create the virtual hub world, the avatars, and their accessories, were custom-made; acquired from the Unity Asset Store [80]; or acquired from child-friendly projects of the Dyslexia Research Collaboration team at KU Leuven, such as Diesel-X [58]. The resulting art style was characterized by flat primary colors, avatars with exaggerated cartoon-like proportions, and simplified basic models and animations suitable for the chosen target age group [63,81].

Main Intervention Task Environment

The main intervention task presented recorded story audio, all in Dutch, with accompanying illustrations (Figure 1A), followed by a story appreciation rating (Figure 1B) and audio questions with a simple multiple-choice system (Figure 1C). Questions were formulated by the research group, and listening comprehension was examined by recalling information explicitly mentioned in the story text. Although not directly assessed, the language level of the questions was intended to match the language and cognitive capacities of children aged 5 years. The question part put a strong emphasis on feedback by awarding 1 coin per correct response, with added flair in the form of animations and sound effects (Figure 1D). Each session contained 3 content-related questions. Hence, given the total amount of 72 game sessions, players could maximally earn 216 coins throughout the game.

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Figure 1. Main intervention task: (A) story listening (© 2016 Clavis Publishing, Hasselt–Alkmaar, New York; illustrations from Lotta ruimt het op from Diane Put and Rik De Wulf); (B) story rating; (C) multiple-choice questions; (D) reward for each correct response.



Virtual Hub World

Similar to classic digital games such as Super Mario Bros, the different game sessions were tied together in a so-called virtual hub world. The virtual hub world provided an overview of each game session in the form of a cylindrical stage. Every time a player successfully completed a game session, his or her avatar jumped from one cylindrical stage to the next, leaving a star on the stage that was just abandoned (Figure 2). As such, players gained information on their progress throughout the game and could earn a maximum of 72 stars (ie, the total number of game sessions).

Figure 2. Completion of a game session shown in the virtual hub world.

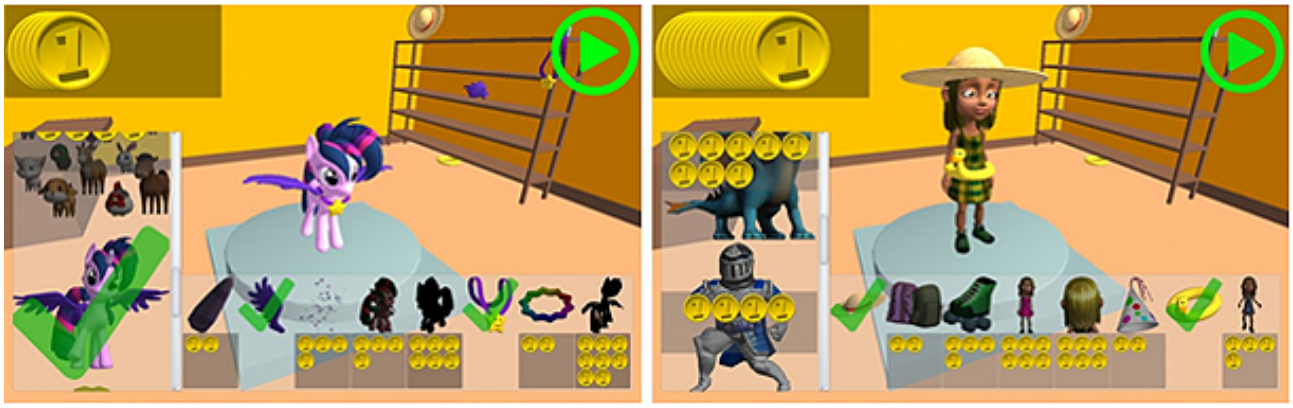


Avatar Customization System

To provide added incentives and rewards to keep the player engaged, an avatar customization system was implemented, which featured a virtual store where players could spend their coins (Figure 3). These coins were earned through correct responses to the content-related story questions in the main intervention task. The store offered new avatars and accessories for current avatars, which were displayed in the virtual hub world. The items put an emphasis on quantity to make sure that the player could acquire roughly one new item per story session without running out long before reaching the end of the story game.

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Figure 3. Avatar customization system of the story game.



Story Game Session

In a single game session, first, players watched a short cut-scene of their avatar positioned on one of the 72 possible stages in the virtual hub world, representing the 72 game sessions and, thus, their progress throughout the game. Second, the main intervention task occurred, in which the player was required to actively listen to 1 or 2 stories, depending on the particular story session. After listening, the player rated the story based on a green or red thumb (ie, like or dislike, respectively) and received 3 content-related multiple-choice questions for which one coin could be earned per correct response. Following the short quiz, the player automatically ended up in the avatar customization system, where the earned coins could be spent on accessories for the avatar or to buy extra avatars. Finally, the player was sent back to the hub world in which the new or newly decorated avatar jumped to the subsequent cylindrical stage while a dancing star appeared on the one that was just abandoned (for a demonstration movie of the story game, see Multimedia Appendix 3). Useful player data for individual player accounts (eg, game progress, question response accuracy [QRA], play dates and hours, and story rating information) were automatically logged on our university server and sent daily to the research group.

Test Battery and Questionnaires

Baseline Listening Comprehension

The subtest *Understanding Spoken Paragraphs* was adapted from the Clinical Evaluation of Language Fundamentals (CELF)-fourth edition, Dutch version [82] and was used to evaluate baseline listening comprehension. The experimenter read 2 short stories aloud. Each story was followed by 5 content-related questions. The child received 1 point per correct response. The maximum score on the test was 10.

Baseline Receptive Vocabulary

Receptive vocabulary was measured using the Peabody Picture Vocabulary Test–III, Dutch version [83], which contains 17 subtests with 12 test trials each. In each trial, the child heard a target word and was asked to select the corresponding picture from the 4 alternatives. The test was interrupted when the child made ≥9 errors in 1 subtest. The raw receptive vocabulary score was computed by subtracting the sum of the errors across all administered subtests from the number of trials that was last assessed. This raw score was then converted into a standard score and represented the final receptive vocabulary score (mean 100, SD 15).

Baseline Morphological Awareness

The *Word Structure* subtest from the CELF Preschool–second edition, Dutch version [84] was used to evaluate morphological awareness. In this task, the ability to correctly apply Dutch morphological rules (eg, conjugation, derivation, flexion, pronouns, and degrees of comparisons) was measured. The test contained 23 items, each containing 2 pictures. The first picture was fully described by the experimenter (eg, “Dit meisje eet” meaning “This girl eats”) followed by an incomplete description of the second picture (eg, “en dit meisje” meaning “and this girl…”), which had to be completed by applying a certain morphological rule of Dutch (eg, “and this girl sleeps” or “en dit meisje slaapt”; morphological rule: conjugation of a regular verb in third singular form). On the basis of the instructions in the test manual, the test was interrupted when the child made 7 consecutive mistakes. The maximum score was 23.

Postintervention Child and Parental Questionnaires

After the intervention period, parents independently filled out a short questionnaire that included three questions related to motivation, encouragement, and sustained attention during story gameplay. Accompanied by a member of the research group at school, intervention enjoyment was also measured in all children using 2 components of the Fun Toolkit survey instrument [85], which was developed to gather children’s opinions on technology. On the one hand, children were asked to assign story game enjoyment on a 5-point Likert scale–based smiley-o-meter, in which the 5 scales were represented by smileys (ranging from a very unhappy smiley meaning *I did not like the game at all* to a very happy smiley meaning *I liked the game very much*). On the other hand, participants were asked whether they were willing to redo the intervention (see Multimedia Appendix 4 for an overview of the 5 child and parental categorical questions and their response possibilities).

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Statistical Analysis

Data Exclusion

Of the 91 children who were asked to play the story game, 7 (8%) were excluded from the data set because of technical game problems during the intervention period (bugs; explained in (Multimedia Appendix 2 [5,47-53,58,62-79]). Approximately 2% (2/91) of children were excluded as they never started the general digital gaming intervention properly (ie, they played <10% of the GG-FL or AC and the story game). Hence, useful story game data were available for 90% (82/91) of the children. Data visualization and statistical analyses were conducted using RStudio [86,87].

Enjoyment Analysis

Story game enjoyment was addressed in 3 ways. First, the postintervention child and parental questionnaire outcomes were analyzed by investigating the relative frequencies per response category of each question. Second, 2 members of the research group independently evaluated the GameFlow criteria by assigning a state of fulfilled, partly fulfilled, or not fulfilled. Then, after reaching a consensus, all criteria received a final, single state. Third, in-game enjoyment–related data were evaluated, such as general story appreciation, which was measured as the proportion of given likes and dislikes per story.

Feasibility Analysis

To gain insights into the feasibility of the intervention, we first defined the general QRA, which indicated the difficulty level and thus the feasibility of the story-listening part of the game. This was computed as the proportion of correct and incorrect responses per question. Second, we visualized the attrition rate, which determined the number of children who completed the intervention and at what point eventual dropouts occurred. Third, we calculated the individuals' final game exposure and training duration. Final game exposure was computed as the ratio (percentage) of the number of actually played sessions to the total number of available sessions (ie, n=72). The individuals' corresponding final training duration represented the number of days the child played, starting from the day of the first story session until the day on which the participant played for the last time, irrespective of game completion. The measure of the final training duration was particularly informative about the feasibility of the training intensity. By analyzing the players' final game exposure and training duration, we categorized players into different gaming profiles based on intervention completion (complete or incomplete) and schedule compliance (compliant or noncompliant). Categorizing participants based on these criteria provided information on the possible need to adjust the training schedule and intervention duration to increase the feasibility of future studies. A total of 4 additional nonparametric median-based Theil–Sen regressions were performed using the *mblm* package in R [88] to predict individuals' final game exposure or final training duration, either based on initial individual story appreciation or QRA. These analyses provided information on how to keep players engaged from the start and prevent them from dropping out or slowing down. The Theil–Sen technique allows for a robust line fitting as the estimation is obtained by calculating the median of the slopes of all possible pairs of data points [89]. This nonparametric regression technique was opted for, given the relatively small sample size and violated assumptions to perform ordinary least square regressions. Initial individual story appreciation and individual response accuracy at the start of the intervention were defined as a player's mean story appreciation and mean QRA in the first two game phases, respectively (ie, mean ratings of the first 12 stories and mean response accuracy for the first 24 questions). As for predicting game exposure based on initial story appreciation or initial individual QRA, the analyses were restricted to a sample of players who did not completely finish the story game (32/82, 39%), as the inclusion of participants who completed the full intervention would render a ceiling effect in the results. As for predicting the training duration based on initial story appreciation or individual response accuracy, we excluded 10% (8/82) of participants who played <80% of the total game content, as their training duration in days did not represent a reliable intervention trajectory. As such, the training duration was predicted based on the data of 90% (74/82) of participants.

Analyzing Growth in Language Comprehension

The third and last part of the *Results* section tackles a possible growth in language comprehension. We considered the mean QRA (percentage) per game phase as an indicator of language comprehension. However, we acknowledge that stories and questions do not belong to a validated language instrument, and we did not directly test the stability of the difficulty of the questions and stories. However, we were obliged to select measures beyond the existing language instruments, given the long intervention period. Each game phase contained 12 content-related questions. Using the *lmerTest* package in R [90], we performed a multilevel linear growth model in the sample that finished at least 80% of the game (74/82, 90%), with game phase as a within-subjects variable and baseline listening comprehension, morphological awareness, and receptive vocabulary as between-subjects covariates. The game phase was coded such that the fixed intercept of the model represented the mean QRA of the first game phase if a score of zero was obtained for all 3 baseline language covariates. We also modeled a randomly varying intercept and slope across individuals and added 3 additional phase×baseline language interaction terms (1 per baseline language covariate). As such, we could test the hypothesis that the mean QRA, which was our indication of language comprehension, improved over the game phase when controlling for each baseline language skill, as well as whether children with lower baseline language skills showed larger growing potentials concerning mean QRA.

Results

Enjoyment

Postintervention Questionnaires

Postintervention child questionnaire data revealed that 74% (61/82) of participants liked the game very much. Moreover, 66% (54/82) of participants confirmed that they were willing to redo the training. Postintervention parental questionnaires revealed (1) that most parents observed a high (39/82, 47%) or

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relatively high play motivation (32/82, 39%) in their child, (2) that most of the players never (43/82, 52%) or only sometimes (25/82, 30%) needed encouragement to play, and (3) that more than three-quarters of the parents (65/82, 79%) observed a state of sustained attention during gameplay.

GameFlow Criteria Fulfillment

Although the GameFlow model was applied in the design process, Tables 1 to 8 clarify the extent to which the game criteria were properly implemented and whether our game did, only partly, or did not fulfill each GameFlow criterion [5]. As shown in Tables 1 to 8, the GameFlow model–based evaluation revealed that only the criteria belonging to the concentration principle were completely fulfilled. As for the other elements, except for the elements of social interaction (as it was intentionally not implemented, given the young age of our participants) and challenge, we concluded that most of their corresponding criteria were completely or partially fulfilled. To avoid plagiarizing from Sweetser and Wyeth [5], the wording of the descriptions of the GameFlow criteria in Tables 1 to 8 differs from the criteria wording used in their article [5], although the meaning of the criteria did not change. However, we want to emphasize that we considered the original wordings when developing and evaluating the story game, as we wanted to take into account the importance of applying evaluation tools in the exact same way as they are validated.

Table 1. Corresponding criteria of the GameFlow element concentration and their implementation and fulfillment in the story game.

Concentration criteria	Implementation in the story game	Fulfillment status
Stimuli are provided in different modalities	Stimuli were aurally and visually presented both in the main intervention task (eg, story audio and accompanying illustrations) as well as in the virtual hub world and avatar customization system (eg, simple tunes and visual animations) at all times.	Yes
Stimuli are worth attending to	Story texts and corresponding story images were selected based on the target age. The virtual hub world and the avatar customization system provided joyful, simple tunes and appeared with flat primary colors and simplified basic models and animations, which are suitable for our target age group [63,81]. Avatars were designed with exaggerated cartoon-like proportions. As such, stimuli seemed appealing, eye catching, and worth attending to for a long time.	Yes
Games must quickly catch and hold the players' attention and must be able to maintain focus at all times	Story texts and corresponding story images were selected based on the target age. The virtual hub world and the avatar customization system provided joyful, simple tunes and appeared with flat primary colors and simplified basic models and animations, which are suitable for our target age group [63,81]. Avatars were designed with exaggerated cartoon-like proportions. As such, stimuli seemed appealing, eye catching, and worth attending to for a long time.	Yes
There are no irrelevant game tasks on top of the main task	When children were required to listen to the story (ie, the main learning task), the game did not require performing other irrelevant side tasks.	Yes
Games should require cognitive workload but should not exceed perceptual and cognitive limits	Players were required to actively listen and stay focused during the whole story-listening phase, as they could only collect rewards (coins) when they responded correctly to the content-related questions. However, stories and content-related questions were chosen to correspond to the cognitive limits of kindergarteners aged 5 years. The virtual hub world and avatar customization system warranted easy-to-use mechanics and simple, colorful animations so that players did not become *lost in the game world* or overstimulated.	Yes
There are no distractors during the game tasks	Tasks in the main intervention and avatar customization phase were clearly defined, such that, when performing the tasks (eg, actively listening to the story, responding to the questions, or spending coins in the avatar customization system), players were not able to perform any other tasks and were not distracted by irrelevant stimuli.	Yes

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Table 2. Corresponding criteria of the GameFlow element challenge and their implementation and fulfillment in the story game.

Challenge criteria	Implementation in the story game	Fulfillment status
Challenges are adjusted to players' skills	As the research group selected age-appropriate stories and invented literal questions that were supposed to match the cognitive skills of kindergarten children aged 5 years and as the virtual hub world and avatar customization system appeared self-explanatory without any form of written language, we concluded that the game tasks were adapted to the skills of the target prereading age group.	Yes
Challenges are player-adjusted	The selection and the order of the stories, along with their corresponding content-related questions, were fixed and the same for all players. Moreover, although we have no direct proof of the stability of the difficulty of the stories and questions, the game was originally not designed to increase in difficulty. In that sense, we concluded that the challenge levels were not individually adapted and did not increase along with progress in player skills.	No
Challenge levels increase to improve the players' skills	The selection and the order of the stories, along with their corresponding content-related questions, were fixed and the same for all players. Moreover, although we have no direct proof of the stability of the difficulty of the stories and questions, the game was originally not designed to increase in difficulty. In that sense, we concluded that the challenge levels were not individually adapted and did not increase along with progress in player skills.	No
The game provides new challenges at appropriate times	Although not directly tested, we assumed that the difficulty level of the stories, the questions, and other tasks remained relatively stable throughout the game. However, book series and storytellers switched every 4 sessions. This required adaptability and possibly formed a new challenge for some (but not all) players.	Partly

Table 3. Corresponding criteria of the GameFlow element player skills and their implementation and fulfillment in the story game.

Player skills criteria	Implementation in the story game	Fulfillment status
The game is playable without an instructive manual	Although the research group provided a short manual for the players' parents or caregivers, the game was designed in a way that children aged 5 years could pass the first and following sessions without any form of explanation. Game mechanics were easy to use, transfers from one game mode to another occurred automatically, and as the target group was considered prereading, there was no form of written text implemented in the game.	Yes
Learning the game is not boring	A learning phase or tutorial game was not implemented, as game sessions were self-explanatory, and players learned to play by doing. When opening the application on the tablet for the first time, players gained enough information on how to progress. Hence, we believed that this criterion did not necessarily need to be implemented.	No
Absorbing tutorial games should teach players how to play the game	A learning phase or tutorial game was not implemented, as game sessions were self-explanatory, and players learned to play by doing. When opening the application on the tablet for the first time, players gained enough information on how to progress. Hence, we believed that this criterion did not necessarily need to be implemented.	No
Web-based help is provided for players in need	The research group did not provide a web-based help service tool. However, parents or caregivers could contact the research group via email or telephone anytime in case of technical or motivational problems. If necessary, a member of the research group visited the players at home to fix possible technical or player-related problems.	Partly
Skill progress occurs gradually at an appropriate pace	Although not directly tested, we assumed that the difficulty level of the questions and other tasks remained relatively stable throughout the game and that they were adapted to the target age. The game did not primarily intend to specifically improve language comprehension (measured based on mean question response accuracy per game phase) of the target group. However, it is possible that for some of the players, mean question response accuracy would gradually increase with higher story game exposure. This will be explored in this paper.	Partly
Skill effort and development is rewarded	Skill effort was rewarded by means of stars. After finishing a session, regardless of whether the responses to the content-related questions were correct or not, all players earned a star, which appeared on a stage in the virtual hub world and indicated the players' progress in the game. Skill development was rewarded with coins, such that the more correct responses were given, the more coins were earned.	Yes
Game mechanics and interface are simple and easy to apply	All actions required the use of a touch screen, as the game was tablet based. Nowadays, in Western society, most children aged 5 years are familiar with these devices. Furthermore, players only had a limited set of actions, as advanced game options were locked with a password. These limited actions (eg, stopping, starting, or continuing the story game; selecting a response for the questions; buying accessories in the avatar customization system) were all self-explanatory (eg, selecting the correct response or a desired accessory by touch screen) or assigned with clear symbols on the screen (red arrow to stop the game and large green play symbol to start or continue the story recording).	Yes

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Table 4. Corresponding criteria of the GameFlow element control and their implementation and fulfillment in the story game.

Control criteria	Implementation in the story game	Fulfillment status
A sense of control over the game avatar and its movements and interactions	During the main intervention task, it was not possible to exercise control over the game avatar. However, following the main intervention task, players were able to customize their avatar or buy new avatars in the avatar customization system, all of which or whom appeared later on the platforms in the virtual hub world. However, as the avatars automatically jumped to the next stage when finishing a session, their movement and interaction control was limited.	Partly
A sense of control over the game interface and device	As children aged 5 years are relatively familiar with tablets in recent times, we believed that the tablet was a suitable device for the intervention program. Moreover, individual player profiles were set in advance on each tablet, and the main menu contained no other option than starting or stopping the game, making the game interface intuitive and self-explanatory.	Yes
A sense of control over the game mechanics (saving and stopping)	Players were able to start and stop the game anytime. However, when interrupting the game during story listening, the progress of the ongoing session was not registered or saved, and players should restart the whole session.	Partly
Errors that will harm the game (eg, bugs) should not occur, and if they occur, support must be available	The game was piloted many times on members of the research group and on children with a similar age as the target group. Although the game appeared bug free at the end of the pilot studies, some players in the actual intervention study (not included in the final data analysis) experienced bugs causing a total crash of the game and loss of in-game data. In those cases, a member of the research group provided support as soon as possible by reinstalling the game at the homes of the players.	Partly
A sense of control over the game world (possibility to shape the game world)	Following the main intervention task and the time spent in the avatar customization system to change the game avatar, the newly dressed or new game avatar appeared in the virtual hub world on one of the stages. In that sense, players exercised control over altering their game world. However, the background animations and models in the hub world were preprogrammed and could not be altered.	Partly
A sense of control over the game actions and strategies	As the order and goal of the game, along with the framed intervention task, was fixed for all players, it was not possible to make use of different strategies and actions to reach the end of the game.	No

Table 5. Corresponding criteria of the GameFlow element clear goals and their implementation and fulfillment in the story game.

Clear goals criteria	Implementation in the story game	Fulfillment status
Final goal is clear from the start	Before the very first session, players viewed the virtual hub world from a *drone's perspective* and flew over all 72 stages that their game avatar had to pass to finish the game. That way, the player was immediately informed of the total amount of sessions. However, as the drone cut-scene was only presented at the start without any form of explanation, the final goal (eg, earning 72 stars) was not clearly emphasized during the entire intervention period.	Partly
Intermediate goals are clear	After playing the first session, it was clear for the player what should be reached during one game session.	Yes

Table 6. Corresponding criteria of the GameFlow element feedback and their implementation and fulfillment in the story game.

Feedback criteria	Implementation in the story game	Fulfillment status
Feedback on progress	After every session, feedback on game progress was visually provided by the game avatar, who jumped from one stage to the next in the virtual hub world. A star appeared on the platform that was just left. When the avatar reached the 72nd platform, all game sessions were finished.	Yes
Immediate feedback on actions	A star was given to all players as immediate feedback on the session completion. When responding correctly to a content-related question, the player received a coin, which was immediately presented after assigning the correct answer with animations and sound effects. Moreover, newly bought accessories or avatars immediately appeared in the virtual hub world.	Yes
Status or score is presented at all times	The number of collected stars was only visible in the main menu. The amount of earned coins was visible in the avatar customization system or could be considered when clicking on a little wallet that was visible in the virtual hub world. Thus, during the main intervention task, no score status was presented as we wanted to prevent players from being distracted by irrelevant stimuli.	No

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Table 7. Corresponding criteria of the GameFlow element immersion and their implementation and fulfillment in the story game.

Immersion criteria	Implementation in the story game	Fulfillment status
Decreased awareness of surroundings when playing the game	Although not measured and not measurable with questionnaires in our young target age group, child and parental questionnaire outcomes revealed that most of the players liked the game very much, were motivated to play, and would be willing to play again. Moreover, most of the parents or caregivers indicated a state of full focus when their child played the game, suggesting that some form of immersion was present in most of the players.	NM[a]
Decreased self-awareness and less everyday worries when playing the game	Although not measured and not measurable with questionnaires in our young target age group, child and parental questionnaire outcomes revealed that most of the players liked the game very much, were motivated to play, and would be willing to play again. Moreover, most of the parents or caregivers indicated a state of full focus when their child played the game, suggesting that some form of immersion was present in most of the players.	NM
A changed sense of time	Although not measured and not measurable with questionnaires in our young target age group, child and parental questionnaire outcomes revealed that most of the players liked the game very much, were motivated to play, and would be willing to play again. Moreover, most of the parents or caregivers indicated a state of full focus when their child played the game, suggesting that some form of immersion was present in most of the players.	NM
Emotional involvement in the game	Although not measured and not measurable with questionnaires in our young target age group, child and parental questionnaire outcomes revealed that most of the players liked the game very much, were motivated to play, and would be willing to play again. Moreover, most of the parents or caregivers indicated a state of full focus when their child played the game, suggesting that some form of immersion was present in most of the players.	NM
Visceral involvement in the game	Although not measured and not measurable with questionnaires in our young target age group, child and parental questionnaire outcomes revealed that most of the players liked the game very much, were motivated to play, and would be willing to play again. Moreover, most of the parents or caregivers indicated a state of full focus when their child played the game, suggesting that some form of immersion was present in most of the players.	NM

[a]NM: not measured.

Table 8. Corresponding criteria of the GameFlow element social interaction and their implementation and fulfillment in the story game.

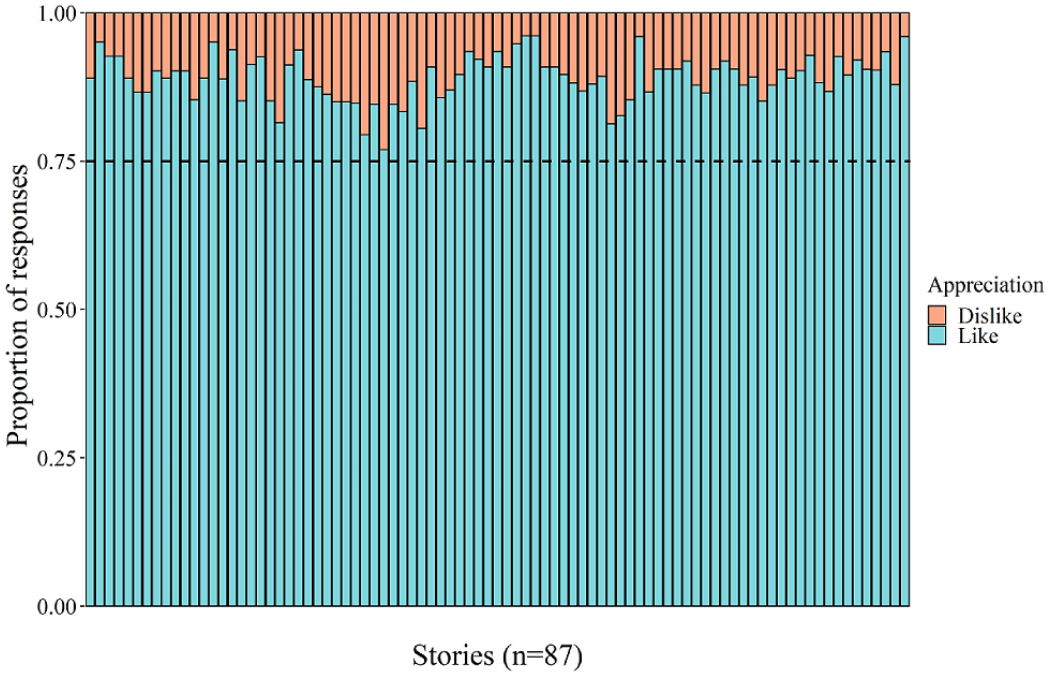
Social interaction criteria	Implementation in the story game	Fulfillment status
Competition between different players	The game did not intend to create competition between different players as participants in this paper were recruited anonymously and independently from each other.	No
Social interaction between different players (eg, chat services)	This was not applicable for our target age group of children aged 5 years.	No
Available social communities about the game	This was not applicable for our target age group of children aged 5 years.	No

In-Game Data Related to Game Enjoyment

Figure 4 visualizes the general story appreciation, calculated as the proportion of available likes and dislikes per story. Each story was liked by >75% (ie, >62/82 listeners) of the listeners for whom data were available, indicating that the stories were enjoyable.

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Figure 4. Overview of the general story appreciation. Each vertical bar represents one story, and the stories are ordered based on their occurrence in the game.

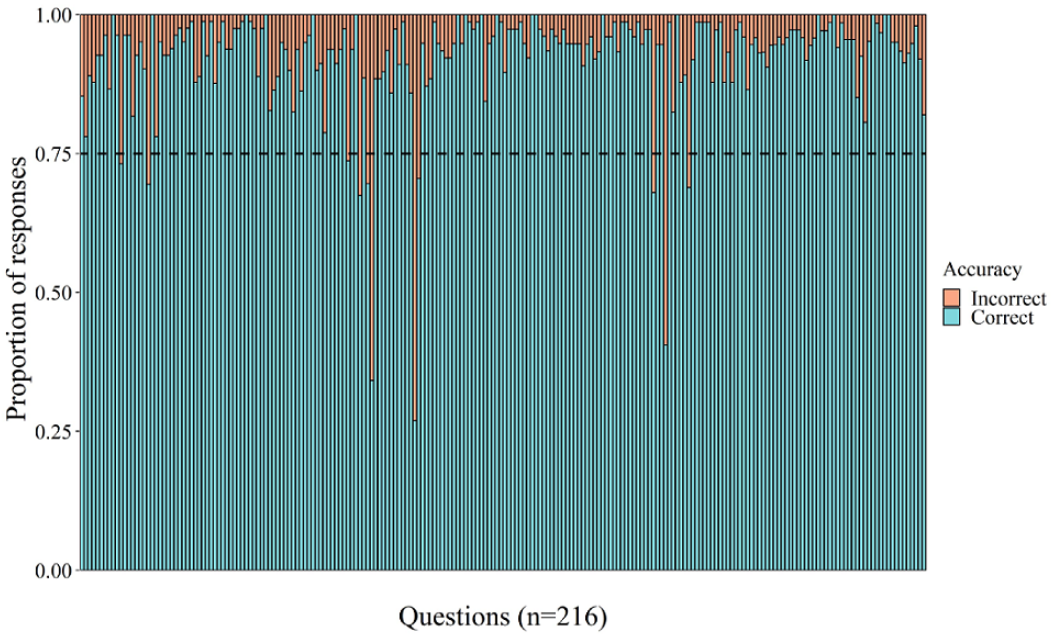


Feasibility

General QRA

Figure 5 visualizes the general QRA, calculated as the proportion of correct and incorrect responses per question. All but 11 questions were answered correctly by at least 75% (62/82) of the listeners for whom data were available, suggesting a rather stable difficulty level for the questions.

Figure 5. Overview of the general question response accuracy. Each vertical bar represents one question, and the questions are ordered based on their occurrence in the game.

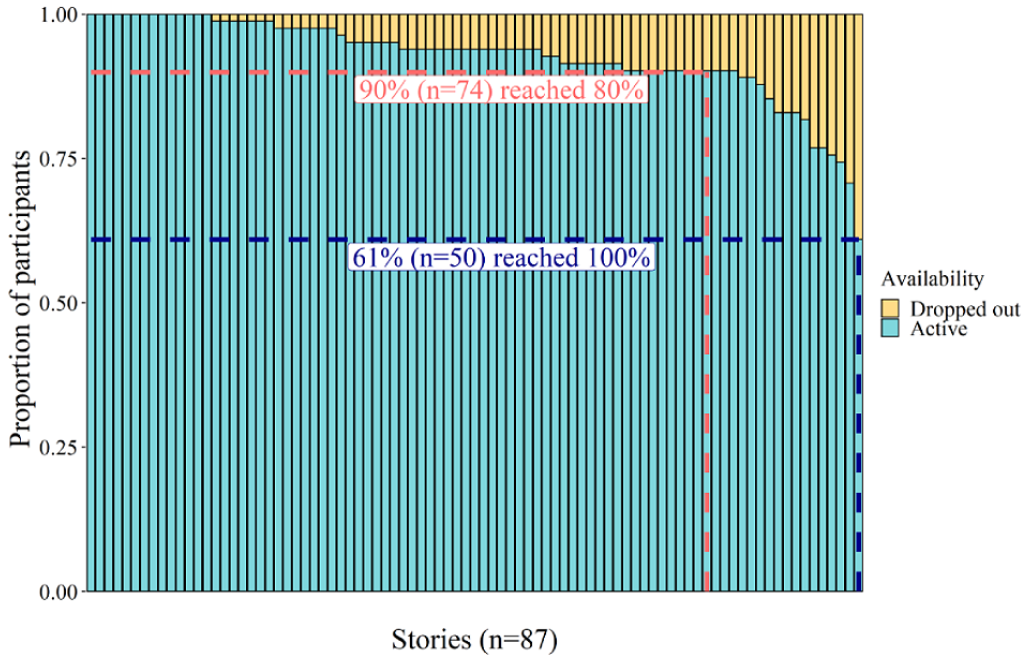


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Attrition Rate

Figure 6 shows the attrition rate and the proportion of active participants and dropouts throughout the entire story game progress. Of the 82 players, 74 (90%) listened to 80% of the stories (approximately 57th session of the total 72 story sessions), and 50 (61%) managed to finish the game completely. Hence, 39% (32/82) of players dropped out at some point during the 12-week intervention. Figure 6 also shows that the first player dropped out after the 12th story, corresponding to the start of the third game phase. From that point onward, the dropout proportion stayed relatively stable until the 80% completion point, after which it gradually increased toward the end of the game.

Figure 6. Attrition rate and dropout occurrence throughout the story game. Each vertical bar represents one story, and the stories are ordered based on their occurrence in the game.



Final Game Exposure, Training Duration, and Gaming Profiles

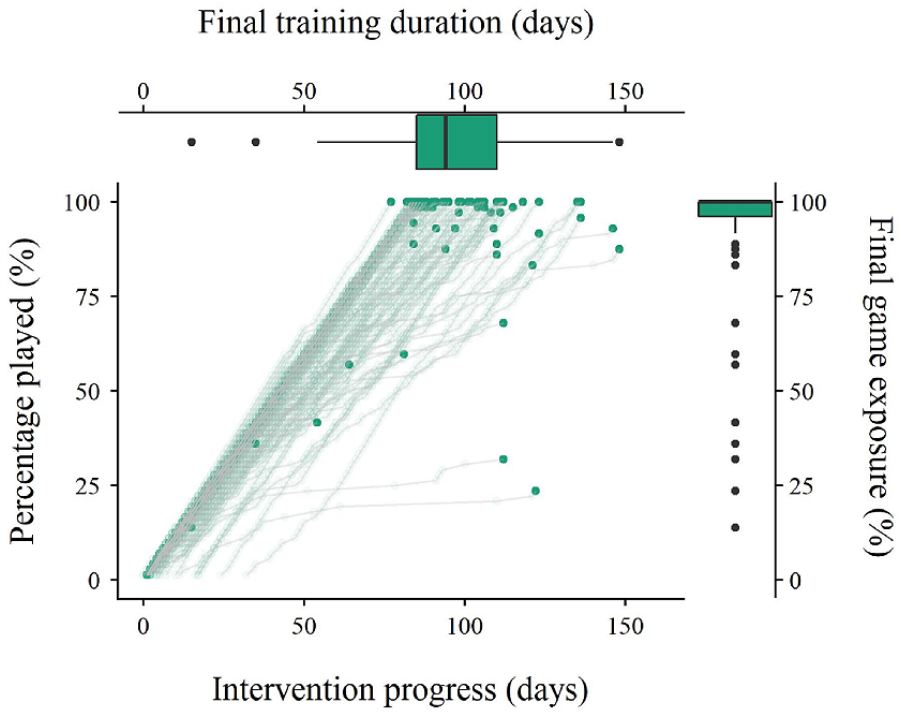
Figure 7 demonstrates individual story game trajectories, individuals' final game exposure and corresponding training duration, and their overall distributions. Apart from the visible finding that a few participants had a low training duration as they dropped out early, Figure 7 also shows a large variation in the training duration in children who nearly or completely finished the story game. On the basis of the categorization criteria (complete or incomplete and compliant or noncompliant), we established three different gaming profiles: (1) complete and compliant players (18/82, 22%; Figure 8A), (2) complete but noncompliant players (32/82, 39%; Figure 8B), and (3) incomplete and noncompliant players (32/82, 39%; Figure 8C). Note that we did not observe any players who perfectly followed the training schedule but dropped out at some point.

The Theil–Sen regression analysis revealed that the mean story appreciation of the first 2 game phases was not significantly predictive of final game exposure among the 39% (32/82) of children who dropped out at some point (β=.15; *P*=.08). Figure 9A shows that most children who quit at some point still assigned positive ratings to all stories of the first 2 phases. In contrast, the Theil–Sen regression analysis revealed that the mean QRA of the first 2 game phases significantly predicted final game exposure, such that a lower accuracy at the start accelerated the dropout point (β=.35; *P*<.001; Figure 9B).

Story appreciation in the first 2 game phases significantly predicted the final training duration in a negative way among the 90% (74/82) of children who finished 80% of the game (β=−0.16; *P*=.003; Figure 10A). These results indicate that players who liked the stories at the start of the game were more likely to play the game at a higher rate. The mean QRA at the start did not significantly predict the final training duration (β=.00; *P*=.68) among children who finished or almost completely finished the story game (Figure 10B).

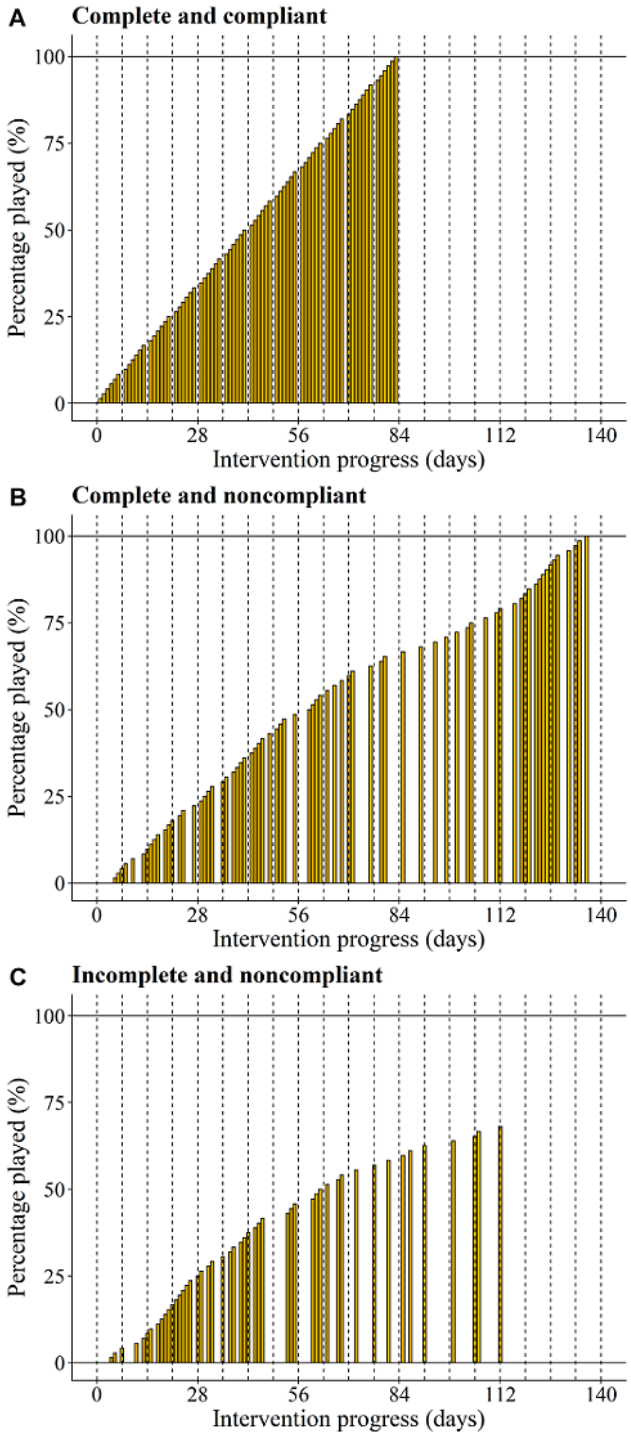
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Figure 7. Individuals' game exposure and training duration and their overall distributions. Bold dots represent the final training duration and final game exposure.



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Figure 8. Examples of the different gaming profiles of the story game. Complete and compliant player (A). Complete and noncompliant player (B). Incomplete and noncompliant player (C). Dotted lines represent the number of intervention weeks.



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Figure 9. Theil–Sen regression outcomes. Predictive relationship between initial mean story appreciation and final game exposure (A). Predictive relationship between initial mean question response accuracy (QRA) and final game exposure (B).

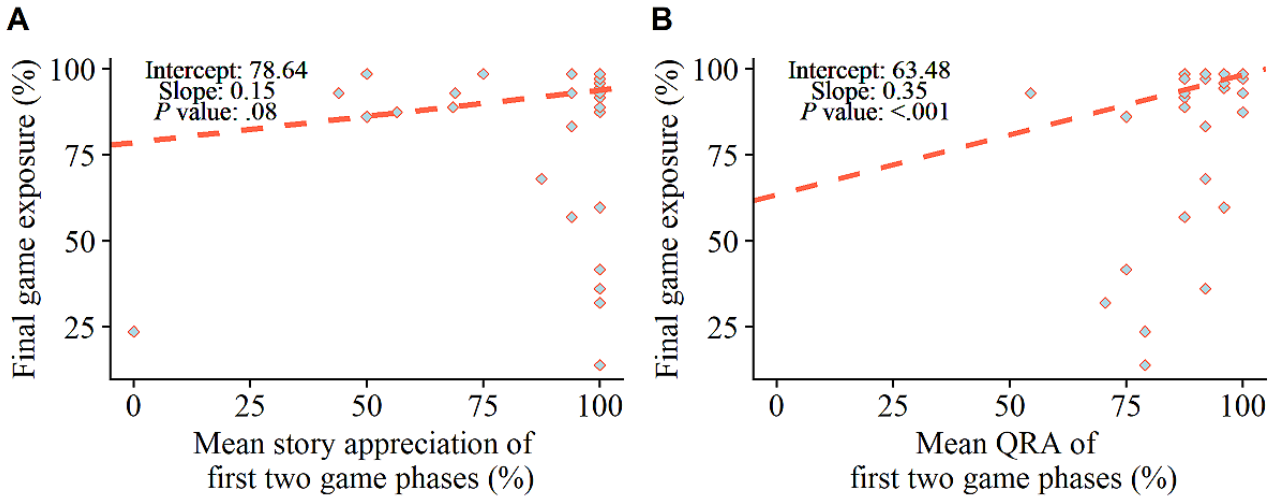
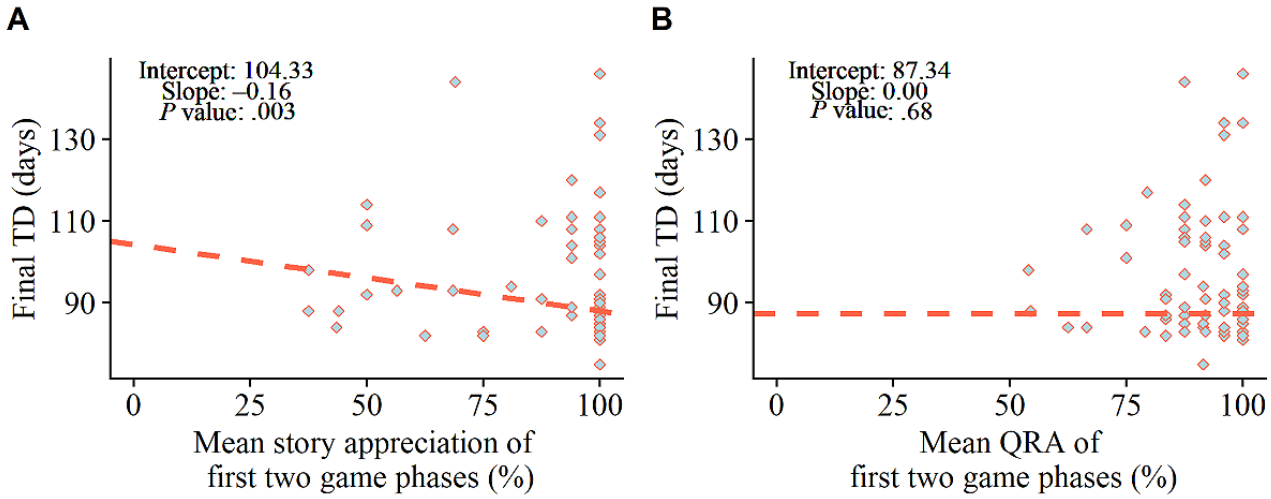


Figure 10. Theil–Sen regression outcomes. Predictive relationship between initial mean story appreciation and final training duration (A). Predictive relationship between initial mean question response accuracy (QRA) and final training duration (B). TD: training duration.



Growth in Language Comprehension

Figure 11 presents the distribution of the mean QRA of the first game phase in all children (74/82, 90%) who completed at least 80% of the game and shows overall high initial accuracy scores, suggesting a small growing potential in a large proportion of children. The outcomes for the linear mixed effects model are presented in Table 9. The game phase significantly predicted mean QRA in a positive direction (β=1.44, SE 0.49; $t_{120.12}$=2.974; *P*=.004). Moreover, there was a positive predictive relationship between baseline listening comprehension (β=1.56, SE 0.49; $t_{71.91}$=3.168; *P*=.002) and receptive vocabulary (β=.16, SE 0.06; $t_{72.27}$=2.64; *P*=.01) on mean QRA. Remarkably, the results also revealed a significant interaction between the game phase and listening comprehension, such that children with lower baseline listening comprehension underwent a significantly larger growth in mean QRA throughout the game (β=−0.08, SE 0.04; $t_{119.83}$=−2.03; *P*=.04).

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Figure 11. Distribution of the mean question response accuracy (MQRA) of the first game phase.

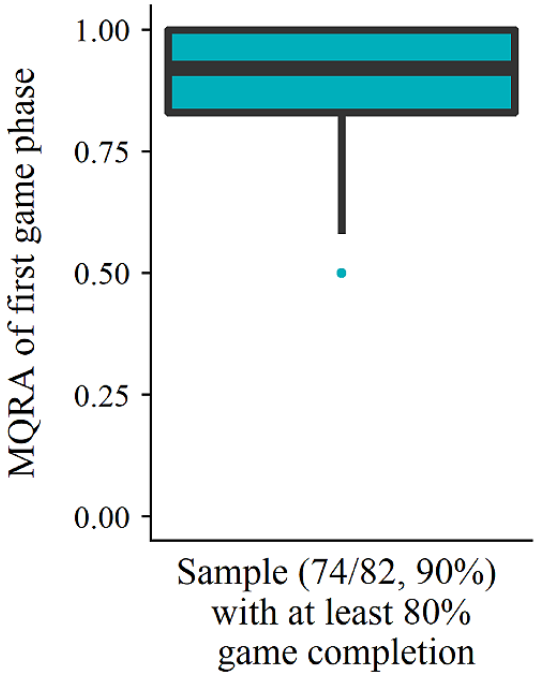


Table 9. Results of the linear mixed model analysis.

Model term	Estimate (SE)	*t* test (*df*)[a]	*P* value[b]
Intercept	63.38 (6.49)	9.77 (71.92)	<.001
Game phase	1.44 (0.49)	2.97 (120.12)	.004
Listening comprehension	1.56 (0.49)	3.17 (71.91)	.002
Receptive vocabulary	0.16 (0.06)	2.64 (72.27)	.01
Morphological awareness	0.23 (0.32)	0.73 (72.19)	.47
Game phase×listening comprehension	−0.08 (0.04)	−2.03 (119.83)	.04
Game phase×morphological awareness	−0.02 (0.02)	−0.60 (123.13)	.55
Game phase×receptive vocabulary	−0.01 (0.01)	−1.27 (123.71)	.21

[a]2-tailed.

[b]Significant at the .05 level.

Discussion

Principal Findings

This study addressed the enjoyment and feasibility of a story-listening game and preliminarily assessed the possible growth in language comprehension. The principal findings on game enjoyment, feasibility, and the impact of the game on language comprehension are discussed in the following sections.

Regarding the enjoyment evaluation, child and parental questionnaires and in-game enjoyment–related data (eg, story appreciation) pointed to a highly positive game experience. Indeed, questionnaires revealed high game enjoyment, motivation, and sustained attention during gameplay for most of the participants. The in-game data that were indicative of game enjoyment also showed that each story was appreciated by minimally three-quarters of the listeners, indicating that the stories fit the interests of kindergarteners aged 5 years with a cognitive risk for dyslexia and that most of the participants experienced the story game as enjoyable. Nevertheless, although a considerable number of GameFlow criteria were fully and partly implemented in the story game, probably benefiting the game enjoyment experience to a large extent, the GameFlow model–based evaluation also implied that there was room for optimizing the game design. Indeed, although the GameFlow model [5] was taken into account during the design process of the story game, the concentration principle remained the only principle for which all criteria were completely fulfilled.

Concerning the feasibility of the intervention in terms of difficulty, the results suggested that the game was adjusted to the cognitive capacities of children aged 5 years with an elevated risk for dyslexia, as almost all questions were answered correctly by minimally three-quarters of the listeners. This was not surprising, as we intended to develop a game that was not too easy or too difficult to ascertain that players were cognitively able to gather many coins but only if they actively listened to the stories. This state of active listening was confirmed by the general QRA results. The fact that only 11 questions were not

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answered correctly by 75% (62/82) of the listeners also suggests a rather stable difficulty level of the questions. As for feasibility in terms of intervention completion and duration, outcomes indicated a positive evaluation on the one hand, as most participants were able to fully or nearly complete the story game, but a negative evaluation on the other hand, as we observed a large variation in training duration (eg, days needed to nearly or completely finish the intervention). Thus, these findings mainly raised doubts about the feasibility of the training intensity, as many participants could finish but were simply not able to follow the rather highly concentrated advised schedule of 6 days per week during 12 weeks. This was also confirmed by the gaming profile outcomes, which revealed that only 22% (18/82) of participants belonged to the *complete and compliant group* and completed the game according to the postulated schedule compared with 39% (32/82) participants who managed to finish but spaced out the sessions over a longer time (eg, the complete and noncompliant group). As for predicting individuals' final training duration and game exposure, we established a significantly negative relationship between initial mean story appreciation and final training duration and a positive relationship between initial mean QRA and final game exposure. These findings indicate that the initial compromised story appreciation decelerated the advised training scheme and that a higher response accuracy at the start increased the number of played sessions.

As for the growth in language comprehension, we established an increase in mean QRA along with the game phase, baseline vocabulary, and baseline listening comprehension. However, most strikingly, children with lower listening ability scores at the start of the intervention period made significantly more progress in terms of QRA than did children with higher preintervention listening ability scores. Overall, these results carefully suggest the potential of the game to train language comprehension with larger gains in children who already exhibit lower language levels at the start.

Limitations and Comparisons to Prior Work

Enjoyment

The game enjoyment–related results give rise to 2 important discussion points. First, caution is required when interpreting the positive questionnaire outcomes. On the one hand, the phenomenon of social desirability (ie, the tendency to provide answers that correspond to widely accepted social norms) could have biased the responses of both children and parents [91]. On the other hand, the short attention span and underdeveloped cognitive capacities of young children could have resulted in extremely positive but less reliable responses on the smiley-o-meter. Indeed, in line with our study, Zaman et al [92] established an overrepresentation of positive responses when applying the smiley-o-meter in young children aged <7 years. Accordingly, in another study, the authors stated that children aged ≤7 years do not yet grasp the principles of a visual analog scale, of which the smiley-o-meter is an example [93]. As put forward by Zaman et al [92], the search for how to optimally measure the enjoyment of technology in preschoolers is still ongoing. The second discussion point related to enjoyment concerns the GameFlow-based evaluation. More specifically, we acknowledge that the agreement of the developed game with the GameFlow model contains a form of subjectivity, as the evaluation was performed by 2 members of the research group who were involved in the design process itself. Irrespective of this limitation, the fully and partly implemented GameFlow criteria embedded in the current game were presumably satisfactory enough to attain a certain level of enjoyment. This assumed enjoyment level was also supported by the cautiously interpreted questionnaire and in-game enjoyment–related outcomes, which indicated game appreciation in most players. Optimizing the partly or nonfulfilled criteria (eg, fixing the remaining bugs and clarifying the end goals) could increase the level of enjoyment even more. To deal with subjectivity, a future study could let adults who were not involved in the design process (eg, parents of playing children) rate the game.

Feasibility

This paragraph discusses 3 relevant points related to feasibility outcomes. First, although most of the participants (50/82, 61%) completed the intervention, we still acknowledge that 39% (32/82) participants dropped out at some point, mostly in the last game phases. This slightly corresponds to another home-based preventive intervention study in Dutch children at risk for dyslexia, which reported an attrition rate of 34% [94]. Unfortunately, the attrition rate of this paper still exceeded the desirable benchmark of 30% [95], and further research on why participants tended to drop out at some point is necessary. In a study by Justice et al [96], who investigated the feasibility, efficacy, and social validity of a 12-week home-based shared storybook reading intervention in preschoolers with language difficulties, the authors compared completers with noncompleters on a variety of child- and parent-specific characteristics and established risk factors of dropout, such as lower maternal age and lower parental educational levels. Distinguishing completers from noncompleters based on intrinsic and extrinsic features did not fall within the scope of this paper, albeit the research methods applied in the study by Justice et al [96] offer possibilities for future research that could be of added value to optimize the feasibility of the current intervention program. Irrespective of the rather high attrition rate, we still established a completion rate of 80% (approximately 57th session of the total 72 story sessions) in 90% (74/82) of the participants, suggesting that shortening the intervention by approximately 15 sessions, which almost equals 4 weeks in this paper, would result in lower dropout occurrence. However, an important sidenote relates to the fact that the participants in this paper combined the intervention with another tablet game (GG-FL or AC games). This could also have affected general motivation and perseverance. The second discussion point related to feasibility bears upon the variation in training intensity among the participants. As treatment fidelity in terms of quality and quantity has been found to predict learning outcomes in previous studies [94,97], the variation in training intensity cannot be neglected when investigating the educational impact of interest in future studies. However, in their reading intervention study, Katzir et al [98] found larger gains in sight word efficiency in a group of grade 1 to 3 children at risk for reading difficulties who received a 44-hour fluency-based therapy over a 9-month period compared with

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children who followed the exact same intervention within a more intensive period of 2 months. Hence, albeit the need for statistical confirmation in a future study, spacing out the story game intervention over time in this paper might have even benefited the expected educational learning outcomes. The last feasibility-related discussion point is linked to the prediction of the final game exposure and training duration based on story appreciation and QRA at the start of the intervention. The outcomes of these predictive analyses point to limitations in the current game design but give rise to suggestions for optimizing intervention feasibility in future studies. For example, given the importance of initial story appreciation to maintain the advised training intensity, a possible suggestion involves offering the storybook series in the preferred order of the participant. More specifically, providing a catalog menu in which players could choose which story series occur first might increase the story appreciation at the beginning and, as a result, the engagement to follow the advised schedule. Moreover, given the role of initial QRA in dropout occurrence, offering player-adapted questions based on an individual's language knowledge and cognitive capacities, which then increase in difficulty, instead of fixed, predefined questions for all participants, might prevent participants from withdrawing from the study. A more interactive approach in which players could request and receive explanations of possible difficult words might also increase the chance of successfully responding to the questions from the start, lowering the chances of early dropout. However, a disadvantage of these proposed adjustments to prevent attrition relates to the fact that the growth of in-game QRA data then becomes less easily interpretable at the group level, as participants would follow an individually adapted trajectory. However, large-scale adaptability has been widely considered as one of the strengths of serious digital gaming interventions [4]. Furthermore, according to our GameFlow-based evaluation in its current form, the criterion of so-called *player-adjusted challenges* belonging to the overall challenge principle is lacking in the current story game. Although this principle was beyond the scope of the story game, its implementation could increase player enjoyment and decrease the attrition rate [5].

Growth in Language Comprehension

The results related to growth in language comprehension must be interpreted with extreme caution, and several important limitations should be elucidated. The first and most important limitation relates to the research design. In fact, the actual impact of the game on language comprehension can only be solidly established by conducting a randomized controlled trial (RCT), which was not performed in this study. Hence, although we found a larger growth in mean QRA in children with lower listening comprehension, the current research design does not allow us to draw univocal conclusions on the potential of the game to train language comprehension. Thus, a future RCT study, preferably including (1) a group that is purely playing the story game without combining it with other interventions such as GG-FL or AC games, (2) a no intervention control group, and (3) a control group receiving an alternative placebo treatment that does not specifically train language skills [99], is of crucial relevance to further disentangle the gaming effects on language comprehension. The second important limitation is related to the concept of content validity. We considered the in-game questions as a measure of language comprehension. However, despite the selection of age-appropriate stories based on library visits and the construction of the questions based on the vocabulary of the story content, the stories and questions did not belong to a validated comprehension test instrument, casting doubt on the certainty that we truly measured language comprehension in our participants [100]. In addition, we are unsure whether all questions and stories implemented in the game were of equal difficulty, although we found relatively stable response distributions for most of the questions. Hence, changes in performance might not be because of the intervention effects but simply because of the varying difficulty of the questions and stories. Conducting the pre- and postintervention measurements of independent language comprehension tests within an RCT design with appropriate control groups (as mentioned previously) would eliminate this concern. The third limitation discusses the distribution of the mean QRA in the first game phase, which already showed a tendency toward the ceiling. Hence, children with high accuracy scores from the start, which were related to higher baseline vocabulary and listening comprehension, did not have the potential to increase any further during the intervention, influencing the interpretation of the game phase–listening comprehension interaction. The high accuracy scores at the start of the study are presumably attributed to the fact that none of the participants in this paper experienced language difficulties. Indeed, originally, the story game was not developed to train language comprehension within the framework of the current research project but rather to investigate the potential of envelope-enhanced speech in children with a pure cognitive risk for dyslexia. Another factor that may influence the high initial accuracy scores relates to the type of posed questions. The questions intentionally only involved identifying or recalling items that were explicitly mentioned in the story text and thus examined language comprehension only at the literal language level [101]. Hence, questions at the inferential level, which, for example, require implying emotions, predictions, and connections between information within the text or with the child's own experiences [102], were not part of the story game in its current form. For preschoolers, inferential questions are certainly more difficult to answer than literal ones [101]. However, given the scope of the story game within the current research project (ie, exposing children at risk for dyslexia, in a joyful way, to either envelope-enhanced or nonenhanced speech), questions were not supposed to be or become difficult but only served as a way of (1) ensuring active listening and (2) ascertaining that players earned as many coins as possible, increasing the chance of maintaining the intervention for 12 weeks. On the basis of these aforementioned limitations, the preliminary and cautiously interpreted results concerning a possible growth in language comprehension give rise to 3 important ideas for story game improvement if it would be used to train language comprehension at some point in populations with specific problems in this domain (eg, children with low socioeconomic status; bilingual children; and children with DLD, hearing impairment, or dyslexia). First, there is a clear need to include inferential questions, as Tarvainen et al [18] emphasized the importance of inferential language training in fostering language comprehension in preschoolers. Second,

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apart from optimizing the research design by conducting RCTs with adequate intervention and control groups, it is also of crucial relevance to include test batteries that assess comprehension at both the inferential and literal levels. The currently used CELF-4th edition, Dutch version [82] and Peabody Picture Vocabulary Test–III, Dutch version tasks [83] mainly focus on language comprehension at the literal level [101], emphasizing the need to add inferential language comprehension test batteries to the research protocol. Finally, researchers must take into account and tackle the possibility that children with lower language levels might show less motivation in storybook interventions than their typically developing peers [103].

Conclusions

Overall, this newly developed story game seemed generally feasible and enjoyable for children aged 5 years with an elevated cognitive risk for developmental dyslexia. Moreover, our results preliminarily but carefully point to a potential for the game to train language comprehension. Hence, we hope to apply the story game in follow-up studies with an optimized study design in children who, for whatever reason, exhibit actual language comprehension difficulties. As such, we will be able to (1) generalize our enjoyment and feasibility findings and (2) draw solid conclusions on the actual influence of the game on language comprehension.

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Authors' Contributions

FVB contributed to the data collection and processing, project administration, and writing of the original draft. ME was involved in project administration and data collection and processing and reviewed and edited the draft. WD programmed the tablet game described in the study and mostly contributed to the multimedia appendices. MV, JW, PG, and JV conceptualized and received funding for the project. Moreover, they supervised the project and were involved in reviewing and editing the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1479 KB - games_v10i1e34698_app1.pdf]

Multimedia Appendix 2
Technical story game development guide.
[PDF File (Adobe PDF File), 1005 KB - games_v10i1e34698_app2.pdf]

Multimedia Appendix 3
Demonstration movie of the story game (© 2016 Clavis Publishing, Hasselt–Alkmaar, New York; illustrations and audiotext from *Lotta en de slodderkip* from Diane Put and Rik De Wulf).
[MOV File , 107306 KB - games_v10i1e34698_app3.mov]

Multimedia Appendix 4
Overview of the child and parental categorical questions and response possibilities.
[PDF File (Adobe PDF File), 180 KB - games_v10i1e34698_app4.pdf]

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Abbreviations

AC: active control
CELF: Clinical Evaluation of Language Fundamentals
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
DLD: developmental language disorder
EE: envelope enhancement
GG-FL: GraphoGame Flemish
KU Leuven: Katholieke Universiteit Leuven
QRA: question response accuracy
RCT: randomized controlled trial

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Original Paper

Developing a Health Game to Prepare Preschool Children for Anesthesia: Formative Study Using a Child-Centered Approach

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Abstract

Background: Every year, millions of children undergo medical procedures that require anesthesia. Fear and anxiety are common among young children undergoing such procedures and can interfere with the child's recovery and well-being. Relaxation, distraction, and education are methods that can be used to prepare children and help them cope with fear and anxiety, and serious games may be a suitable medium for these purposes. User-centered design emphasizes the involvement of end users during the development and testing of products, but involving young, preschool children may be challenging.

Objective: One objective of this study was to describe the development and usability of a computer-based educational health game intended for preschool children to prepare them for upcoming anesthesia. A further objective was to describe the lessons learned from using a child-centered approach with the young target group.

Methods: A formative mixed methods child (user)-centered study design was used to develop and test the usability of the game. Preschool children (4-6 years old) informed the game design through playful workshops (n=26), and usability testing was conducted through game-playing and interviews (n=16). Data were collected in Iceland and Finland with video-recorded direct observation and interviews, as well as children's drawings, and analyzed with content analysis and descriptive statistics.

Results: The children shared their knowledge and ideas about hospitals, different emotions, and their preferences concerning game elements. Testing revealed the high usability of the game and provided important information that was used to modify the game before publishing and that will be used in its further development.

Conclusions: Preschool children can inform game design through playful workshops about health-related subjects that they are not necessarily familiar with but that are relevant for them. The game's usability was improved with the participation of the target group, and the game is now ready for clinical testing.

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KEYWORDS

anesthesia; child-centred design; children; digital health; educational games; health games; hospital; patient education; serious games; surgery; user-centred design; video games

Introduction

Young children worldwide undergo anesthesia in relation to various medical procedures, including surgery, dental procedures, physical examination, and medical imaging, and the uncertainty of the upcoming procedure may cause anxiety and distress. The reported prevalence of such anxiety is up to 50% in preschool children [1]. Children may experience fear because of the unfamiliar hospital equipment, environment, and staff, as well as pain, separation from parents and family, and being left alone [2,3]. In the short term, the child's anxiety can cause difficulties in the induction of anesthesia and may precipitate perioperative complications, such as delirium and postoperative pain [4,5]. In the long term, behavioral changes, such as apathy, bedwetting, sleep disturbances, feeding difficulties, temper tantrums, and fear of medical personnel, are well known [6,7].

Among successful nonpharmacological interventions that can reduce procedure-related anxiety in children are education about the upcoming procedure and cognitive behavioral therapy [8]. Education about the upcoming procedure can take place in discussion with health care professionals and parents [9]. Discussions help children separate imagination from reality, build trust, reduce uncertainty, and increase children's belief that they can cope with stressful situations [10]. Cognitive behavioral therapy, such as positive self-talk, relaxation, and deep-breathing exercises, have also been successful in reducing procedural distress and pain in children [11]. However, such techniques need to be taught and practiced before the procedure in order to be beneficial. Combined educational approaches, such as play therapy with information provided through video, modeling, puppet shows, or visits to the operating theater, have also been successful in reducing children's anxiety [8,12-14]. The limitations of many such programs are poor accessibility and high costs, including human resources [15], but information technology, such as educational games, offers new and more feasible approaches to preparing children for medical procedures [8].

Games are a medium that can be useful for teaching and supporting coping skills and thus strengthening self-efficacy, health literacy, and knowledge in young children. Only a few health games have been developed to help prepare children for hospitalization and surgery. Promising results in improving children's knowledge and tackling their anxiety have, for example, been achieved with the health games HospiAvontuur [16] and CliniPup [17]. A virtual reality approach, presenting the preoperative process with gamification, has also been effective in reducing anxiety in young children 5-8 years old [18].

The input of users is acknowledged as fundamental for success in designing technology. User-centered design addresses the whole user experience during the iterative process of design and development and includes multidisciplinary perspectives and skills [19]. It focuses on gaining an understanding of the user of the product and involves the user throughout the design and development phases [20].

Child-centered design derives from user-centered design and acknowledges the notion that it is desirable to incorporate children's perspective, rights, and needs in the design process [21] in order to increase the usability and acceptability of the technology, and also that young children are able to participate and give their opinions if the design and involvement is presented in a child-oriented manner. Children can be involved as users, testers, informants, or design partners, depending on their participation at different stages of the design process [22]. Involving young, preschool children may be challenging [23] as their physical, cognitive, social, and emotional development and skills, such as motor skills or social skills, vary, both within the same age group as well as between different ages in general [21]. Abilities in abstract and logical thinking, and translating experiences into verbal statements, are not yet fully developed in young children [24], and they may have difficulties putting their feelings into words [23]. This means that when assessing their engagement during testing of a product, more than 1 evaluation method is required [23]. An observation of a set of behaviors, rather than their responses to questions, may be a better way to understand their true thoughts [24]. Therefore, children's level of engagement during testing a product or participating in the design can be monitored or assessed with behavior such as frowns and yawns [25], fiddling, shrugs or ear-playing [26], vocalization (either positive or negative), concentration, smiling, or laughing [24]. When designing with children, using age-appropriate language, avoiding unfamiliar and abstract concepts, and paying attention to their existing attitudes, beliefs, previous experiences, and motives related to the health topic may all influence children's understanding and their willingness to use the health information [24]. These can be explored during the user-centered design process.

An objective of this formative study was to describe the development and usability of a computer-based educational health game intended for preschool children to prepare them for upcoming anesthesia. A further objective was to describe the lessons learned from using a child-centered approach with the target group.

Methods

Study Team

A multidisciplinary team of researchers, pediatric and emergency nurses, a pediatric psychologist, a preschool teacher, and nurse anesthetists from Iceland and Finland initially identified the need for improved preparation of children for anesthesia and created the basic idea and concept of the game. In collaboration with a private game company and a composer, the team was expanded for the purpose of designing and implementing game techniques, graphics, and music.

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The development and evaluation of the game followed a child-centered design, a process starting with the identification of a need and leading to a product that meets child-specific requirements [19,27]. The approach used included 2 steps: (1) specifying product requirements and producing design solutions through participatory design (workshops) and (2) evaluating the usability of the design by children through usability testing.

To specify the context of use, information was first collected on the current situation in clinical practice from both within the research group and with interviews with clinicians (1 anesthetist and 2 anesthetist nurses). In addition, the parents of 17 children were interviewed about their experiences of having and managing children undergoing anesthesia. Throughout the design process, the game was tested by children in the target group and simultaneously the interview frame used in the usability testing was created. The game was developed, tested, and published in 2019-2020.

Development of the Game

Workshops

Preschool children were invited to inform the design process and to specify the product requirements through playful workshops after the initial idea of the game had been formed. The aim of the workshops was to explore the children's general perceptions and knowledge about hospitals and emotions that were relevant to the game project. The workshops were planned with parallel protocols in both countries and first piloted with a comparable group of children. Minor adjustments were made to the setup and tasks after that.

Preschools in Iceland and Finland were contacted for collaboration purposes to assist with finding participants and to provide locations for the workshops. A purposive sampling method [28] was implemented, and those eligible for participation were children aged 4-6 years who could understand Icelandic/Finnish. The workshops were held in a preschool classroom and facilitated in Iceland by 1 preschool teacher and 2 nurses from the research group and in Finland by 1 nurse researcher. During the workshops, data were collected with direct observation (free text notes), interviews (open-ended questions with probing to deepen, develop, or clarify the interview answers), photos, and the children's drawings. The researchers documented the age and gender of the children. All the workshop sessions were audio-video-recorded.

The workshops included 3 tasks: a board game, a poster walk, and drawing (Table 1).

Table 1. An overview of the workshops.

Task	Aim	Equipment	Children, n	Facilitator, n	Duration, minutes
Board game	Explore ideas about hospitals and emotions.	• Dice, counters, board, bag with hospital equipment, 2 boxes with questions (on hospitals and emotions)	4-5	1	20-30
Poster walk	Explore preferences and emotions.	• Printed posters presenting different types of characters, color palettes, and surroundings • Posters used to address the subject of emotions	2	1	10
Drawing	Explore ideas about hospitals through drawings and conversations.	• Paper and crayons	2-3	1	10

Each workshop had a group of 4-6 children who knew each other so that everyone would feel comfortable talking and communicating. The classroom was prepared before the children entered, with a big printed-out board game on the floor, and pictures with different color schemes and figures were hung on the walls. Sitting on the floor, after an introduction, the workshop facilitator explained the purpose of the workshop to the children and that it would be video-recorded and asked for the children's consent for doing so. The children were asked whether they wanted to participate and told they could quit any time they liked.

Board Game

The board game was chosen as a medium to explore the children's perceptions and knowledge about hospitals and their understanding of emotions related to the game project (ie, fear, excitement, pain, courage, relaxation, and anxiety). Playing the board game included throwing a pair of dice, moving a counter on a premarked surface, and, depending on the color of the surface, getting a different type of question to answer about (1) hospital and illness, (2) common hospital equipment, and (3) emotions. When playing the board game, the researchers tried to get into a fairytale way of thinking and talking to encourage the children's creative thinking. The questions about hospital and illness were open ended to get the children to express their thoughts and ideas and included the following: *Why do people go to hospitals? What happens in a hospital? What people would you see, or meet in the hospital? What does a nurse and a doctor do? What is a medicine and why do you get it? What "things" (equipment) are in a hospital?* When the children got a question about hospital equipment, they were asked, *What do you think this is used for (demonstrating a stethoscope, a facemask, an*

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intravenous cannula, a syringe, an anesthesia balloon with an attached mask, or a Band-Aid)? The children were also asked about each of the 6 emotions relevant for the game, for example, *Sometimes we need to be brave; do you know what that means? Sometimes we are scared of something; what does that mean?* During the gameplay, the discussions were also directed to the children's favorite foods and drinks (to use in the preoperative fasting levels) and what kind of helpers (ie, soft toy or figure) to escort the game's character and selection of rewards they would like the game to offer.

Poster Walk

Next, the group was divided into pairs, and each pair was invited to take part in a poster walk with the workshop facilitator. The aim of the children's poster walk was to inform the game design through conversation and simultaneously provide a sense of security by pairing each child with a friend. The children were asked to pick from a selection of posters the color palettes, characters, and surroundings they liked the most. Each child was given 9 stickers, 3 for each selection. In pairs, they explored the options with the workshop facilitator and then put a sticker on the posters they liked the most. When they had selected their favorite posters, they were asked why they had chosen that picture and the conversation guided them to why they liked or disliked certain things.

Drawings

While some children participated in the poster walk, the others sat at a table with paper and crayons. They were invited to draw a picture about hospitals to help them communicate and process their thoughts and give the researchers insight into their perceptions or knowledge about hospitals.

Usability Testing

The usability of the game was tested by first observing children play the developed game and then interviewing them afterward. The aim of the usability testing was to evaluate the ease of use, attractiveness, and functionality of the game from the children's perspective. In Iceland, the group comprised children (n=9, 56%) who had also participated in the game design workshops described in the Development of the Game section 1 year earlier. The testing took place in the children's playschool. In Finland, children (n=7, 44%) were recruited for testing by convenience sampling [28]. The testing was conducted at the children's homes (n=2, 13%) or, due to the COVID-19 pandemic, via teleconferencing software with parental assistance (n=5, 31%). The researchers documented the children's age and gender, and data from each child were marked with a code letter to replace their name. Each session was audio- and video-recorded.

Observation

In Iceland, the usability testing was facilitated by 2 or 3 researchers. The children were divided into groups of 2 or 3, and each child was given a headphone and a tablet computer with the game ready to play. The children were asked to play the game, and while they did so, 1 researcher sat beside each child, observed what happened, and was available to help, when needed. In Finland, the children were observed by the researcher during gameplay via teleconferencing software in 5 cases.

To determine *ease of use*, the children were observed to see whether they were able to move between the levels and start and play the levels independently and without problems. Researchers also observed how the children solved problems during the gameplay, whether they were stuck or confused, and whether they were able to proceed within the game without help. *Attractiveness* was evaluated by observing each child's engagement and signs of enjoyment and interest. *Functionality* was evaluated by observing whether the game functioned without technical difficulties, and if not, such difficulties were noted.

Interviews

After playing, the children were interviewed, either in groups (Iceland) or individually (Finland), by the facilitator about their gaming experience, using an interview framework that was developed during the game design process (Textbox 1).

Textbox 1. Interview framework for usability testing.

- What did you think about Mina the Owl and the Land of Dreams—the music and the colors in the game?
- What was fun or dull, and easy or difficult in the game?
- What did you think about the exercises? When can you use these exercises? Can you show me how to do it?
- What do you think happens when you have to go to the hospital? What would you tell other children will happen if they have to go to the hospital?
- Do you feel that you would like to play the game all over again/continue playing?
- Have you used a tablet computer like this before? Have you played a computer game before?

Data Analysis

To analyze the data, descriptive statistics and directed content analysis were used [29]. With this qualitative approach, meaning is interpreted from the content of data. Codes are derived from theory or relevant research findings and defined before or during data analysis, thus supporting or extending the existing theory. Coding is conducted with the predetermined codes, and data that cannot be coded are analyzed to determine whether they represent a new category [29].

Data analysis was performed by 1 researcher in each country (authors BI/KG and EL). To enforce reliability, a detailed analysis frame was created for the video recordings, which was discussed thoroughly and collaboratively by the research group, both before and during the data analysis, and the researchers verified coding with each other. The recordings from each session (workshops and usability testing) were watched/listened

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to and analyzed first, and then a summary of all sessions was written to describe the findings.

When preparing the analysis of data from the workshops, 2 categories were predetermined: *ideas about hospitals* (with subcategories on what happens in hospitals, people in hospitals, equipment in hospital) and *ideas about emotions* (with subcategories on each emotion explored, ie, fear, courage, excitement, relaxation, pain, and anxiety). The data, that is, the observations (video recordings), field notes, and drawings were analyzed from these 2 categories.

When analyzing data from the usability testing, the analytic framework included both evaluation of the child's perspective (ease of use and attractiveness) and technical issues (functionality). Coding was performed by marking a plus (+) or a minus (–) for each factor, depending on whether there was or was not a problem requiring assistance or whether the child did or did not look to be engaged, interested, or enjoying during playing. The usability was evaluated by counting the frequencies, that is, how many children, of the 16 participants, managed to start each level and proceed with playing the game without problems and how many looked to be engaged, interested, or enjoying playing the game. Thus, possible scores ranged between 0 and 16, with higher scores indicating higher usability. A copy of the observation sheet can be found in Multimedia Appendix 1. For the interviews that followed the game-playing, *attitude toward the game* and *what happens in the game* were chosen beforehand as categories for coding.

Ethical Considerations

The study was approved by the National Bioethics Committee in Iceland (VSN-19-093) and the ethics committee of the University of Turku, Finland (December 16, 2019). The researchers also acknowledge the United Nations' Conventions on the Rights of the Child [30], which states children's right to freedom of expression, including to seek, receive, and impart information and ideas of all kinds. In addition, this study was guided by the Children's Design Guide, which aims to refine a new standard for the development of products and services that have ethics and children's best interests at their core [31].

The parents in both countries received written information and signed an informed consent form before their children participated in the study. In Finland, the information was given to the children in a written but age-appropriate way, and the parents were asked to read the information to their children and discuss the study with them. Both parents and children signed the written consent form before participation in Finland; in Iceland, only the signature of a parent was required.

Results

Development of the Game

Workshops

A total of 26 children (13 girls and 13 boys, 50% each: Finland n=12, 46%; Iceland n=14, 54%) participated in the 1-hour-long workshops. When asked about their thoughts and perceptions concerning hospitals, the activities happening in hospitals, and the people they could expect to meet there, the children gave various responses. They perceived hospitals as places where you go "to be fixed," "to be examined," "they take your weight or put you to sleep," or "they cut and there is blood." The people they met in the hospital settings were "nurses, doctors, and patients," and they also expected to see "ambulances" and "machines to take pictures of your bones" in the hospitals. Other hospital-related issues the children mentioned included medicines, which they referred to as something "you have to eat to get cured if you are ill." The fun things children expected in hospitals were "prizes, toys, and juice cartons." When children drew pictures related to their perceptions about hospitals, they illustrated themselves often as small figures against the huge hospital equipment and isolated from their loved ones. Examples of the drawings are presented in Figures 1-3.

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Figure 1. Me in a hospital (1).



Figure 2. Me in a hospital (2).

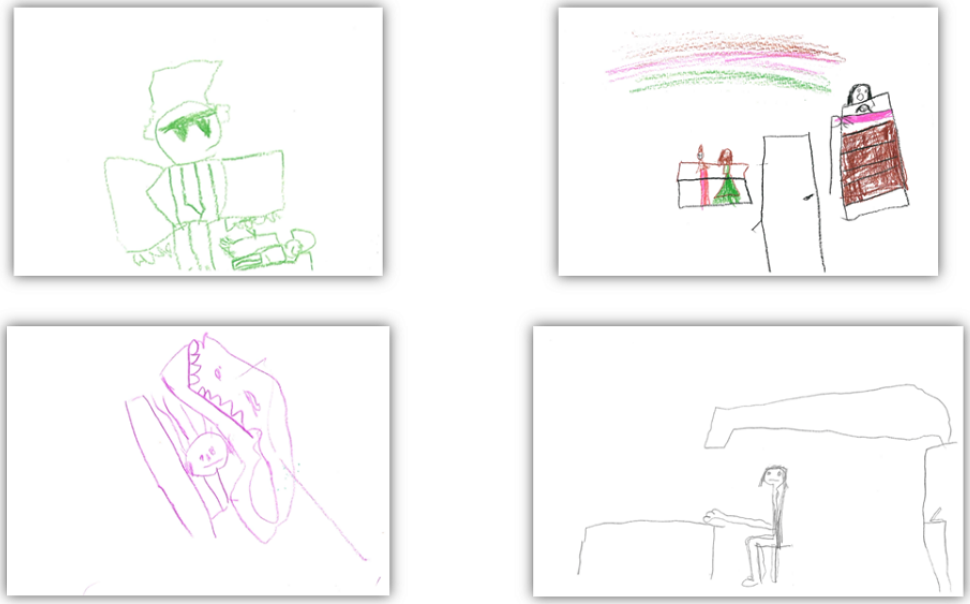


When showed commonly used hospital equipment and asked whether they knew its purpose, the children could easily recognize the purpose of a stethoscope (“to listen to the heart”), a syringe (“for a medicine,” “for an injection, then it has a needle on”), a Band-Aid (“when there is blood,” “when it hurts”), an anesthesia mask (“you use it to breathe in medicine for your lungs”), or a medical mask (“it is this thing, when you have something, you put it on so that the bacteria won’t spread from

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the doctor," "you put it on the mouth"). The drawings also represented knowledge and realistic ideas about hospital equipment, for example, the big lamp, X-ray equipment, faces with masks, and syringes (see Figures 1-3).

Figure 3. Me in a hospital (3).



When discussing feelings and emotions, the children perceived *courage* as a sense or an action, for example, "you save someone," "being alone in the dark," "not being scared when something is exciting," "going where there is a monster," or "going somewhere when you don't know what is there." A child with hospital experience said that you need to be courageous there but will be rewarded with various prizes and treats. When talking about *pain*, the children had experienced pain in the stomach, ears, and arms and after vaccinations and pain could be relieved by medicine, massage, and rubbing; by a Band-Aid; or by going to a doctor or a hospital. Being *scared* could be related to games, such as pretending to be a ghost, scary animals (eg, lions), watching television, and nightmares, and could be fixed by going to one's parents or other adults or cuddling a soft animal. *Relaxation* was when you are resting, doing something quietly, sleeping, or sitting. Being *excited* was both a positive experience (eg, feeling excited when going to the playground or having a birthday) and a negative one ("it is like being scared, being nervous about what is going to happen") and could be eased by being with your parents or "just don't go there."

When asked what kind of "helpers" or soft toys they would like to bring with them to the hospital, the children suggested unicorns, kittens, foxes, teddy bears, and a frog. They were also asked about their favorite foods and drinks, and popular were pizza and pasta, carrots, rice pudding, chocolate milk, juice, water, hamburgers, hot dogs, and ice cream. For a reward they would like to get in the hospital, the children suggested treats, such as ice cream, a medal, a trophy, toys, and stickers.

Design of the Game

The design solutions were produced by using the results from the workshops, the expertise of the multiprofessional team, a literature review, and discussions with parents and clinicians. The team met regularly to exchange ideas and perspectives and find solutions that met the purpose of the game of being educational while simultaneously providing basic game elements, such as goals, fun, markers of success, and rewards. We decided to design a game that would be available in 3 languages (English, Finnish, and Icelandic), playable both in iOS and Android cell phones or tablets, and freely accessible from Google Play Store and Apple App Store. The game was designed to meet the developmental stages of 4-6-year-old children and to be played at home, with parental supervision, before the medical procedure.

The final game was programmed in the C# programming language and designed in the Unity game development environment [32]. Throughout the design process, the game was tested by children in the target group.

The game is a mixture of adventurous and realistic contents and presents a child's trip to the hospital through a landscape inspired by Icelandic nature. The child in the game is escorted by a narrator (Mina the Owl). The game starts with a short introduction and an invitation to choose from a selection of 4 avatars (characters) and 4 helpers (unicorn, fox, cat, teddy bear). The storyboard consists of 9 game levels, which are divided into 2 main sections. Levels 1-5 are set in nature, and the subject is preparation for hospitalization, that is, preoperative fasting, bathing, and teaching coping skills with positive self-talk, encouragement, and relaxation exercises. The second section, levels 6-8, introduces the hospital environment with a mixture

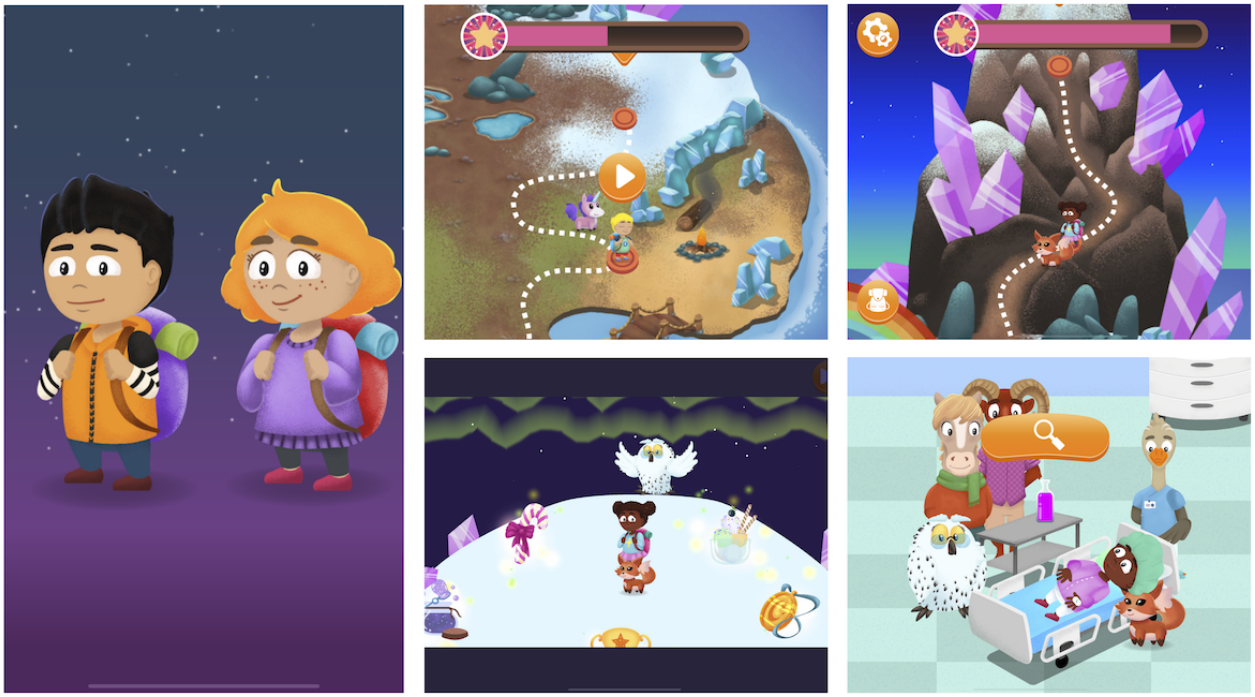
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of illustrated animations and 6 short (circa 30-second) real-life videos with a teddy bear in the role of a patient. The videos were recorded in a hospital and focus on the equipment, surroundings, and sounds that the child can expect to see and hear there. Other characters appearing are animals (horse, goose) that represent family and hospital staff. The interface includes a courage meter, which monitors the child's success and gradually fills up during the game; pause and start buttons; and collectible items, which are retrieved during the game. Figures 4 and 5 present screenshots from the game's interface.

Figure 4. Screenshots from the hospital videos integrated in the game.



Figure 5. Screenshots from the different game levels.



The soundtrack for the game is original, and the composer's aim was to create an atmosphere that matched the intention of the game, suggesting both mysterious adventures and a safe environment. A flute, a cello, and a vibraphone were used for the music, which was recorded in an old church in rural Iceland and then edited to match with environmental sounds in the game, both in nature and within the hospital. Table 2 presents the game's storyboard and the tasks tested in the usability study,

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with information about the children's input into the original game design.

A short trailer of the game can be viewed on YouTube (Multimedia Appendix 2).

Table 2. Description of the interface, related tasks, and the children's contribution to the game design.

Interface description	Tasks for the children to engage in	Children's input into the game design
Mina the Owl greets the child and explains the game.	Listen to the introduction.	NA[a]
Four avatars (characters) to choose from.	Choose an avatar.	NA
Four helpers to choose from: unicorn, fox, bear, and cat.	Choose a helper.	They gave a list of their favorite soft toys.
Landscape with food distributed on the ground. A stomach fills up with each collected food item.	Level 1: Collect food.	They gave a list of their favorite foods.
Mina teaches the child an exercise.	Level 2: Learn deep-breathing exercises. Choose between proceeding or replaying the level.	They showed how to blow soap bubbles and do deep-breathing exercises.
Landscape with water (river, waterfall, rain, ponds) and drinks to collect. A bottle fills up and needs to be shaken to complete the level.	Level 3: Collect drinks, shake the bottle, and drink.	They gave a list of their favorite drinks.
A rag doll and a robot appear, and Mina teaches the child to relax and repeat the movements.	Level 4: Learn relaxation. Choose between proceeding or replaying the level.	They discussed the concept of excitement and relaxation.
Landscape with bathing gear distributed on the ground.	Level 5: Collect bathing gear.	They discussed what is needed when one takes a bath.
Hospital environment with additional characters (representing hospital staff and family).	Level 6: Visit 3 rooms and find and watch 6 short videos.	They expressed through drawings and discussions that the environment can be overwhelming, with huge and bright lamps, staff with green/blue hats, parents who are isolated from you, painful procedures, etc. These findings led to the decision to add to the game both figures representing family members and short, realistic hospital-based videos.
Hospital environment, preparation for anesthesia. The child falls asleep, flies in the sky in the Land of Dreams, and then wakes up.	Level 7: Preparation room, operation room, and back to preparation room. Find and attach an intravenous infusion and a mask.	See the "Children's input into the game design" for level 6.
Trophy room with a selection of trophies.	Level 8: Choose a trophy.	They provided ideas about attractive trophies or rewards that they would like to receive in a hospital.

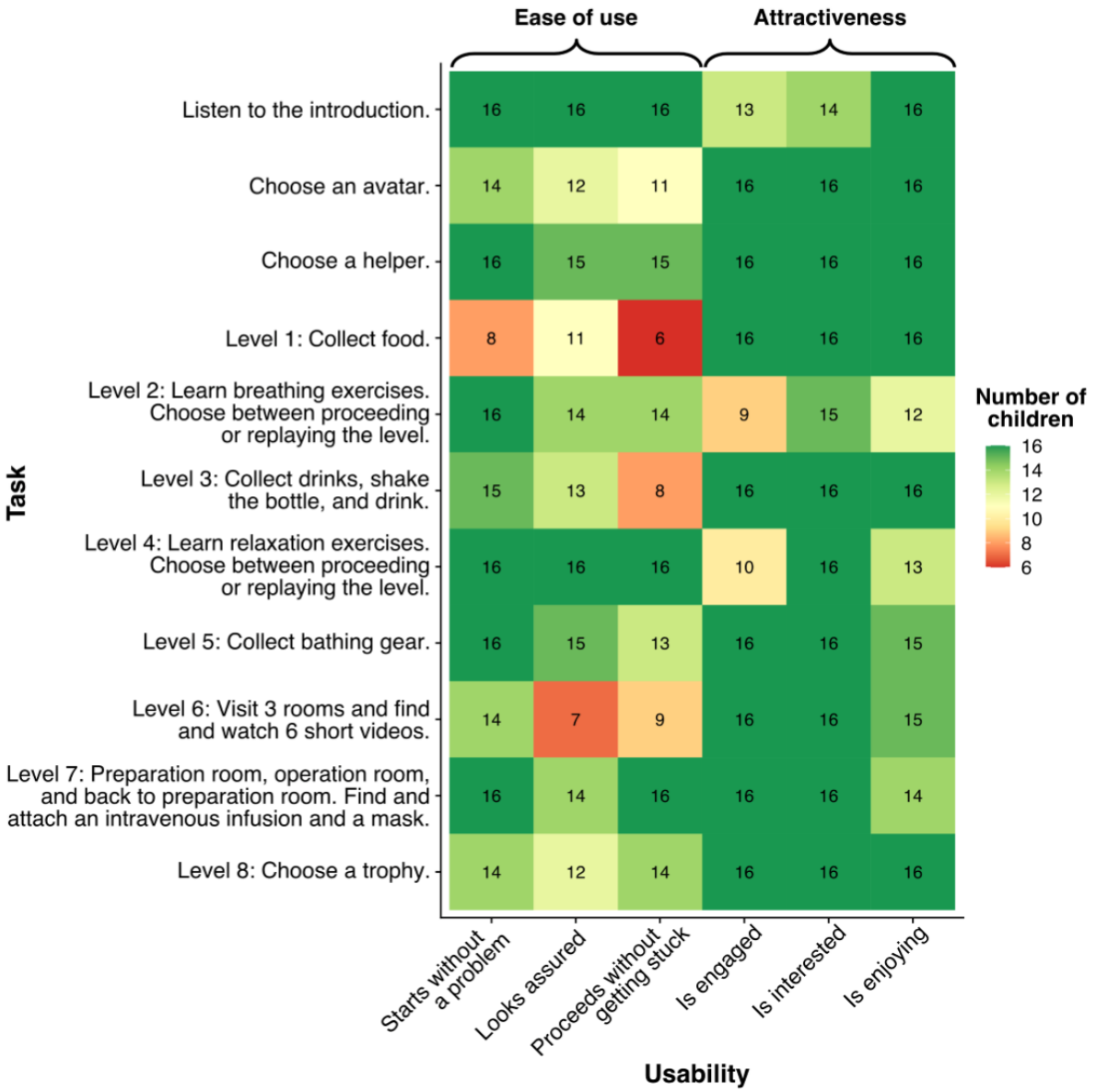
[a]NA: not applicable.

Usability of the Game

A total of 16 children (12 [75%] girls and 4 [25%] boys: Finland n=7, 44%; Iceland n=9, 56%) participated in the usability study. Their median age was 5 (range 4-6) years. Four children had not played a computer game before, but all were familiar with a tablet computer. The results from the usability testing are presented in Figure 6.

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Figure 6. The children's (n=16) perspective of the usability of the game.



Ease of Use

The assessment of *ease of use*, that is, the degree of difficulty in starting or moving between the levels, revealed that only a few problems arose with these tasks (Figure 6). No child gave up or refused to continue playing. Overall, the children began, paused, and stopped at each level without assistance or with minimal assistance and were quick to learn how to proceed.

Attractiveness

In the beginning, the guide and narrator, Mina the Owl, greets the player and starts the game with an introduction, and throughout the game, as each level unfolds, she breaks in with explanations. It was observed that although some of the children started to listen attentively when the owl spoke, others lost interest and got impatient to proceed or even tried to continue while she was still talking (which was not possible). During the interviews with the children, this was confirmed: they liked the owl, but she "talked too much." This was especially evident in the 2 exercise levels, which include the deep-breathing exercises and relaxation. The children observed and listened attentively while the owl explained and encouraged them to try the exercises, but few children wanted to practice the exercises; some of them became a little distracted and wanted to proceed to the next level.

The children liked the game's characters and helpers and chose them quickly. The unicorn and cat were the most popular helpers (6 [38%] children chose each), followed by the fox (n=4, 25%), and no one chose the teddy bear. The characters in the hospital levels representing staff and parents were perceived as a bit strange but funny as they were not humans but animals.

In general, the children showed interest and were engaged throughout the game-playing. They expressed both concentration

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and joy through smiling and chuckling while learning to gather the collectibles (food, drink, bathing gear) and interest, curiosity, and concentration when they entered the hospital levels. At this stage, they noticed more the courage meter and the incoming points and got more excited about this. The game finishes in the trophy room, where the children can choose different prizes. At this point, some of the children had had enough and did not want to listen to the Mina the Owl completing her talk.

During the interviews, the children could recall detailed information from the game, such as that the intravenous fluid was for surviving, and could describe the equipment in the hospital room quite well. What they found most fun was choosing the characters; walking in nature while retrieving the collectibles; eating, bathing, and drinking to get energy; going to the hospital; moving the characters; and getting the trophies. They also referred to watching the video clips as enjoyable and could easily recite what happened to the teddy bear in the hospital. At the hospital, the character flies to the Land of Dreams when the anesthesia is initiated. This was a well-recalled level. The music was perceived as nice, but some children did not notice it. All but 2 (13%) children replied that they would like to play the game again.

Functionality

This part assessed whether the game functioned well without technical difficulties. All the children (n=16, 100%) managed to complete the game in a similar time; it took them approximately half an hour to play (median 30 minutes, range 25-37). Although no technical issues arose during the testing in Iceland, a few functionality problems were noticed in Finland, which were repaired after the usability study.

Discussion

Principal Results

This paper presented in detail how preschool children were involved in the development and testing of a serious health game targeted at their own age. A well-defined and structured process was followed, linking design and research to gain better evidence on this novel approach to educating young patients. An interdisciplinary approach in 2 countries was used to ensure diversity in the game design, and the robust data collection methods and appropriate sample size ensured the quality of the study. Professionals were chosen to facilitate the workshops and usability testing and to communicate with the children in a way that was appropriate for their developmental stage.

The purpose of a study like this is not to produce data to generalize from but rather to describe in detail the process of the design and the lessons learned and thus to add to the available knowledge about child-centered design. With this paper, the authors are responding to a discourse within serious game design where researchers have called for and emphasized the importance of reporting and describing more and better the design process and the end users' involvement and conducting research parallel to the design process [33,34]. This is important for serious games to have credibility as educational tools in health care.

Comparison With Prior Work

Few previous studies have described similar information where the participants are only preschool children. A child-centered design of games was mainly reported from projects with the participation of children around the age of 7-11 years [22]. During the design process of Mina the Owl and the Land of Dreams, the target group, children aged 4-6 years, were able and eager to articulate their thoughts and perceptions about hospitals, related emotions, and preferences regarding various relevant issues in the game design.

Lessons Learned About Designing With Children

A fact relevant to the game design with this age group is that children have difficulties with abstract thinking; their size and motor skills define their abilities to handle equipment such as computers and accessories, their attention span is limited, and they mainly express themselves through playing [21,24]. They are just starting to practice their literacy skills and are becoming able to read and write simple text [35]. The game was therefore designed using audio recordings of the narratives with subtitles, and tablet computers or smartphones were chosen as platforms, both of which are easy for small children to use. The motor skills that the game-playing requires were appropriate for this age group, and the children accepted the use of tablet computers easily.

Using playful workshops, including playing a board game and encouraging expressions of ideas about hospitals through drawings, was successful, probably because these methods were appropriate to the children's developmental stage. Their cognitive level was carefully considered when abstract concepts, such as different emotions related to hospitalization, were introduced in the game, and it was recognized that at this age, children are just starting to learn to describe their feelings and emotions [22].

The participating children were able to express their preferences about, for example, food, drinks, and toys, and perceptions of hospitals and emotions through discussions and drawings during the game development. They had a common understanding about the purpose of hospitals and what happens there and could identify the various types of hospital equipment presented to them. They used their experience, creativity, and imagination to conceptualize and explain the various emotions relevant to the game. Of special interest are the concepts of fear and courage, which are at the center of the game. The children's drawings indicated a fear of hospitals and a fear of being alone, and pain and blood were found to be part of the expected experience. These findings supported the initial intention of the research group of letting the concept of courage and coping strategies be the focus of the game and confirmed the appropriateness of having the courage meter as a central part of the interface. These findings also led to the decision to add more characters to the game that represent the health care professionals and family members in a playful way. Drawings are a strong medium for children to convey their experience and perceptions about hospitalization [36], and their use proved to be fruitful and conveyed important information for the game design.

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An important issue to consider when working with young children is the power structure linking the child, the researchers, and the game designers. Children are generally expected to be led and directed by adults, but in the developmental process of a game, it is important that the children experience trust and collegiality [22]. Their self-efficacy can be supported with such participation, and it increases the success of implementation of a game.

A child-centered design acknowledges the right of children to have a say in matters that concern them [21], but including children in research entails several ethical considerations, such as awareness of the child's vulnerability, how to gain consent, which methods to use, and how studies are executed [37]. Other authors have emphasized the need to avoid overprotection because of vulnerability and rather view children as social actors who can have a say in their participation in research, but taking this stand requires researchers to communicate effectively with children [38].

It is important and beneficial to interview children in an environment where they feel safe and comfortable [39]. In this project, a trusting relationship and a comfortable atmosphere were created and reflected in the enthusiasm and willingness of the children to share their opinions and thoughts with the researchers. Both workshops and usability testing were conducted in a familiar and safe environment for the children, and they had support from their peers or family. Other measures that the researchers applied to create trust were to deliberately put 1 researcher with a pedagogical background in the front as the main communicator and facilitator of the workshops and usability testing; to carefully introduce themselves, explain the purpose of the game, and seek permission to work with the children; and to use play to communicate with the children and listen carefully to what they had to say. In the play schools, conversations took place on the floor, where the children could freely move, handle toys, and interact with their friends as they were assisted to communicate their thoughts and ideas. All this contributed to the success of the design process and can be strongly recommended.

Overall, the design process helped understand what hospital- and anesthesia-related subjects and concepts need to be explained in the game, and how, in order to ensure they are age-appropriate for the target group.

Lessons Learned About the Usability of the Game

In the usability study, the game proved to be easy to use and was accepted intuitively and easily by the children. They needed minimal assistance, even those who were not so familiar with a tablet computer, and they quickly learned how to proceed in the game. Children nowadays are often familiar with the use of smartphones; a recent study in the United States found that around 60% of children are reported to begin engaging with a smartphone before the age of 5 years [40]. However, there are households that do not support children's use of such equipment, and therefore, computer games should be regarded as an addition to current educational practices and not a replacement.

The content of the game was chosen and designed based on evidence about what creates fear in hospitalized children and on beneficial interventions to tackle children's perioperative anxiety. Children use many coping strategies for hospital-related fears, especially ones where they play an active role and are in control [41,42], and the strategies that were chosen for the game, that is, relaxation and deep-breathing exercises, have proven to be effective [11]. Although the children attentively watched the 2 levels with exercises, they did not join in practicing them during the usability testing, even when invited to do so. This could be a sign of no interest or that the situation and environment were not optimal. Perhaps the children did not understand that when entering the levels with the exercises, different actions were required by them, such as stepping out of the game and into practicing the exercises. This indicates that in future real situations, and for them to be useful, children will need support from parents/adults to learn and practice the game's exercises before entering the hospital. This was an important result from the usability testing and an example of a lesson learned: children do not necessarily think or act in the way adults might suggest or suppose them to. This also highlights the importance of children participating in the development process and in the matters that concern them.

The attractiveness of the game was confirmed with the long attention span the children showed during the 30 minutes it took for them to play. They were engaged and attentive, especially enjoying the interactive parts. This time far exceeded the research group's initial plan of the game's length, recognizing that attentiveness in children of this age group is limited [22], but this time was needed to convey the educational content to the children. It is likely that the engagement was a result of the interactivity in the game and reward system as well as how it features both adventurous animation of nature and a realistic environment of the hospital presented with videos and addressing different actions and educational modules.

The usability testing revealed that the narrative (or the script) of Mina the Owl, who is educating and explaining, was too long, as many children became impatient waiting for the owl to finish talking so that they could proceed in the game. This led to the script being cut down when the game was revised after the testing and before the game was published.

Limitations

The lack of a validated tool to use in the usability study can be regarded as a limitation of this study. The analysis of each of the video recordings was performed by 1 researcher, but the researchers created a detailed analysis plan together beforehand and followed it rigorously. Furthermore, it may also be regarded as a limitation that it was not possible to ensure that an equal number of boys and girls participated in the usability study, which may have affected the results.

The study has provided important information, both about designing a game with young children and also about this particular game, and the findings led to adjustments and changes before the game was published. The study also provided further ideas about how the game could be improved in its next versions. A future feasibility and implementation study within the clinical environment will explore and provide evidence on the efficacy and effects of the game on children's perioperative anxiety, self-efficacy, knowledge about what to expect in the

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hospital/clinic, and coping strategies when undergoing anesthesia.

Conclusion

Preschool children can actively participate in developing educational, computer-based games as a target group and can provide important information about their preferences, understanding of abstract concepts, and the usability of a game. It is important to use child-oriented methods, such as playful workshops, in the design process that safeguard children's rights in research, support trust in the researchers, and are conducted in a safe environment. The usability of the tested game was high in terms of ease of use, attractiveness, and functionality, but long narrative parts were rather challenging for this age group. Important lessons were learned by the study to take into the next phase, where the effectiveness, efficacy, and feasibility of implementing the game in practice will be explored.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The structured observation schedule used in the usability testing.
[PNG File , 98 KB - games_v10i1e31471_app1.png]

Multimedia Appendix 2
Trailer of the game.
[MP4 File (MP4 Video), 3686 KB - games_v10i1e31471_app2.mp4]

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Original Paper

Using Virtual Reality to Induce and Assess Objective Correlates of Nicotine Craving: Paradigm Development Study

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Abstract

Background: Craving is a clinically important phenotype for the development and maintenance of nicotine addiction. Virtual reality (VR) paradigms are successful in eliciting cue-induced subjective craving and may even elicit stronger craving than traditional picture-cue methods. However, few studies have leveraged the advances of this technology to improve the assessment of craving.

Objective: This report details the development of a novel, translatable VR paradigm designed to both elicit nicotine craving and assess multiple eye-related characteristics as potential objective correlates of craving.

Methods: A VR paradigm was developed, which includes three Active scenes with nicotine and tobacco product (NTP) cues present, and three Neutral scenes devoid of NTP cues. A pilot sample (N=31) of NTP users underwent the paradigm and completed subjective measures of nicotine craving, sense of presence in the VR paradigm, and VR-related sickness. Eye-gaze fixation time ("attentional bias") and pupil diameter toward Active versus Neutral cues, as well as spontaneous blink rate during the Active and Neutral scenes, were recorded.

Results: The NTP Cue VR paradigm was found to elicit a moderate sense of presence (mean Igroup Presence Questionnaire score 60.05, SD 9.66) and low VR-related sickness (mean Virtual Reality Sickness Questionnaire score 16.25, SD 13.94). Scene-specific effects on attentional bias and pupil diameter were observed, with two of the three Active scenes eliciting greater NTP versus control cue attentional bias and pupil diameter (Cohen *d*=0.30-0.92). The spontaneous blink rate metrics did not differ across Active and Neutral scenes.

Conclusions: This report outlines the development of the NTP Cue VR paradigm. Our results support the potential of this paradigm as an effective laboratory-based cue-exposure task and provide early evidence of the utility of attentional bias and pupillometry, as measured during VR, as useful markers for nicotine addiction.

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KEYWORDS

nicotine; craving; cue-exposure; virtual reality; attentional bias; pupillometry; development; smoking; addiction; eye-tracking

Introduction

Craving for substances is considered essential for understanding the pathogenesis and maintenance of addiction, as highlighted by the incentive salience model [1,2] and for the inclusion of craving as a criterion for substance use disorder in the Diagnostic and Statistical Manual of Mental Disorders (5th edition; DSM-5) [3] and the International Classification of Diseases (10th edition; ICD-10) [4]. Nicotine craving specifically has been shown to predict lapse to cigarette smoking following cessation [5,6] and is frequently identified by individuals as an important barrier to quitting and maintaining

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abstinence [7]. Thus, craving represents a clinically important phenotype of nicotine addiction [8] with great potential for intervention.

Accurate assessment of craving is essential for the identification, management, and treatment of nicotine and tobacco product (NTP) use and the use of other substances [9,10]. In human laboratory studies, craving for nicotine and other abused substances is commonly measured using the cue-exposure paradigm. The translational value of the cue-exposure paradigm to the naturalistic environment is predicated on the observation that relapse to drug use is often precipitated by exposure to drug-related cues that provoke craving [11,12]. However, naturalistic cues can be very complex and involve a number of contextual factors that are difficult to replicate in laboratory-based cue-exposure paradigms [13], limiting their ability to invoke a *true* craving state [9,14]. New technologies such as virtual reality (VR) afford the opportunity to increase the ecological validity of cue-exposure paradigms through the implementation of interactive and immersive presentations of cues within the typical context of use (eg, the presence of others within a setting where the substance is commonly taken), greatly enhancing our ability to invoke craving in the laboratory [9]. Studies using VR cue-exposure have found great support for its effectiveness in inducing subjective, and in some cases objective, craving for tobacco [15-17], as well as alcohol [13,18], cannabis [19], and methamphetamine [20].

Furthermore, despite decades of research, the field of addiction has yet to establish reliable, objective measures of craving. A number of objective correlates of craving have been investigated, including psychophysiological (eg, heart rate variability and skin conductance) and neurological (eg, functional magnetic resonance imaging and blood oxygenation level dependent activation) measures with varying success [14,21]. Attentional bias, or the ability of drug cues to capture the attention of the user, can be conceptualized as a behavioral marker of incentive salience [22] and represents an objectively measurable and clinically important phenomenon for the study of addiction. Attentional bias toward smoking cues has been previously demonstrated among regular tobacco smokers [23-26], and importantly, it has been related to the risk of subsequent relapse following smoking cessation [27].

Multiple theoretical models suggest that cue-induced subjective craving and attentional bias reflect closely linked underlying processes [1,28,29]. Not surprisingly, measures of attentional bias have been shown to correlate with subjective craving [30]. However, the method of assessment appears to be key—direct measures of attention such as the assessment of eye movement, exhibit larger craving correlations [30] and greater reliability [31-34] than indirect measures such as reaction time. Assessment within naturalistic settings has also independently improved the reliability [35] and validity [36] of attentional bias measurement; yet, the naturalistic constraints of these methods prohibit advanced clinical application of these paradigms. New technological advances in VR implementation allow for the assessment of eye movement in a noninvasive and cost-effective manner and demonstrate early success in distinguishing smokers and nonsmokers on the basis of eye fixations to smoking cues in a virtual world [26].

Spontaneous eye blink rate (EBR) represents another, much less studied, potential objective correlate of cue-induced craving. EBR has been closely linked with striatal dopaminergic function and has been advanced as a reliable [37], more cost-effective, and minimally invasive alternative to positron emission tomography (PET) to assess dopaminergic functioning [38]. Dopamine release in the basal ganglia (including the striatum) inhibits the spinal trigeminal complex, leading to increased EBRs, as demonstrated in both rat and human trials [39]. In line with this theory, preclinical research has shown that direct dopaminergic agonists and antagonists increase [40] and decrease EBRs [39-41], respectively. Furthermore, a PET study in monkeys found a strong positive correlation between EBRs and dopamine (D_2) or D_2-like (D_3) receptor availability in the striatum [42]. Given the observed modulation of striatal dopamine during cue-elicited substance craving [43,44], it may be possible to detect NTP cue-induced dopamine changes through EBR measurement. Nonetheless, no studies to date have investigated this hypothesis.

Lastly, pupillometry represents an additional potential objective craving correlate. Pupil dilation is an indirect measure of norepinephrine (NE) release from the locus coeruleus and is associated with reward processing [45], including sensitivity to rewards [46], and engagement of cognitive resources [47]. Pupillary responses also seem to index changes in the allocation of attention and have been advanced as an ideal measure for related constructs that may not pass the threshold for overt behavior or conscious appraisal [48]. To our knowledge, only one study has investigated pupillometry as a measure of response to substance cue-exposure. Kvamme et al [49] found that pupillary bias toward alcohol versus neutral cues, but not subjective craving reports, predicted relapse to alcohol use in a sample of detoxified patients with alcohol dependence [49], suggesting that cue-induced changes in pupillometry may ultimately serve as a useful biomarker for addiction research and clinical care.

This study was intended to outline the methods underlying the development of a novel VR-NTP cue-exposure paradigm with embedded eye-characteristic assessments. Preliminary analyses on a pilot sample of participants are also provided as a proof of concept for the potential utility of this paradigm for the induction of subjective craving in the laboratory, assessment of potential biomarkers of craving (ie, attentional bias, EBR, and pupillary dilation), and prediction of NTP use behaviors.

Methods

NTP Cue VR Paradigm Development

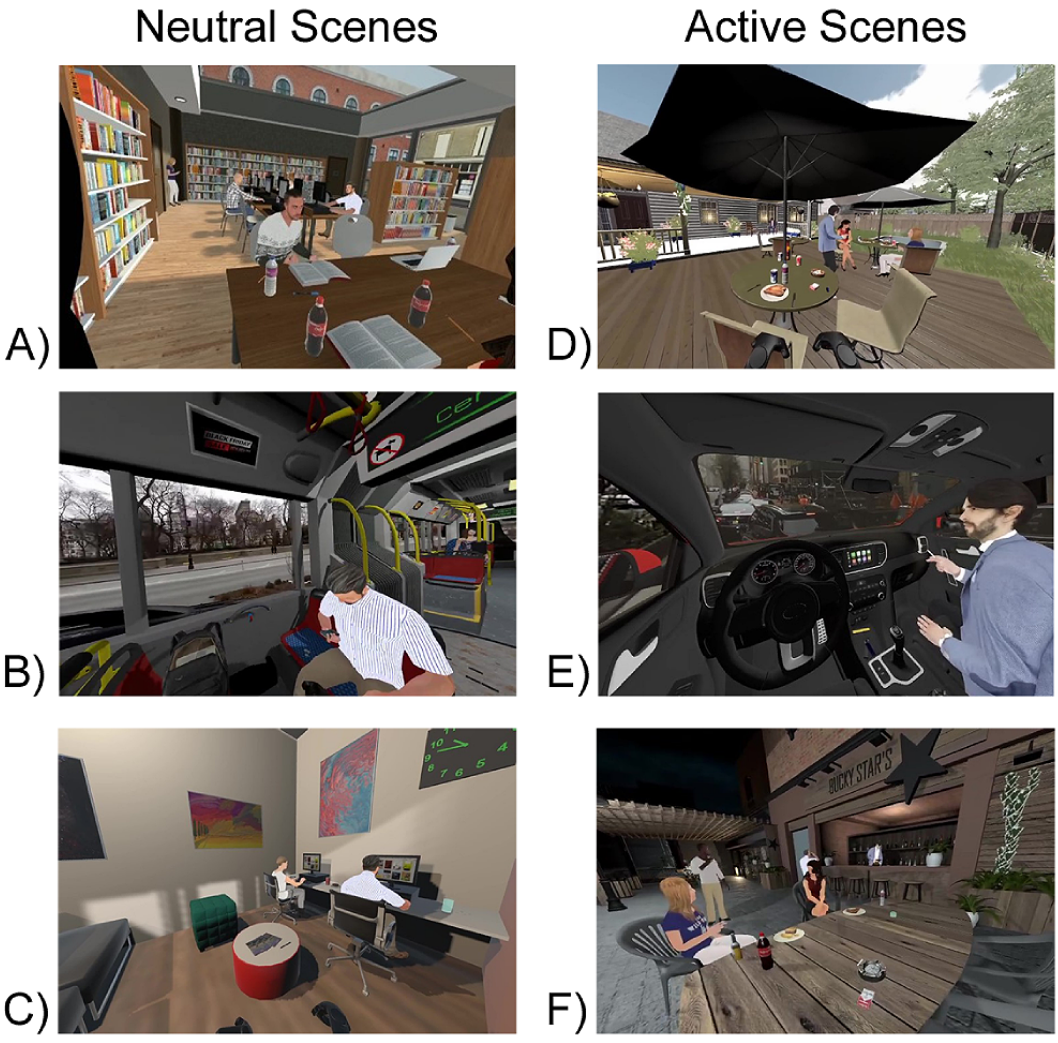
The NTP Cue VR paradigm uses a virtual reality environment built using Unity. The HTC Vive Pro Eye VR headset (HTC) was used to enable VR capabilities and collect eye-related data. HTC's SRanipal SDK [50] was used in conjunction with Tobii's (Tobii Technology) Tobii XR SDK [51] to provide access to various data from the eye tracker. Specifically, Tobii XR SDK handled object selections, determining what participants were looking at, with its Gaze-to-Object Mapping (G2OM) algorithm, while the rest of the data were retrieved from the SRanipal SDK. The participants were free to move around (via teleportation)

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and interact with various objects within the VR environment using 2 hand-held Vive controllers. Surveys (a visual analogue scale [VAS] with a range of 0-100) assessing depressed mood and anxiety were presented at the start of the paradigm (following the initial training and test scenes) and additional surveys assessing subjective craving ("How much are you craving nicotine right now?") and scene relevance ("How relevant was that scene to your own life?") were presented between scenes within the headset. A VAS survey was chosen as the in-task measurement of subjective craving owing to its high face-validity, ability to capture the dynamic fluctuations in craving [52], and low burden on participants, especially over frequently repeated assessment. Survey responses were made by adjusting a slide bar using one of the controllers. Participants were instructed to "Just explore everything around you until the scene changes" and "During the task, we will be measuring what you pay attention to, and we will be asking you to rate your craving level between each scene."

Three Active scenes (Driving, Patio, and Outdoor BBQ) and three Neutral scenes (Bus, Waiting Room, and Library) were developed and included in the final paradigm (see Figure 1 for screenshots of the scenes). The Active scenes include NTP-related cues, while in the Neutral scenes, all cues are neutral. Active cues include ashtrays, lighters, JUUL devices, cigarettes (individual and packs), Puffbars, hookahs, as well as the presence of human models engaged in smoking or vaping behaviors. Neutral cues (eg, water bottles, cellphones, pens or pencils, magazines, and candies) vary depending on the scene context. All cues are interactable such that the participants are able to pick up, throw, and collide the items with other items in the scene. All scenes (Active and Neutral) include the presence of at least one animated human model. Smoke and vapor effects are incorporated with the animated human models in the Active scenes to increase the immersiveness of the experience. All scenes include background music and audio effects consistent with the scene and the participants' interaction.

Figure 1. Screenshots of the 6 scenes from the NTP Cue VR paradigm. Neutral scenes include the (A) Library, (B) Bus, and (C) Waiting Room. Active scenes include the (D) Outdoor BBQ, (E) Driving, and (F) Patio. NTP: nicotine and tobacco product; VR: virtual reality.



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NTP Cue VR Paradigm Procedure

The NTP Cue VR paradigm begins with 3 "test scenes," which are approximately 3 minutes in duration, depending on participant comfort and abilities with the VR hardware. The first scene is the Practice Room. This is a square room with cubes systematically placed around corners of the room. The participants are asked to gaze at each of the boxes to confirm that the eye-tracking is functioning as intended. Then, the participants are asked to practice using the controllers to teleport to 4 different locations in the room. The second scene is the Practice Slider room, which instructs the participants how to answer the survey questions and provides the opportunity to practice adjusting the slider to answer the scales. The third test scene is the Blink Calibration room. In this scene, the participants are asked to blink 5 times after being prompted by an audio signal. The purpose of this room is to collect pupil diameter data when the participants actively blink to assist with increasing the accuracy of blink detection algorithms. Following the completion of the initial test scenes, the 2 mood surveys are presented, and the 6 scenes (3 Active and 3 Neutral) are pseudorandomized within scene type such that the general scene order is maintained (Active, Neutral, Active, Neutral, Active, and Neutral). The participants are then placed in each scene for 5 minutes. The entire paradigm is approximately 30 minutes in duration.

Data Collection

There are 2 types of data recorded within each scene, regular time series and event-based data that is recorded at event onset. Regular time series data are collected at every 10-millisecond interval (100 Hz), independent of the frame time. The following data are recorded periodically: (1) timestamp, (2) raw gaze intersection point, (3) position and forward direction of the participants' headset, and (4) pupil diameter and eye openness (calculated by SRanipal SDK). The following events and corresponding timestamps are recorded when they occur: (1) blinks, including number of blinks and the object of gaze at the time of the blink; (2) button presses on the controller, including time, button pressed, and object of interaction (if applicable); and (3) object of gaze when eye gaze switches to a new object.

Gaze Statistics Calculation

Raycasting from the eye position was initially used to enable object selection in the direction of gaze. However, this raycasting method did not perform well in our experiments, especially for very small objects, owing to the limited precision and accuracy of the eye tracker, microsaccades, etc. Therefore, for small objects of interest, we utilized the G2OM algorithm provided by the Tobii XR SDK, which is a machine learning–based object selection algorithm that aims to improve small object– and fast-moving object–tracking. Based on our testing, this algorithm improved object selection over the naïve method but still lacked selection quality. Thus, to further improve object selection, we introduced an additional mechanism to "lock" the object selection when an object is manipulated such that whenever a participant actively picks up a virtual object, the object selection algorithm will always select the picked object until the participant releases the object. If the participant is not interacting with an object, the G2OM algorithm is employed, or if no small objects are within the field, naïve raycasting is employed.

To calculate eye-gaze statistics toward active and neutral cue objects, 4 dictionaries corresponding to 4 different types of objects (Active, Neutral, Miscellaneous, and Background) are initialized prior to the start of participant involvement in the paradigm. These dictionaries are then used to store the cumulating gaze fixation or dwell time durations as values for individual objects belonging to each object and type. When a participant gazes at an object, the object is searched in the dictionary on the basis of its name and type. If the object was encountered before, the current fixation time is added to its cumulative fixation time. If the object had not been encountered before, a new entry is created for the object. The fixation time is then calculated as the difference between the timestamp of current entry and that of the next line of entry.

Following the completion of the paradigm, total fixation time indices are produced, which reflect the sum of values within each dictionary (Active, Neutral, Miscellaneous, and Background). The mean fixation time indices are also created, which reflect the total fixation time divided by the number of objects (number of keys) gazed at by the participant.

Blink Detection

Initially, we tested a measurement of eye openness, as calculated by the HTC SRanipal SDK, as an indicator for blink detection. However, given the lack of established thresholds of eye openness for blink detection, we instead chose to rely on estimates of pupil diameter. Consistent with previous studies, an eyeblink is herein defined as complete eyelid closure with the pupil covered for 50-500 milliseconds [53,54]. For any given timepoint, we consider a missing pupil diameter reading as a possible complete eyelid closure where the pupil is completely covered by the eyelid. These eye closure durations are blink candidates. If either pupil is covered for less than 50 milliseconds, the candidate is discarded as it is more likely owing to noise or an eye tracker limitation. If either pupil is covered for more than 500 milliseconds, the candidate is also discarded as this is more consistent with a microsleep [54,55]. Using this blink detection definition, the blink count for the majority of the current participants fell within 12-40 blinks per minute, which appears to align with the consensus of spontaneous blink rates in the literature [55-58].

Participant Recruitment and Screening Procedures

Participants for this ongoing study are recruited through flyers and web-based (eg, Facebook, Craigslist, and San Diego Reader) advertisements posted in the San Diego community. Interested individuals call the laboratory and complete a telephone-screening interview to determine initial eligibility. Inclusion criteria for the ongoing study are the following: (1) age >18 years, (2) nondaily (average use on 4-27 days per month in the past 3 months) or daily NTP use (average use on 7 days per week in the past 3 months), and (3) an NTP use history of ≥1 year. Exclusionary criteria are the following: (1) medical or psychiatric history affecting brain development (ie, history or treatment of neurologic disorders, severe head trauma with loss of consciousness for >2 minutes, or current severe DSM-5

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psychiatric disorders other than tobacco use disorders), (2) nonfluency in English, (3) visual problems that may make task completion difficult (eg, severe motion sickness, blindness, and glasses).

Eligible participants are then invited for the in-person laboratory assessment and instructed to bring their NTP products with them for use immediately after the assessment to control for effects related to expectations of imminent substance availability [59]. They are asked to abstain from cannabis and alcohol use for at least 24 hours, and from NTP use for at least 1 hour, prior to testing.

Ethical Considerations

Upon arrival to the laboratory, participants receive a full explanation of the study procedures and provide written, informed consent. The study protocol was approved by the University of California, San Diego Human Protections Program institutional review board (protocol 180719) and is in accordance with the Helsinki Declaration of 1975, as revised in 2000.

Psychological Measures

Following consent procedures, participants undergo an extensive clinical interview and complete several self-report questionnaires covering demographic, psychological health (Mini International Neuropsychiatric Interview [MINI] for DSM-5 [60]), and substance use (90-day Timeline Follow-Back [TLFB] [61], PATH Tobacco Dependence [TD] [62], Customary Drinking and Drug Use Record [CDDR] [63], and Tobacco Craving Questionnaire-Short-Form [TCQ-SF] [64]) domains. The TLFB has high test-retest reliability for intervals ranging from 30 to 360 days prior to the interview date, with an intraclass correlation coefficient=0.92 for “Total number of cigarettes smoked per interval” [65]. Thus, past 90-day NTP use episode count from the TLFB was used in the quantitative analyses presented below. All study interview and self-report data were collected and managed using REDCap electronic data capture tools hosted at the University of California, San Diego.

Participants then undergo the NTP Cue VR paradigm, which includes repeated (postscene) assessments of subjective nicotine craving and scene relevance to the individual participant (VAS; see *NTP Cue VR Paradigm Development*). Upon completion of the paradigm, additional assessments on VR-related outcomes such as VR presence (Igroup Presence Questionnaire [IPQ] [66]) and VR-related simulator or motion sickness (Simulator Sickness Questionnaire [SSQ] [67]) are administered. The IPQ total score was calculated using a simple averaging method to obtain a single average perceived presence score ranging 0-100. Similarly, the SSQ was scored in concordance with procedures outlined to assess VR-specific sickness (Virtual Reality Sickness Questionnaire [VRSQ] [68]), which involves a simple averaging method to obtain a single average sickness score with a range of 0-100.

Statistical Analysis of Pilot Data

These analyses include the first 31 participants to complete the study protocol; however, data were missing for some subjects on a subset of indices owing to technological difficulties (as indicated by the degrees of freedom for each test presented in the results section). Owing to safety restrictions related to COVID-19, no biological verification of abstinence was conducted. Group differences are not being investigated in the present pilot analyses since the goal of this study is to describe the development and general validity of the paradigm and to maximize statistical power. Statistical analyses were conducted using a repeated measures (ie, paired samples) *t* test (2-tailed) or Pearson correlation framework. The threshold of significance was set at $P<.05$ for all analyses. SPSS Statistics for Windows (version 27; IBM Corp) software was used for all analyses.

Results

Results Overview

Demographic information is presented in Table 1. In general, the sample is predominantly male (61%) and White (61%), and 61% had no or very limited (one time) previous experience with VR.

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Table 1. Sample demographics (N=31).

Variable	Value
Age (years), mean (SD)	30.77 (16.33)
Sex (male), %	61.3
Ethnicity (White), %	61.3
Education (college level), %	74.2
Previous experience with virtual reality, n	
Never	12
Once	7
A few times	9
Many times	3
Nicotine and tobacco product use days (in the past 90 days), mean (SD)	60.10 (33.39)
Nicotine and tobacco product use episodes (in the past 90 days), mean (SD)	772.29 (1008.20)
Tobacco Craving Questionnaire score at baseline, mean (SD)	105.32 (9.46)
VR[a] presence (Igroup Presence Questionnaire score), mean (SD)	
Spatial presence	65.74 (16.46)
Involvement	62.08 (21.59)
Experienced realism	52.22 (23.87)
Total	60.05 (9.66)
VR-related sickness (Virtual Reality Sickness Questionnaire score), mean (SD)	
Oculomotor	16.94 (14.60)
Disorientation	15.56 (15.43)
Total	16.25 (13.94)

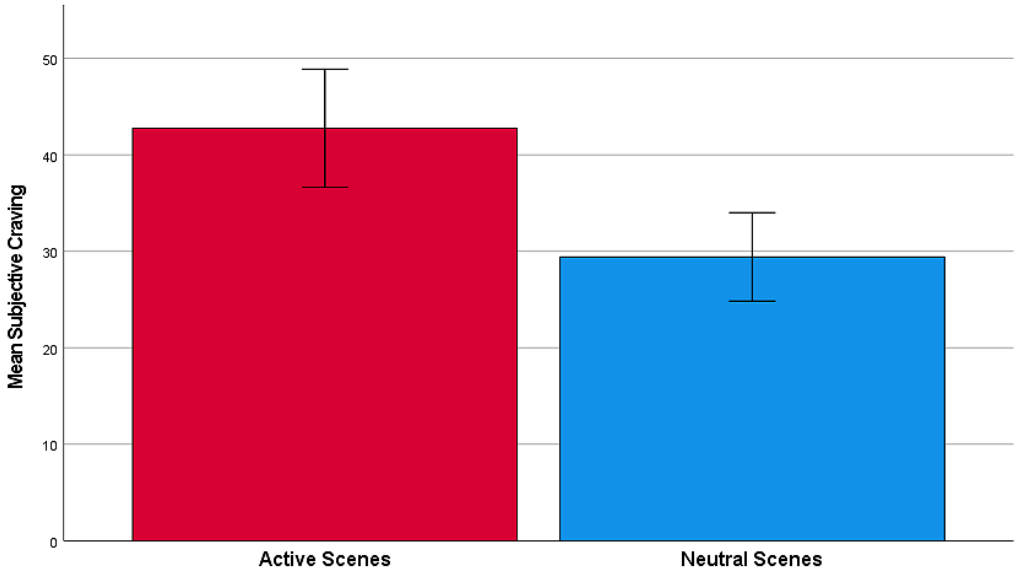
[a]VR: virtual reality.

Subjective Craving

The paired samples *t* test, which investigated subjective craving during the paradigm, revealed a significant effect of scene condition on craving (t_{30}=4.24, *P*<.001; Cohen *d*=0.76, 95% CI 0.36-1.16), with Active scenes (mean 42.77, SD 34.07) eliciting greater subjective craving than Neutral scenes (mean 29.42, SD 25.54; Figure 2). Pairwise comparisons tested among all Active scenes revealed that craving ratings were greater after the Driving scene (mean 48.77, SD 35.67) than after the Outdoor BBQ scene (mean 43.50, SD 35.79; *P*=.01) and the Patio scene (mean 40.00, SD 33.69; *P*=.01); yet, no difference in ratings was observed between the Outdoor BBQ and Patio scenes (*P*=.33).

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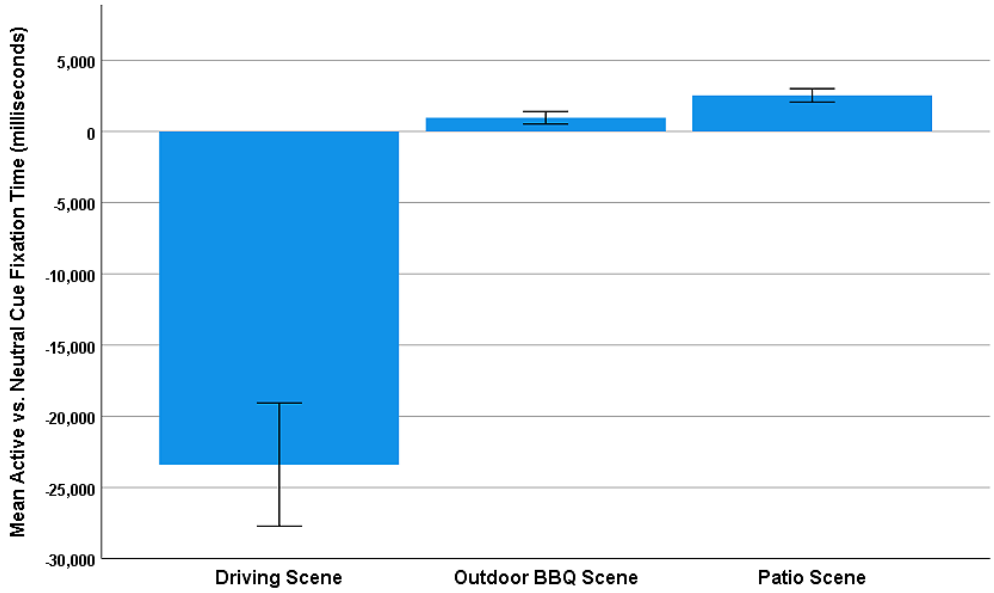
Figure 2. Mean subjective craving rating averaged across Active and Neutral scenes. Error bars indicate an SE of 1.



Attentional Bias

The paired samples *t* test, which investigated eye-gaze fixation time during the paradigm, revealed a significant effect of cue-type on fixation time during the Active scenes (t_{30}=–4.76, *P*<.001; Cohen *d*=–0.85, 95% CI –1.26 to –0.44), with greater mean fixation time toward Neutral cues (mean 12,888.52, SD 6314.20 milliseconds) compared to Active cues (mean 5807.98, SD 3002.78 milliseconds). Additional *t* tests within each Active scene (see Figure 3) revealed a greater Active (mean 4364.32, SD 2541.85 milliseconds) versus Neutral (mean 1962.32, SD 812.64 milliseconds) cue fixation time in the Patio scene (t_{29}=5.05, *P*<.001; Cohen *d*=0.92, 95% CI 0.49-1.35), and a greater Active (mean 3060.69, SD 2183.26 milliseconds) versus Neutral (mean 2111.13, SD 972.85 milliseconds) cue fixation time in the Outdoor BBQ scene (t_{29}=2.24, *P*=.03; Cohen *d*=0.41, 95% CI 0.03-0.78). However, we observed a lower Active (mean 10,238.44, SD 6037.01 milliseconds) versus Neutral (mean 34,723.50, SD 19,114.72 milliseconds) cue fixation time in the Driving scene (t_{30}=–5.83, *P*<.001; Cohen *d*=–1.05, 95% CI –1.48 to –0.60).

Figure 3. Mean Active versus Neutral cue fixation time (in milliseconds) within the 3 Active scenes. Error bars indicate an SE of 1.



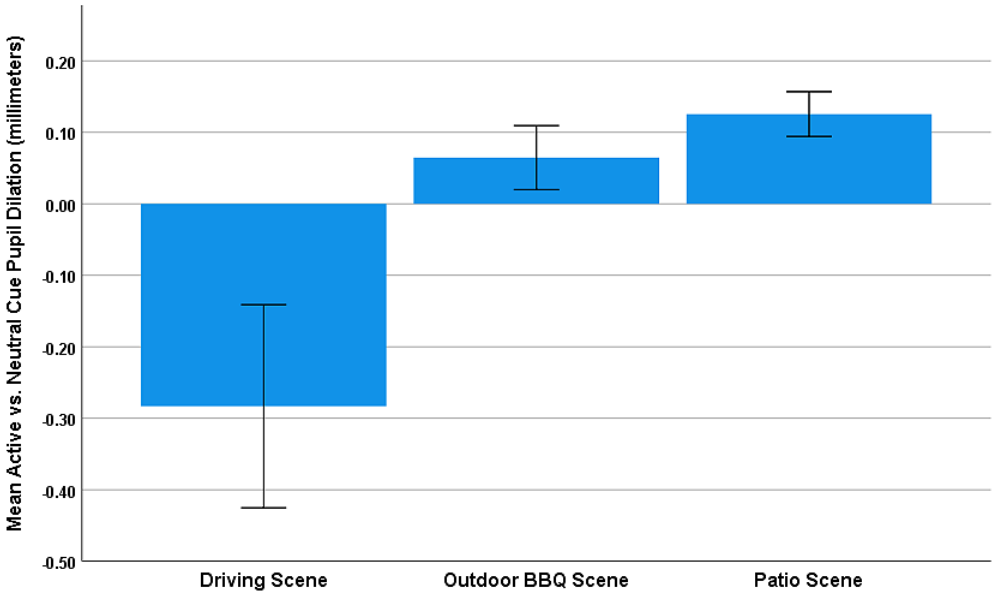
Pupil Diameter

The paired samples *t* test, which compared mean pupil diameters, revealed a smaller pupil diameter in response to Active cues (mean 3.87, SD 0.78 mm) than for Neutral cues (mean 3.97, SD 0.71 mm; t_{28}=–2.01, *P*=.05; Cohen *d*=–0.37, 95% CI –0.75 to 0.01) averaged across Active scenes. Additional *t* tests within each Active scene (see Figure 4) revealed a greater Active (mean 3.95, SD 0.63 mm) versus Neutral (mean 3.83,

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SD 812.64 mm) cue pupil diameter in the Patio scene (t_{27}=3.95, P<.001; Cohen d=0.75, 95% CI 0.32-1.16), and a trend for greater Active (mean 3.78, SD 0.61 mm) versus Neutral (mean 3.71, SD 0.59 mm) cue pupil diameter in the Outdoor BBQ scene (t_{27}=1.60, P=.12; Cohen d=0.30, 95% CI –0.08 to 0.68). As observed for attentional bias, a lower Active (mean 4.16, SD 1.13 mm) versus Neutral (mean 4.43, SD 0.80 mm) cue pupil diameter was observed in the Driving scene (t_{28}=–2.07, P=.05; Cohen d=–0.38, 95% CI –0.76 to –0.003).

Figure 4. Mean Active versus Neutral cue pupil diameter (mm) within the 3 Active scenes. Error bars indicate an SE of 1.



Spontaneous Eye-Blink (EBR)

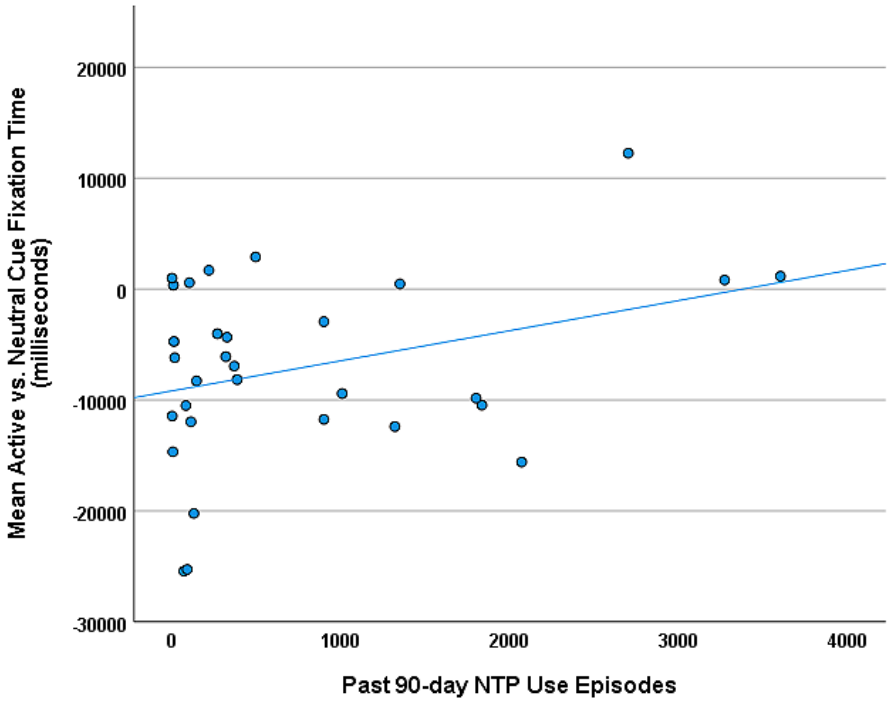
The paired samples t test revealed no significant differences in EBR during Active and Neutral scenes (t_{30}=0.49, P=0.62; Cohen d=0.09, 95% CI –0.26 to 0.44). Within Active scenes only, pairwise comparisons revealed that the Outdoor BBQ scene (mean 197.86, SD 96.80) was associated with a greater EBR than the Patio scene (mean 173.83, SD 76.90; P=.04; Cohen d=0.41, 95% CI 0.02-0.78). No differences were observed between the Driving scene (mean 193.47, SD 85.98) and the Outdoor BBQ (P=.53; Cohen d=0.12, 95% CI –0.24 to 0.47) or Patio scene (P=.21; Cohen d=0.24, 95% CI –0.13 to 0.60).

Relationship to NTP Subjective Craving and Use

Exploratory Pearson correlations were investigated to provide an initial estimate of the potential for these objective metrics to serve as an indicator of subjective craving and past NTP use. Attentional bias (mean Active vs Neutral Cue fixation time across Active scenes), pupil diameter, and EBR were not found to significantly correlate with in-task subjective craving ratings (attentional bias: $r_{Driving}$=–0.09, r_{Patio}=0.16, $r_{Outdoor\ BBQ}$=0.26, P>.05 for all; pupil diameter: $r_{Driving}$=0.16, r_{Patio}=0.01, $r_{Outdoor\ BBQ}$=0.06, P>.05 for all; EBR: $r_{Driving}$=0.12, r_{Patio}=0.28, $r_{Outdoor\ BBQ}$=0.19, P>.05); however, attentional bias was found to positively correlate with past 90-day NTP use episodes at a trend level (r=0.33, P=.06; see Figure 5). Similar positive correlations were observed for each scene separately (r=0.19-0.31). No relationships were observed between past 90-day NTP use and pupil diameter (r=–0.27, P=.17) or EBR (r=–0.05, P=.79).

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Figure 5. Scatter plot depicting the linear relationship between mean Active versus Neutral cue fixation time (in milliseconds) averaged across the 3 Active scenes and past 90-day nicotine and tobacco product (NTP) use episodes.



Discussion

Principal Findings

This report describes our approach to the development of a novel NTP cue VR paradigm designed to simultaneously induce and assess potential eye-based objective correlates of nicotine craving in naturalistic and translatable virtual settings. The preliminary statistical analyses support the potential of this paradigm in its ability to induce subjective craving while instilling a moderate sense of presence in the virtual world and only low levels of VR-related sickness.

The preliminary results outline a potential context-specific effect of NTP-related attentional bias and pupil dilation in this pilot sample. Consistent with the literature on attentional bias [23-26] and pupil dilation [49], we observed greater Active NTP versus Neutral control cue-related effects in 2 of the 3 Active scenes (Patio and Outdoor BBQ). The similarity observed in the pattern of effects between attentional bias and pupil dilation provides early evidence of a potential cross-validation of these metrics. No effects were observed for the EBR metric; however, the size of this effect, if present at all, may be smaller than we are currently able to detect with the limited sample.

The observed reversal of attentional bias and pupil dilation toward neutral cues in the Driving scene warrants further investigation, given the large effect size. Potential explanations for this include the presence of especially engaging neutral cues in the Driving scene, as a 360° video of a busy city street is presented in the background, which participants report as entertaining to watch. Despite the overall bias toward neutral cues reflected in the global attentional bias metric, and within the Driving scene alone, participants with greater attentional bias toward NTP cues (even if negative) were found to endorse greater NTP use in the previous 90 days. This effect appears to be driven by the higher-frequency NTP users in our sample and is consistent with the literature supporting the validity of attentional bias as a clinically important indicator of nicotine addiction [27]. Additional analyses are planned to assess direct and indirect relationships between scene eye-related outcomes and relevance to the individual, scene-specific craving level, randomization of scenes, engagement with specific cues, and NTP use groups (ie, nondaily vs daily NTP users) once more data are collected.

Strengths and Limitations

This pilot study has several strengths and limitations. Strengths include the development of a cutting-edge VR cue-reactivity task that incorporates the latest technological advances in graphic design to increase translatability to the real-world and simultaneous assessment of multiple potential eye-related indices of cue-reactivity in a 3D virtual environment. Limitations include the absence of biological verification to confirm self-reported NTP use and the inability to investigate NTP use profiles in the analyses owing to limited power. Importantly, given the limited sample size, we caution against over interpretation of our results. It remains unknown whether the absence of significant results, particularly with respect to the correlations between objective eye-related indices and subjective craving ratings, are the result of limited power to detect these relationships or true independence of these indices. However, we believe that the general pattern of scene-related effects on attentional bias and pupil dilation are encouraging and warrant further study. The identification of reliable objective correlates

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("biomarkers") of craving would allow for greater examination of the underlying neurobiological processes involved, and inform new avenues for the development of psychological and pharmacological treatments.

Conclusions

To our knowledge, this is the first attempt to investigate eye-tracking indices (attentional bias, pupillometry, or EBR) within a VR substance cue-exposure paradigm. Taken together, the results of this preliminary data analysis suggest that this paradigm may prove useful for laboratory-based studies of NTP cue-reactivity and provide a platform for further investigation of eye-based markers of psychophysiological processes that may subserve the subjective craving experience. Once thoroughly tested and validated, this paradigm could function as a translatable platform for which experimental manipulations and craving interventions could be tested.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CDDR: Customary Drinking and Drug Use Record
D_2: dopamine
DSM-5: Diagnostic and Statistical Manual of Mental Disorders (5th edition)
EBR: spontaneous eye blink rate
G2OM: Gaze-to-Object Mapping
ICD-10: International Classification of Diseases (10th edition)
IPQ: Igroup Presence Questionnaire
MINI: Mini International Neuropsychiatric Interview
NE: norepinephrine
NTP: nicotine and tobacco product
PET: positron emission tomography
SSQ: Simulator Sickness Questionnaire
TCQ-SF: Tobacco Craving Questionnaire-Short-Form
TD: PATH Tobacco Dependence
TLFB: 90-day Timeline Follow-Back
VAS: visual analog scale
VR: virtual reality
VRSQ: Virtual Reality Sickness Questionnaire

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Original Paper

Immersive Virtual Reality Exergames for Persons Living With Dementia: User-Centered Design Study as a Multistakeholder Team During the COVID-19 Pandemic

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Abstract

Background: Advancements in supporting personalized health care and well-being using virtual reality (VR) have created opportunities to use immersive games to support a healthy lifestyle for persons living with dementia and mild cognitive impairment (MCI). Collaboratively designing exercise video games (exergames) as a multistakeholder team is fundamental to creating games that are attractive, effective, and accessible.

Objective: This research extensively explores the use of human-centered design methods that involve persons living with dementia in long-term care facilitates, exercise professionals, content developers, game designers, and researchers in the creation of VR exergames targeting physical activity promotion for persons living with dementia/MCI.

Methods: Conceptualization, collaborative design, and playtesting activities were carried out to design VR exergames to engage persons living with dementia in exercises to promote upper limb flexibility, strength, and aerobic endurance. We involved a total of 7 persons living with dementia/MCI, 5 exercise professionals, 5 community-dwelling older adults, a VR company for content creation, and a multidisciplinary research team with game designers, engineers, and kinesiology experts.

Results: An immersive VR exergame called Seas the Day was jointly designed and developed and it is freely available to be played in state-of-the-art VR headsets (Oculus Quest 1, 2). A model for the triadic interaction (health care institution, industry partner, academia) is also presented to illustrate how different stakeholders contribute to the design of VR exergames that consider/complement complex needs, preferences, and motivators of an underrepresented group of end users.

Conclusions: This study provides evidence that a collaborative multistakeholder design results in more tailored and context-aware VR games for persons living with dementia. The insights and lessons learned from this research can be used by others to co-design games, including remote engagement techniques that were used during the COVID-19 pandemic.

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KEYWORDS

virtual reality; exergames; persons living with dementia; physical activity; head mounted displays; participatory design; co-development; gaming; older adults; elderly; design; dementia; VR; user-centered; physical activity; exercise; COVID-19

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Introduction

Background

Technology has a key role to play in supporting people of all abilities' fundamental rights to inclusion and participation. The essential purpose of technology is enabling people to do things they could not otherwise do. However, applications need to be specifically adapted to the needs and abilities of end users for them to be accessible and meaningful [1]. Top–down approaches where designers independently create technologies can lead to well-intended but poorly suited solutions, especially for older adults (defined here as aged 60+) with cognitive, physical, or sensory impairments, such as people living with mild cognitive impairment (MCI) or dementia [2-4]. To meet the needs of such end user groups, a multistakeholder team has been shown to better understand the experiences, challenges, and adoption of technology from different perspectives (eg, end users, health care professionals, service providers, researchers from multiple disciplines, industry designers/developers, and engineers) to form a holistic view [1]. Combining this diversity of knowledge enables creation of novel solutions that can be effective, usable, and adoptable by the end users [5]. Human-centered design (HCD) is an approach where solutions are created by focusing on understanding the context, needs, behavior, and preferences of the people whom the solution will serve. In HCD, the end users' needs, system requirements, and technology specifications are defined using data from observations, interviews, and participatory design activities. Participatory design is one of the techniques used in HCD in which end users and other stakeholders are actively involved as partners throughout the design process [4,6].

Adopting participatory and collaborative design approaches in HCD has been shown to result in the development of effective solutions and improve the effectiveness of serious games in promoting healthy lifestyles among the end users [7]. However, many requirements of these approaches are reported as barriers that can be difficult to overcome [8]. For instance, increased time and effort are required to come to a common and shared understanding of the problem and possible solutions [9]. As a result, technology development still predominantly relies on conventional and less participatory approaches that often come at the cost of a greater chance of misalignment of the technology with the intended user population [5]. This is particularly the case when designing solutions for people with complex needs or impairments. For instance, understanding the desires, needs, and abilities of older adults with cognitive impairment can be extremely complex, dynamic, and unpredictable considering the physical and cognitive challenges faced by this population [10]. While there is a general agreement on the importance of having a multistakeholder co-design approach to design, implicit complexities such as different viewpoints (eg, people from different sectors or schools of thought), conflicts of interest (eg, intellectual property of the designed solutions), and access to end users that are willing to participate in the design process limit widespread adoption [11].

As put forward by Dixon and Lazar [12], technology for persons living with dementia should support activities that are meaningful to them in a way that respects and reflects their needs, abilities, and perceptions of personhood. As persons living with dementia have wide and dynamic preferences and abilities that are difficult (sometimes impossible) to simulate or speculate about, it is crucial to have their voice as a central part of the design process of technologies intended for them. While actively involving persons living with dementia in technology development has already started and multiple articles have documented valuable insights [2,3,13], the adoption rate is quite low and appropriate/effective methods for supporting their involvement are still being explored.

This paper presents the participatory cocreation of *Seas the Day*, an exergame (ie, a game that is intended to promote exercise) designed to include persons living with dementia/MCI as core end users. *Seas the Day* uses immersive head-mounted virtual reality (VR) to encourage players to engage in exercises that can be beneficial for their health and well-being. The research described in this paper was guided by the question: "How can human-centered participatory design methods be used to involve multiple stakeholder groups in the collaborative creation of VR exergames to promote physical and mental well-being among persons living with dementia/MCI?". We present our work as a case study of a collaborative co-design wherein we discuss main considerations, roles, and lessons learned through our process of co-designing VR exergames for persons living with dementia/MCI; this includes strategies that were adopted to steer the design process while being involved in the COVID-19 pandemic, a situation that brings many challenges due to the limited access to the target stakeholder groups. We describe how we tackled previously reported issues in designing games targeting older adults with cognitive impairment, in particular: (1) creating solutions that are designed with and for persons living with dementia/MCI by identifying where exceptional needs (eg, cognitive, physical, sensory impairment, and technology literacy) of this population exist and complementing them [14]; (2) integrating players' needs and preferences early in the design process [15]; and (3) balancing both attractiveness and effectiveness to create enjoyable and useful immersive experiences [8]. This research highlights specific considerations regarding designing exergames for head-mounted displayed-VR (HMD-VR) technology and specifies how using HMD-VR impacted the design choices we made throughout the iterative and participatory process.

Supporting Aging in Persons Living With Dementia Using Physical Activity: The Opportunity of Exergames

Dementia is an umbrella term for a number of progressive diseases and disorders, such as Alzheimer disease, Lewy Bodies, and Parkinson disease. Symptoms of dementia involve deterioration in cognitive function including impairment in memory, reasoning skills, and the ability to perform everyday activities as well as changes in behavior and mood [16,17]. MCI is a high-risk state for dementia where individuals experience a decline in cognitive abilities, which is not yet sufficient to hinder functional independence. There is ample evidence on numerous physical and psychological health benefits of regular physical activity participation for older adults [18]. For persons

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living with dementia or those with MCI in particular, physical activity has been recognized as a practical and side effect–free therapeutic strategy for both mitigating and managing the symptoms of MCI and dementia. Regular participation in physical activity can improve functional performance, mobility, activities of daily living (ADLs) among persons living with dementia and those with MCI, and may have a positive impact on their global cognition and balance [19-21].

While some guidelines recommend that persons living with dementia/MCI exercise at least twice a week [22], other guidelines recommend they participate at the same level of activity as healthy older adults—150 minutes of moderate intensity or 75 minutes of vigorous aerobic physical activity and strength training twice a week [21]. However, despite strong evidence supporting physical and mental benefits of physical activity for persons living with dementia/MCI, physical activity participation and adherence are particularly restricted in this population due to the motor and cognitive changes associated with the condition. Various individual, social, and environmental barriers such as lack of motivation, low levels of self-efficacy, apathy, poor access to exercise opportunities, lack of dementia-appropriate exercise programs or safe and accessible community infrastructure, transportation challenges, and societal stigma have been reported as contributors to sedentary behavior among persons living with dementia/MCI [23-26].

Given the increasing number of dementia cases worldwide (expected to double by 2050) [27] and considering the significant health benefits of regular physical activity, it is imperative to develop innovative and effective strategies to facilitate physical activity participation and maintenance among both healthy older adults and those living with cognitive impairment. Serious or applied games, such as exergames, are one plausible strategy to promote physical activity among older adults by motivating participation through the enjoyment of play [28]. VR exergaming is a novel strategy that can encourage physical activity participation and offer exercise routines that require minimal guidance and supervision from the therapists [29,30]. The multisensory and immersive environment of VR exergames (especially those employing HMD-VR) have been previously employed as a therapeutic tool to promote the health and wellness of older adults and to support rehabilitation [31,32]. Studies that explored VR exergames for older adults have shown positive results and demonstrated that exercising using exergaming systems can benefit motor learning and neural plasticity [33-37]. VR exergaming has been found to be a feasible strategy to complement conventional exercise interventions [32,38].

Exergaming During the COVID-19 Pandemic

Older adults are among the most vulnerable and profoundly impacted during the COVID-19 outbreak and its physical and mental health impacts [39]. Staying physically active during the COVID-19 pandemic is particularly important for older adults because physical activity is a protective factor against viral infections that can increase the immune response as well as the positive benefits toward supporting overall physical and mental well-being [40,41]. However, with the contact restrictions, isolation measures, and exercise facilities closure in response to the COVID-19 pandemic, older adults are facing restrictions of physical activity behaviors that can lead to short- and long-term adverse health consequences [42,43]. For those living in long-term care (LTC) homes or apartment buildings where going outdoors requires moving through shared spaces, risks for physical inactivity and its various adverse health outcomes are even higher. Reduced social connection and increased feelings of loneliness may also decrease older adults' motivation for physical activity during the COVID-19 pandemic [44-46].

To mitigate the negative impacts of COVID-19 on the health and well-being of older adults (with and without cognitive impairment), various remote and technological solutions have been suggested, such as [47-50]. Concurrently, literature indicates the growing feasibility of using exergaming strategies to enhance physical activity among older adults during the COVID-19 pandemic [51-54]. For example, VR exergaming has been introduced as a coping strategy to facilitate older adults' at-home physical activity and enhance favorable health outcomes among this population [55,56]. This can be due to the fact that virtual environments are customizable and can be tailored to the participants' functional and cognitive abilities, including those with MCI/dementia. For individuals reluctant to participate in exercise, the immersive and interactive environment of VR can provide an engaging, entertaining, and motivational means of exercising and target desired physical activity outcomes through the gameplay [57].

While there is promising potential for VR exergames to support older adults, research on preferences of VR exergames among older adults with various cognitive abilities is limited. Additionally, the availability of custom-made content and easy-to-use VR hardware often limit the technology uptake by older adults [58]. Moreover, public health measures to contain the spread of COVID-19 have made it more challenging to carry out participatory and collaborative cocreation activities with vulnerable end users such older adults and persons living with dementia/MCI during the pandemic. Therefore, despite the growing need and technological advances in VR systems (eg, standalone headsets), the use of VR exergames to promote exercise among older adults is still very limited.

What We Know About Serious Games and Cocreation for Persons Living With Dementia

In order to provide a comprehensive understanding of what has been done in the field of serious games for persons living with dementia/MCI, we present below a comprehensive review of the literature, specifically literature covering VR technologies. The rise of consumer-level HMDs and accessibility of the content have fostered the creation of literature related to both nonimmersive and immersive VR systems adopted for dementia care. Examples are reflected in the following publications: (1) a review of nonimmersive games and simulations including tools for ADL to "brain" games (eg, games for cognitive training or assessment) [59]; (2) a review on the cost-effectiveness of exergaming interventions and their impact on physical, cognitive, emotional, and social functioning of persons living with dementia/MCI, which revealed that only 3 studies met the inclusion criteria (eg, randomized controlled trials, participants

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diagnosed with dementia, exergames); (3) a minireview of 10 studies on interactive interventions to promote well-being of persons living with dementia/MCI revealed that virtual experiences were enjoyable for the participants and improved their mood and apathy [60]; and (4) the effectiveness of VR (full-immersive and semi-immersive) for persons living with dementia/MCI was reviewed in a recent meta-analysis of 11 studies concluding that immersive VR is a cost-effective, comprehensive, flexible, and potentially useful tool for patient-centered care [61].

The future of VR technologies to foster interactive and therapeutic experiences for persons living with dementia/MCI presents several challenges that have been repeatedly mentioned in most of the reviews. These challenges can be grouped as follows: (1) the need to establish practical guidelines for VR design and implementation for people with cognitive impairments [61]; (2) the need for less anecdotal, more consistent, and more therapeutically and scientifically valid interventions (eg, randomized controlled trials) to systematically document the effectiveness of VR interventions in persons living with dementia/MCI [62]; (3) the opportunity to include noninvasive measurements (eg, gameplay metrics, physiological signals) and system intelligence (eg, machine learning [63]) to better examine changes, propose novel ways for tracking the VR intervention progress, and better quantify its impact [60]; and (4) the need to improve the rationale behind specific game elements (eg, mechanics, technology) and their impact on the outcome measures (eg, cognitive, physical) in order to better define the goals of the interactive interventions [64]. For instance, there is a need to better define the role of the level of immersion offered by the technology (eg, HMDs, 2D screens) in game user experience variables such as engagement or replayability.

Methods

Cocreation of the Seas the Day Exergame

This section describes how we carried out our co-design of the *Seas the Day* VR exergame, including presenting the ideation stages, involvement of stakeholders, and a table summarizing the iterative and collaborative design and development process, which was partially carried out during the COVID-19 pandemic.

Our process of cocreating *Seas the Day* was sparked by conversations with exercise therapists in LTC facilities. They expressed a desire for additional ways to engage persons living with dementia/MCI in exercise routines that are fun, particularly for those who do not enjoy or have trouble participating in group-based exercises. They wanted interventions that were not only interactive and engaging, but also inclusive and informed by the participant's therapeutic goals. They were also interested in exploring what kinds of objective data could be automatically collected through gameplay to track changes/progress in physical and cognitive function over time.

The multistage collaborative design process that ensued occurred over the span of 15 months and was driven by multidisciplinary researchers, exercise therapists, VR game developers, persons living with dementia/MCI in LTC facilities, and community-dwelling older adults. The process is divided into 2 main stages: (1) ideation and planning and iterative design and (2) development process. A special emphasis has been put in describing the techniques, activities conducted, and people involved during each stage.

Preliminary Work on VR and Exergames for Persons Living With Dementia/MCI

The design process described in this paper is heavily inspired by previous research conducted before COVID-19 by our research team where a set of VR exergames were prototyped and tested. Initially created as a proof of concept, a set of activities in a virtual farm setting was created to engage persons living with dementia/MCI in the use of HMD-VR [65,66]. Important insights from that study were as follows: (1) end users had positive perceptions of the exergame experience using HMDs and were able to engage in the exercise program, (2) involving health care professionals and persons living with dementia/MIC in the design process was incredibly beneficial to creating usable VR environments for persons living with dementia/MCI, and (3) qualitative and quantitative measures demonstrated comparative results between exercising with the VR exergaming program and conventional human-guided exercises. Results from this pilot study were crucial to define the next steps and to identify opportunities of using HMD-VR technology in promoting physical activity among persons living with dementia/MCI [67]. Furthermore, an analysis of the main strengths, weaknesses, opportunities, and threats (SWOT) was conducted to better shape the next steps of the project (Table 1). This approach is conventionally used among companies for strategy building, marketing, and project planning. A focus of the SWOT analysis was to consider how rapidly evolving VR technology could be used to create a solution that could be adopted by persons living with dementia/MCI in dementia care and by elder care institutions.

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Table 1. SWOT[a] analysis of VR[b] exergames previously developed and piloted [67].

Strengths	Weaknesses	Opportunities	Threats
• Demonstrated feasibility of using HMD-VR[c] in persons living with dementia • Successfully scaffolded a human-centered design process with persons living with dementia • Included 3 activities placed in different scenarios (diversity) • Simplified interaction (guided through voice instructions) • Included a calibration process for range of motion	• Hard to replicate due to hardware and software limitations • Discomfort of sweating while using HMDs • More suitable for stretching than conditioning exercises • Limited visual aesthetics • Interactivity errors that can lead to frustration • Can get monotonous if used too frequently • Data logging system can be difficult to interpret	• Use less cumbersome VR system (eg, standalone rather than desktop) • Include engaging game mechanics and integrate gamified activities • Simplify and improve data logging • Facilitate system calibration • Explore metrics to track physical and cognitive performance • Include full-body interaction	• Difficulty in technology uptake due to system's complexity and cost • Content and platform sustainability • Design and development time longer than time for student MASc degree • Potential motion sickness for some people • Users with hearing or visual impairments might not be able to engage fully in content

[a]SWOT: strengths, weaknesses, opportunities, and threats.

[b]VR: virtual reality.

[c]HMD-VR: head-mounted displayed-virtual reality.

Ideation and Planning

Overview

This stage consisted of a set of activities carried out by the multidisciplinary research team to identify, define, and plan for research approaches and goals, game design concepts, and prototyping methodologies required to create VR exergames using HCD methodologies. The process is described in 2 main stages as follows:

Defining Research Approach and Partnering With Industry

The initial research team was formed by academic researchers, including professors and graduate students (master's, PhD, and postdoctoral) with interests/expertise in engineering, human factors, and assistive technologies (n=3); kinesiology and applied health sciences with a focus on exercise programming and delivery for older adults with and without cognitive impairments (n=4); and a game designer with experience in health care applications (n=1) as well as exercise professionals from a local LTC home (n=5). Among the exercise professionals, kinesiologists and recreational therapists with more than 10 years of experience were engaged and were champions during the design process. The strategy to engage exercise therapists consisted of inviting interested professionals of the LTC homes to be part of the research team, involving them in the decision-making processes, and inviting them to take part in the strategic planning of the participatory design process.

The next step was to find an industry partner interested in conducting participatory game design who had related experience/expertise and know-how in developing custom-made VR content and commercialization in health care. This step was particularly challenging as human-centered and participatory design research with older adults has mostly been conducted in academic settings [11]; this is mainly due to differences in the time frames between academia and industry as well as relative novelty of the technology. Our strategy to find our industry partner consisted of researching local company directories and communities to identify potential candidates. One of the researchers met with company representatives, presented the project vision, and discussed ways to establish collaboration.

A healthy, robust, and valued partnership is grounded in perceived benefits that are equal to or greater than the investment for each partner. The nature of the stakeholder with their specific interests, key people, required investment (eg, time, activities), and benefits are summarized in Figure 1. The main investment for the LTC facility is represented as the time spent by the exercise professionals to partake in the participatory design process, playtesting sessions, and performance evaluation of persons living with dementia/MCI participating in the design process. Additional resources, rooms in the home to meet about the project, availability of the exercise professionals and other personnel, and use of display devices (eg, projectors or TV screens) for facilitating discussions were part of the LTC stakeholder investment (in-kind contribution). As a benefit, the LTC facility will get a discount on the final product for 5 years and will have a tailored solution that implements needs and ideas from their staff and residents, thus facilitating technology uptake. A shared intellectual property agreement was also negotiated that defined up-front how innovation from the project would be shared in a way that was deemed to be equitable to the researchers, industry partner, and LTC facility.

To facilitate technology deployment, the industry partner provided 2 state-of-the-art, standalone VR equipment (eg, Oculus Quest) for both the research team and the LTC facilities. As part of their in-kind investment, the company allocated a specialized development team to create the virtual environments as well as to conduct research on new gameplay metrics. The company also spearheaded the development of the business model of the envisioned system to provide a sustainable and financially feasible proposal to the team. The benefit for the industry partner is having the exclusivity of commercializing the product as well as gaining experience and insights on working closely with both potential clients and a multidisciplinary research team. By engaging with academia, the industry partner is eligible to receive government grants to

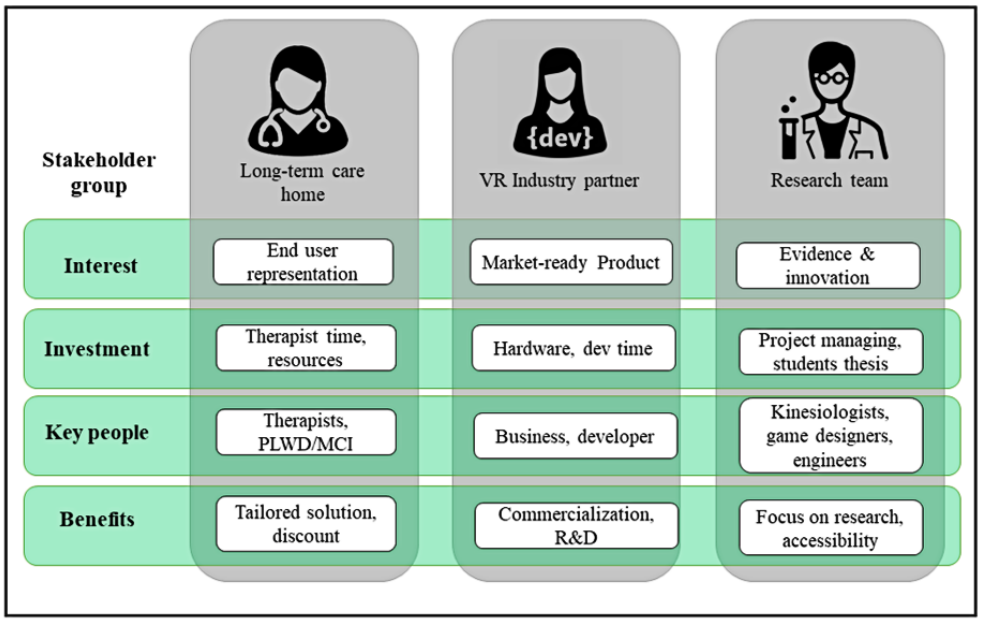
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support research and tax breaks; our team has taken advantage of both.

Finally, the research team had the mission of carefully planning and managing every step of the process; this included creating activities to appropriately engage all of the stakeholders by designating academic subteams with graduate students, research assistants, and principal investigators aligned to the different research outputs. Having an industry partner facilitated the designing and development of usable and scalable games and allowed the researchers to stay more focused on the scientific aspects of the activities (eg, game user research, evaluation, design of evidence-based games). The involvement of an industry partner also increased the chances of creating immersive exergames that are widely accessible (eg, through purchase, freemium) for both health care and academic settings compared with when no perspective or active stakeholder is involved in commercialization during the design process.

The output of this planning process is a detailed and structured *Work Plan* that is shaped and agreed upon by all stakeholders and that serves as the guide for the design that allows for the creation of the activities, timelines, and milestones for the team.

Figure 1. Components of the triadic interaction between the research team, industry partners, and LTC homes. LTC: long-term care; MCI: mild cognitive impairment; PLWD: person living with dementia/MCI; R&D: research and development; VR: virtual reality.



Defining the Game Design Concepts and Requirements for VR Exergaming in Persons Living With Dementia/MCI

Purpose

After assembling the multidisciplinary team, a series of design activities (described below) were conducted to explore the different perspectives of the team and to create cohesion, empathy, and mutual understanding. Because some of the team members were not familiar with the symptoms and abilities associated with MCI and dementia, we used existing user personas to describe some of the characteristics as well as the most representative needs and motivations to facilitate the exchange of information among the team members [15,59]. Three researchers who were new to MCI/dementia shadowed 3 exercise sessions in LTC to gain some first-hand experience with exercise programming and delivery for persons living with dementia/MCI in this setting.

Physical Activity and Therapeutic Requirements

To narrow down the scope of physical activities to ones that are appropriate for this population (including considering limitations [21,22] and risks of using HMD-VR technology with older adults [68]), we consulted with team members who have expertise in exercise therapy on multiple occasions via dedicated ideation meetings. This resulted in our decision to focus our design on exergames targeting upper limb movements that have been shown to improve endurance, flexibility, and balance. This decision is supported by the results of a systematic review on the effects of exercise on persons living with dementia/MCI in care homes, which reported that exercise intervention that combined aerobic, strengthening, and stretching activities had the greatest benefit [69]. We intentionally designed and developed seated exergames to increase player's safety and reduce risk of falls [15,70] while simultaneously incorporating guidelines that consider both physical and cognitive capabilities for exergames in persons living with dementia/MCI [71].

A list of desired movements and targeted joints along with their correlation with physical fitness was defined (Table 2), which considers (1) exercise routines carried out in the LTC facilities with persons living with dementia/MCI, (2) recommendations for exercise prescription in older adults [72], and (3) physical challenges specific to persons living with dementia/MCI (eg, on average a decrease in mobility, balance, and strength) [21,69].

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Table 2. List of movements to be included in the VR[a] exergames for persons living with dementia/MCI[b].

Targeted joint/limb	Desired movement(s)	Application for persons living with dementia/MCI
Cervical	• Neck flexion and extension (bending the head forward and backward) • Neck rotation (turning the head to the left and right)	• ROM[c] • Flexibility/Mobility • ADL[d]
Shoulder	• Shoulder flexion (frontal arm raise) • Shoulder abduction and adduction (side arm reach) • Shoulder rotation (360° circumduction) • Overhead arm stretch	• ROM • Flexibility/mobility • Endurance • ADL
Elbow/Wrist	• Elbow flexion and extension (biceps curls) • Elbow supination and pronation (outward and inward rotation of the forearm) • Wrist flexion and extension (tilting toward the palm and tilting toward the back of the hand)	• ROM • Flexibility/mobility • Endurance • ADL
Trunk	• Trunk flexion and extension (bending forward and backward) • Lateral flexion (side bending) • Trunk rotation	• ROM • Flexibility/mobility • Weight shifting and postural balance (seated) • Core strength • ADL

[a]VR: virtual reality.

[b]MCI: mild cognitive impairment.

[c]ROM: range of motion.

[d]ADLs: activities of daily living.

Concept Ideation and Brainstorming Activities

Three main activities were conducted to conceptualize the VR exergames: (1) literature review of exergame design frameworks, (2) inclusion of simplified game design elements to improve communication among stakeholders, and (3) brainstorming sessions.

Exergaming and Design Frameworks

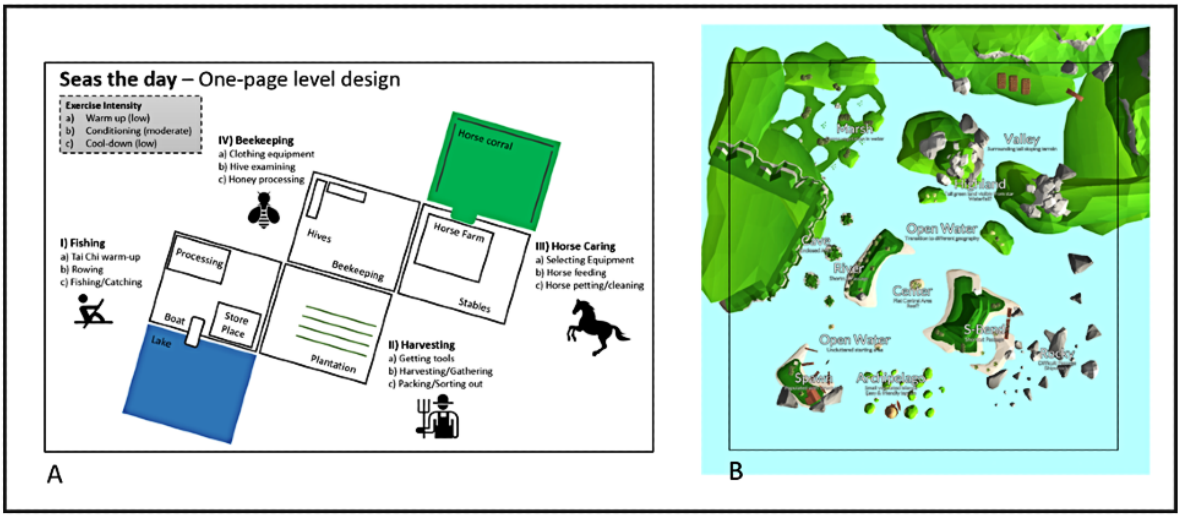
A literature review was conducted to explore existing design frameworks used to create engaging and effective exergaming experiences [73]. One of the design frameworks specialized in exergaming for healthy lifestyle promotion, called the *dual flow model* [8], was used to guide the design process. In the dual flow model, the design is guided by balancing both effectiveness and attractiveness in exergames to maximize the level of engagement while keeping the beneficial aspect of the games. The implementation of the dual flow model framework was achieved by mapping the 3 main components of an exercise training session (ie, warm-up, conditioning, and cool-down) with individual activities suggested by persons living with dementia/MCI and their therapists [65]. These activities were integrated in each stage of the exercise session (ie, warming up, conditioning, cool-down) using a different game mechanic for each one considering the recommended exercise intensity and duration.

One-Page Level Design

To facilitate the communication across the research team and stakeholders, a 1-page game level design (Figure 2A) [74] was used where exercise components (eg, stages, intensity) were outlined and 4 different game levels were initially proposed. The farm theme was chosen as suggested by the results of our pilot study and because of its broad acceptability among persons living with dementia/MCI and exercise therapists [66]. The game is named *Exerfarm Valley* and its concept consists of 4 different levels that recreate a productive farm: fishing, harvesting, horse caring, and beekeeping; these activities were chosen from a list of activities generated through discussions with the exercise therapists and researchers and in consideration with their mapping to the movements defined in Table 2. *Exerfarm Valley* was envisioned by the game designers, integrating the input from different stakeholders and considering other similar exergaming approaches found in the literature [15,70]. The initial design was presented and discussed with the research team for further refinement. Each game level has 3 different stages including specific activities that reflect warm-up, conditioning, and cool-down movements. In the iterative design and development stage, details of each game level were discussed and integrated to facilitate a more concrete and streamlined development process. For instance, Figure 2B shows the design of the rowing/fishing level (called *Seas the Day*) after discussing it with the development team.

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Figure 2. One-page level design of the Exerfarm Valley concept. (A) Four-level design sketch representing the activities and main game levels envisioned (including Seas the Day). (B) Seas the Day level design discussed with the development team of the virtual reality company specifying the spatial characteristic of the elements in the virtual environment.



Envisioning and Brainstorming

To further explore the initial design, 2 brainstorming sessions were conducted to create paper prototypes and discuss possible game mechanics and scenarios of the VR exergames.

The *first brainstorming session* (Figure 3A) was carried out with (1) 2 VR specialists (from our industry partner), (2) 3 health care professionals (1 per each institution: university, LTC partner, industry), (3) 2 external researchers with experience in designing digital technologies for persons living with dementia/MCI, and (4) 2 graduate students with experience in user experience design. The goal of the session was to create multidisciplinary subgroups to (1) introduce and expose participants to the different perspectives of the team and (2) collect ideas on the activities and narratives of the envisioned games. The scenario was defined as instructions that were given as follows:

- *Target population:* persons living with dementia/MCI in LTC settings (persons living with dementia/MCI personas were used [75]);
- *Game purpose:* engage players in seated upper limb exercises wearing a standalone VR headset; and
- *Interaction structure:* 15 minutes of exergaming using the VR headset eliciting physical activity responses according to the warm-up, conditioning, and cool-down stages (exertion cards were used to filter the ideas [76]).

Figure 3. Brainstorming sessions. (A) Introductory session carried out involving multiple stakeholders of the project. (B) Exploratory sessions carried out with exercise therapists to introduce the head-mounted displayed-virtual reality technology and collect ideas about game mechanics.



The final result encompassed a set of ideas of virtual activities for various game levels (eg, fishing, rowing, animal care). These ideas were used to create a game design document (ie, document detailing the envisioned game specifying game elements such as mechanics and aesthetics) to be used as an input for the VR company to start off with the prototyping process; having the industry partner as an active stakeholder in the brainstorming session was invaluable to building a shared understanding of the opportunities and challenges as well as creating a backdrop with which they could frame ideas.

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The *second brainstorming session* (Figure 3B) was conducted in 2 LTC facilities with 11 exercise professionals: (1) 2 physical therapists, (2) 3 kinesiologists, (3) 3 recreational therapists, and (4) 3 kinesiology students. The session aimed at exploring ideas on exercise movements, activities, and game mechanics. The game concept was introduced by defining the farm theme and the 3 intended stages (warm-up, conditioning, cool-down) with their respective timing and intensities. The goal of the session was twofold: (1) to gather therapists' feedback on the use of the HMD-VR technology in promoting physical activity in persons living with dementia/MCI and (2) to collect ideas on specific activities, feedback modalities, and instructions in each stage. We used a large paper layout dividing the 3 stages and specifying the exercise intensities and asked the therapists to write down or sketch the specific activities they would like to see on each stage, providing as many details as possible. Three researchers analyzed the qualitative results using an affinity diagram approach after moving the concepts to sticky notes and clustering the ideas to build affinity maps [77]. These generated themes centered around (1) the feasibility and requirements of using standalone HMD-VR devices in the LTC (eg, network connectivity, privacy, and adaptation of existing spaces or elements) and (2) specific game mechanics that can be used by persons living with dementia/MCI in the envisioned *Fishing* (Figure 2A) game level (eg, exploring while rowing, fishing with rod, hand-biking, scuba diving, and beach activities such as stretching or playing sports).

Iterative Design, Development, and Playtesting

An iterative, agile, and cyclical human-centered development process was carried out to merge research concepts, design requirements, and technical feasibility to shape the requirements of the prototype. Each iteration consisted of short prototyping–testing–evaluation cycles, coordinating the research team, exercise therapists, end users, and the development team from our VR partner. Playable prototypes were developed approximately every 2 weeks during a 6-month period. Versions of the games were installed on the VR equipment and then playtested by the research team, end users, or therapists to collect feedback and prepare a playtesting report suggesting required changes and potential improvements for the new prototype. Playtesting sessions were carried out both in-person (before the COVID-19 pandemic) and virtually via audiovisual conference platforms (during the COVID-19 pandemic). While the exergame was initially designed with and for persons living with dementia, because of the limitations of accessing persons living with dementia/MCI in LTC due to the pandemic, we conducted a remote, 1-week pilot with community-dwelling older adult volunteers who agreed to receive the headsets at their home and play our exergame 3 times. The development was initially focused on the creation of experimental game mechanics associated with the movements and therapeutic requirements previously discussed. Other game design elements such as aesthetics and story were gradually added to our exergame, based on feedback from the end users and other stakeholders during the playtesting sessions. In total, 3 playtesting sessions were conducted with 7 persons living with dementia/MCI (6 females; mean age 81.3 years) from 2 LTC homes, a total of 9 exercise providers (both from LTC and community, including the ones in the research team) with experience in dementia care (7 females; mean age 38.1 years), and the researchers to evaluate different aspects of the exergame. Table 3 summarizes the objectives, participants, and insights of each playtesting session. After completing the first playtesting session with persons living with dementia/MCI, the COVID-19 pandemic and public health restrictions forced us to halt in-person research, resulting in access restrictions to persons living with dementia/MCI and exercise providers at LTC homes. Similarly, other preplanned participatory design activities to continue cocreating and playtesting different game design concepts with exercise professionals and persons living with dementia/MCI had to be paused.

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Table 3. Playtesting sessions.

Playtesting name	Objectives	Participants	Methods	Main insights
Rowing and desired visual elements (number of sessions: 2)	*Game mechanics:* • Rowing forward • Rowing backward • Rowing turning (left, right) *Game aesthetics:* • Desired visual elements *Game technology:* • Motion sickness and comfort	• 7 persons living with dementia • 5 exercise therapists (from LTC[a] facilities)	*Face-to-face playtesting:* • 20 minutes interaction • Individual, semistructured • Overseen by exercise therapists • Debrief with the therapists at the end of the session.	• All players learned easily how to row in VR[b] using the prototype • Rowing backward/forward and turning left/right were intuitive for most participants • When asked about desired visual elements, end users preferred animals (eg, fishes and birds), nature and landscape (eg, sunset, mountains), and other boats and more people. • One player could not complete the test because the headset was uncomfortable. • Therapists mentioned the importance of adding cues or elements to guide the navigation.
COVID-19 outbreak				
Rowing improvements and game level design (number of sessions: 1)	*Game mechanics:* • Rowing and navigation around the level designed (Figure 3B) *Game aesthetics:* • Oars aspect and positioning • Game objects and water effects *Game technology:* Capture player's responses and behaviors	4 community exercise providers with experience in dementia care (who were not working in LTC)	*Remote playtesting:* • 1-hour discussion • Online (through Zoom) • Semistructured focus group	• Add configurable menu to define (1) session duration, (2) player's position calibration to facilitate rowing. • Add configurable menu to define (1) session duration, (2) player's position calibration to facilitate rowing. Modify world physics to have more natural tree shaking and water waving effects. • Adding cues to guide participants (eg, signs, audio clips).
Conditioning and cool-down stages, rowing and fishing integration (number of sessions: 3)	*Game mechanics:* • Rowing and fishing cohesion • Dolphin as exercise intensity modulator *Game technology:* • Player's responses and behaviors • Game aesthetic, story • Narrative to aid engagement	Research team (without LTC exercise therapists)	*Remote playtesting:* • 1-hour discussion online (through Zoom)	• Add strategies to avoid getting stuck while rowing. • Better define the virtual world limits by adding buoys regarding the dolphin: (1) sounds should be added to facilitate prompting, (2) dolphin's behavior should help in meeting exercise intensities in conditioning. • Variables such as attention paid to the animals in the scenario as well as the response of players to haptic stimulus can be used to quantify reaction time. • Consider movement limitations when fishing to avoid persons living with dementia from getting frustrated.

[a]LTC: long-term care.

[b]VR: virtual reality.

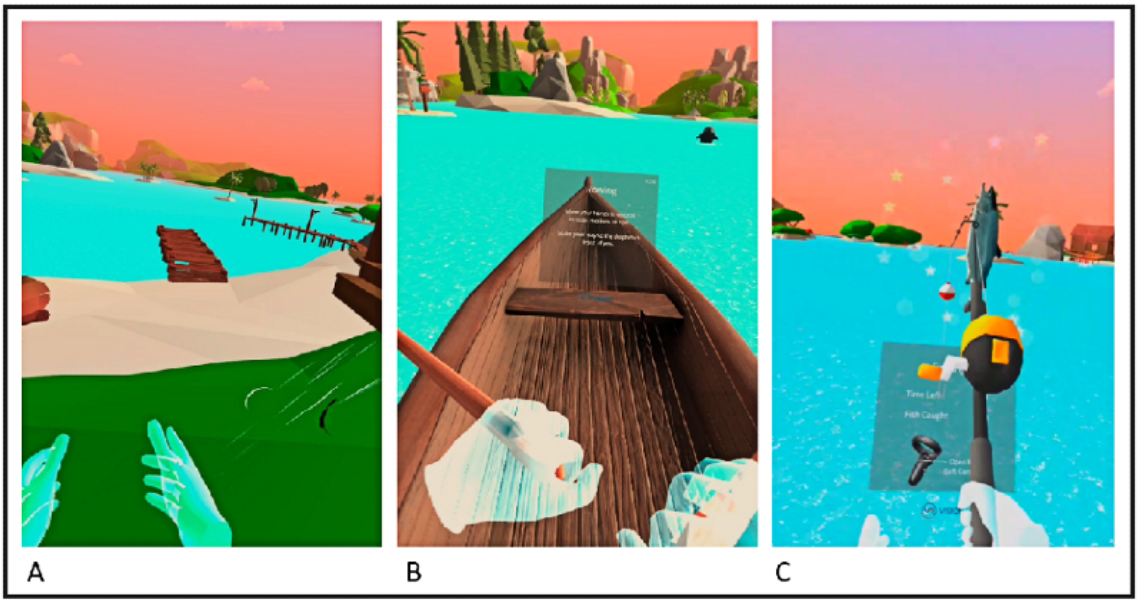
Results

Seas the Day: Final Game and System Overview (Description)

Seas the Day is an immersive HMD-VR experience that transports seated players to a virtual seaside with different activities that encourage exercise movements that have been shown to be beneficial to persons living with dementia/MCI [21,69]. *Seas the Day* places the players in a tropical environment surrounded by animals, hills, and water. Three activities lasting a total of 15 minutes were created (Figure 4 and Textbox 1) to align with the design requirements and needs identified in conceptualization and playtesting sessions.

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Figure 4. Seas the day screenshots showing the game levels of Tai Chi (warm up, left), rowing (conditioning, middle), and fishing (cool-down, right).



Textbox 1. Activities to align with design requirements and needs identified in conceptualization and playtesting sessions.

Tai Chi (warm-up, 3 minutes)

A set on a beach with a sunset in the horizon and birds seen and heard in the virtual scene. Players start the experience with a short Tai Chi routine that encourages upper limb movements that are connected with the virtual scene (Figure 4A). To guide players in performing the correct movements, a leaf-shifting metaphor is used wherein players are instructed to hold a floating leaf with 2 hands and guide it through trajectory paths drawn up in front of the players. Examples of the incorporated Tai Chi movements for range of motion are “wings of a bird” (moving arms to the side followed by a folding-like movement of the arms toward the chest), “open the door” (raising arms straight up and bring down with elbows bent) and “flower shifting with the breeze” (hands moving side to side).

Rowing (conditioning, 9 minutes)

The activity invites players to explore the tropical environment while rowing in a boat using 2 wooden oars attached to their virtual hands. This stage has been created as a conditioning phase as the rowing game mechanic involves exercising the muscle groups described in Table 2 aiming to improve strength and aerobic fitness (Figure 4B). As shown in Figure 4C, this game level has different spaces to explore such as a marsh, small archipelagos, and a valley and rocky spots among others. Hanging bridges, waterfalls, and thatched cottages are some of the objects that players will see while rowing. Five different animals have been included based on the suggestions collected in the playtesting sessions: fish, dolphins, dogs, cows, rabbits, and birds. To guide players, 2 aids have been included: (1) a virtual dolphin that swims specific paths and encourages players to follow along and to explore the virtual environment while keeping an adequate pace, and (2) voice-over narrations recorded by an experienced exercise therapist aiming to guide players on the movements and activities to perform. Following the dolphin is optional and, if players do not wish to do so, they will still be able to explore the environment at their own pace and preference. In this way, players are encouraged to keep exploring the environment by rowing the boat while multiple stimuli appear at different times and places to make the conditioning exercise more enjoyable. Figure 4B shows a screenshot of the rowing activity with the virtual boat, virtual hands, the environment, and the dolphin.

Fishing (cooldown, 3 minutes)

The activity comes after rowing, where players are transported to a fishing scene where they are encouraged to fish using a rod attached to their virtual hands. Neck rotations, elbow flexion, and elbow extensions are the main movements included in this game mechanic (Figure 4C). Fish are placed in the visual periphery (180°) and jump intermittently. The players are asked to use one of their hands to throw the fishing line to a targeted spot. Once in the water, the bait is ready for the fish to take; when one does so, the controller will start vibrating and players have to “pull” the rod out to hook the fish. Once hooked, players have to carry out a series of 6-10 repetitions of the desired movement (elbow flexion–extension) to get the fish and put it inside a bucket in the boat. By bringing the fishing rod close to the other hand, the players will be able to switch the hand used to hold the rod and repeat the fishing process. Figure 4C shows a screenshot of the moment where the player catches a fish and brings it to the boat. The game rewards the fishing efforts by displaying the fish in front of the player and moving it to the bucket.

Main Characteristics

Key features of *Seas the Day* are presented in Textbox 2.

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Textbox 2. Key features of Seas the Day.

Three exercise stages with 3 game mechanics

Seas the Day has been specifically designed to align with exercise recommendations for persons living with dementia/mild cognitive impairment (MCI) by creating an experience that is accessible and autonomously adjusts the exercise intensity for appropriate warm-up, conditioning, and cooldown stages of the exercise training. This is achieved by proposing different game mechanics (ie, Tai Chi, rowing, fishing) for each subgame that are suitable for persons living with dementia/MCI using data from playtesting sessions along with exercise professionals' recommendations. Game mechanics were designed to be intuitive, realistic, and adapted to the older population (ie, no buttons required, no teleportation) without frustrating those with limited mobility, as suggested by guidelines for exergames for persons living with dementia/MCI [71]. The main goal was for the game mechanics to achieve a balance between the serious intent of the game while keeping the fun and joy of playing in an immersive environment [74].

Narrative guiding players through the activities

From the playtesting sessions and previous research [67], we noticed that guiding players in performing targeted activities was a key component to create an effective gameplay experience and to elicit the desired physical responses. Thus, a game narrative approach was integrated into *Seas the Day* by using voice clips recorded by an exercise therapist within the research team with expertise guiding persons living with dementia through exercise therapy. Narrative has been found to be an experience booster in both exergaming and virtual reality (VR) experiences that enhances engagement [78], positively impacts perception of physical activity [79], and reduces motion sickness [80]. For instance, the following script was used as a voice over to encourage players to initiate and guide rowing: "There is nothing better than a trip in a rowboat! You're holding the oars for the boat in your hands. Can you see the dolphin? I think she wants to play...let's try to follow her!"

Automatic data logging

Seas the Day includes a data logging system that automatically captures movement and game variables during the gameplay. After each session, the system creates a data file containing the time series reflecting the changes of the game variables for the session and stores it in the headset internal memory. Examples of game events being recorded are (1) Tai Chi (time that players were following the path, time to complete each exercise); (2) Rowing (boat speed, distance traveled, number of strokes [total, right, and left oar], boat collisions, dolphin status [eg, away, following], birds approaching the boat, and time for the player to respond to it); and (3) Fishing (number of fish caught, pulling the rod up [repetitions], fish taking the bait, and time for the player to respond). As capturing physical and cognitive performance of players was a feature frequently discussed among exercise therapists and the research team, Seas the Day includes experimental variables in all the game levels that aim to capture (1) head and upper limb range of motion of players using kinematic variables (eg, position and acceleration from headset and controllers) and (2) reaction time using game events associated with cognitive function (eg, birds approaching/landing on the boat, pull out the controller after vibration when fishing).

Configurable options to customize the exercise session

To facilitate the customization of the experience, a configuration menu was integrated where therapists can modify components of the exercise session: (1) *duration* of 10, 15, or 20 minutes was given for each session; the distribution of time for each exercise stage is automatically configured and (2) *calibration* of the position in the boat for rowing with adjustable height of the avatar's position to ensure that rowing can be performed smoothly. Novel standalone VR systems (as the Oculus Quest 2) also have improved the calibration by including inside-out tracking technology (the cameras are in the headset and therefore, the calibration of the player position is automatic).

Seas the Day is freely available to be played using the Oculus Quest 1 and 2 headsets and can be found at Reality Well platform [4] and at the Oculus digital store [81]. The game complements a suite of VR content (360 videos, 3D tours, and interactive games) created by our VR industry partner and is (to the authors' knowledge) the first effort toward creating content through a participatory design process (involving various stakeholders such as the company, research team, persons living with dementia/MCI, and exercise therapists) and making the game available to anyone who wishes to use it.

Pilot of At-Home System Deployment With Community-Dwelling Older Adult Volunteers

Because of subsequent access restrictions to our target population (persons living with dementia/MCI) due to the COVID-19 pandemic, we decided to carry out a final pilot playtesting and co-design session with community-dwelling older adults. The goal of this pilot was to gather feedback regarding the exergame and overall user experience as well as to co-develop a workable protocol for remote deployment in the community of the system, using the exergame, and remote physical and cognitive assessments to quantify potential outcomes of playing our VR exergame (Multimedia Appendix 1). The resulting protocol will be used in our future feasibility study, which aims to remotely deploy the exergame with 20 community-dwelling older adults.

The study protocol, including safety and hygiene procedures for using HMD-VR devices safely at home and within the COVID-19 context, was approved by the University Ethics Board (Multimedia Appendix 2). We then shipped the equipment to our community-dwelling older adult test group members; shipping was done via a prepaid courier service. Five community-dwelling older adults were added as test group members, and the remote activities in Textbox 3 were carried out.

Upon completion of the pilot playtesting and remote assessment sessions, our older adult team members indicated several important aspects related to their experiences and opportunities for improvement, which are summarized in the 4 categories in Textbox 4.

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Textbox 3. Remote activities for the community-dwelling older adults.

Week 1: Introduction to virtual reality and conducting assessments

An Oculus Quest 2 virtual reality (VR) headset with the *Seas the Day* exergame was shipped to the participants along with a custom-designed, printed manual to facilitate the technology uptake at home. Remote sessions with a research assistant were also conducted on how to use the system and play the games. A battery of assessments were conducted during Week 1 to estimate cognitive and physical abilities: (1) *Cognitive function* (Montreal Cognitive Assessment, Verbal Fluency Test, Oral Trail Making Test, Flanker Test, 4 perceptual tasks [response time, simultaneity judgment, sound-induced flash illusion, temporal order judgment]); (2) *Mental well-being* (Geriatric Depression Scale and Physical Activity Affect Scale); and (3) *Physical activity* (Physical Activity Scale in Elderly, Exercise Self-efficacy).

Week 2: Playing Seas the Day

Older adult test group members were asked to play the exergames 3 times during Week 2 at their convenience with a maximum of 1 time per day. They were asked to play the game for 15-20 minutes while seated, and when finished playing, rate their level of perceived physical exertion and enjoyment. We also asked them to make notes regarding their observations and thoughts about the VR exergaming experience.

Week 3: Debrief with the research team

Two activities were conducted during this week: (1) a 30-minute long semistructured interview with each older adult, and (2) a 90-minute long focus group with all 5 older adults, members of the research team, and a member from our industry partner. The purpose of conducting interviews and the focus group session was to better understand experiences and to collaboratively figure out how to improve the protocol.

Textbox 4. Aspects related to experiences of older adult team members and opportunities for improvement.

Study process and remote support

The older adults in the test group enjoyed the social aspect of high levels of interaction with the researchers but felt communication through email was overwhelming. They stated the Week 1 process and assessments needed to be simplified to avoid confusion, such as not finding the correct links or having difficulties to complete the tasks. Test group members also wanted to know more about the purpose of assessments, their test scores, and final results of the future study. They suggested having more introductory sessions with the virtual reality (VR) equipment to facilitate the use of the system (eg, calibration, content selection, exiting the game) and improve rapport with the research team. Overall, the experience of receiving and shipping back the headset and printed material was satisfactory.

Exergaming experience and playability

Overall, playing the exergame was perceived as a positive experience and the virtual environment produced a pleasant and engaging exercise experience for the test group. They reported that the most challenging part of the game was when they were asked to row while following a virtual dolphin. The rowing mechanics were perceived to be unrealistic for people with previous rowing experience, although it was easy to follow for other users. The members of the test group found the game easy to play, and the voice and sound effects were considered to be relaxing. Playing the game was perceived as a light-intensity physical activity for all 5 test group members; some suggested making the gameplay more challenging and others wished there were more diverse activities to do. Finally, some participants indicated interest in knowing more about the exergaming design and development process and how our study results may impact future development of the games.

VR technology experience

The experience of using the VR hardware for at-home exercise was generally positive but still challenging for most participants. While the instructions in the custom-made VR manual were found to be sufficient (although somewhat lengthy), issues related to calibration, buttons, and locating the controllers in the physical environment after wearing the headset were mentioned during the interviews and focus group sessions. Some participants also reported the need to ask for family members technology support while playing (eg, for troubleshooting or calibration). Launching and exiting the game were also challenges among test group members who were interacting with a VR system for the first time. None of 5 community-dwelling older adults in the test group reported motion sickness or feeling disorientated after the sessions. However, during the introductory session, 1 of the older adults in the test group had difficulties to launch the game and, while troubleshooting with the research team, she spent more than 30 minutes using the VR and reported feeling nauseous.

Remote assessment

The test group found performing the online assessments challenging. The computer-based tasks were perceived as being monotonous and repetitive, which resulted in test group members feeling bored or overwhelmed by the amount of time spent in the assessments. A more integrated accompaniment of researchers was suggested to better support participants when completing the online tasks. There was a disparity in technology that was used and some test group members reported having difficulties in completing the tasks when using certain devices (eg, touch computers with small keyboards).

Discussion

Principal Findings

Our research assembled a collaboration of disparate professionals and people with lived experience to form a cohesive, productive, and focused multidisciplinary team to create engaging and tailored exergames that can promote physical activity for older adults, including persons living with dementia/MCI. While most research is conducted under specific circumstances (including adhering to COVID-19 restrictions), a key contribution of our work is to demonstrate a working model that blends the interests, investments, key stakeholders, and benefits of an interaction among the academics and private institutions that develop dementia-centered solutions with the potential of being adopted in LTCs as well as generates a sustainable business model for the private sector. The second key contribution of this research is establishing and describing a process, including the purpose, inputs, methods, and outputs of each stage, in a way that others can adopt and adapt it.

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Providing details regarding the HCD-based digital games for persons living with dementia/MCI is crucial if we are to learn from each other, which in turn will result in appropriate, viable, and replicable methodologies [32]. Clear methodology and careful processes for collaborating with persons living with dementia/MCI are particularly important to ensure their needs and perspectives are considered in the conceptualization, design, and development. While our process still has room for improvement, this research provides a real-world scenario, exposes major challenges, and highlights important design aspects that should be considered when creating immersive games for persons living with dementia/MCI.

While serious games for persons living with dementia/MCI offer much promise, they are far from realizing their full potential. The time, money, and other resources required to design, develop, and implement a VR system must be clearly offset by the benefits for the end users. To achieve this, more efforts must be made by the content creators toward defining, refining, and implementing strategies that support the inclusion of persons living with dementia/MCI and their care partners in the creating process. Accessible solutions should reflect the abilities, values, and needs of the end users to support the uptake and enhance sustainable use of the technology.

Lessons Learned Through the Creation and Piloting of Seas the Day

Leave the Laboratory to Create a Cohesive and Complementary Team

We challenge researchers to leave their laboratories and seek out industry and other nonacademic partners. These partners substantially contribute to the design, scalability of the solution, and enable the team to take a larger, systems-based approach. Connecting with and involving partners from the beginning enabled us to collaboratively define project scope, methods, and outcomes that complemented and benefited all partners. This approach was crucial to building trust, motivating engagement, and creating shared feelings of success when milestones were achieved. In our case, our industry partner goals are well-aligned with our project, this is, they have complementary leadership (eg, the Vice President is an experienced nurse), and have a genuine interest in making a positive change in the lives of persons living with dementia/MCI. This synergy helped to provide momentum through roadblocks. Our LTC partner was keen about the project from the onset. They supported the project by approving their therapists to be core members of the research and offering to pay for backfill (eg, someone to do the therapists' job while they were working on our project). This resulted in therapists as key team members who guided the process, including facilitating access to LTC, learning about exercise with older adults, and access to persons living with dementia/MCI, all of which have been found to be significant barriers to the development of supportive technologies for persons living with dementia/MCI [14].

Now Is the Time to Develop Usable VR for Persons Living With Dementia/MCI

The popularity of VR and its potential to be adopted during and after the COVID-19 pandemic are unprecedented (eg, telemedicine [82]). The pandemic has significant adverse effects on the well-being of persons living with dementia/MCI in LTC homes. These challenges should be quickly and efficiently addressed. VR is well positioned to mitigate some of these challenges; however, there is much work to be done to realize this opportunity. First, the design of custom-made solutions using VR that can be safely implemented in LTC homes during COVID-19 requires close collaboration with therapists and staff, who are finding their time more limited during COVID-19 because of work demands. Second, playtesting with end users (and especially persons living with dementia/MCI) is very challenging or impossible because, at best, they need support from the therapists to start using the system and, at worst, are simply unavailable for research because of COVID-19 restrictions. In our process, we relied on iterative objective (eg, data recorded from the system) and subjective (eg, opinions and observations) feedback from exercise therapists and persons living with dementia/MCI who playtested to guide our design process. In their absence, we have been relying on recordings that team members watch remotely when in-person playtesting is not an option; however, this is significantly slower and less informative.

Therapists Are Problem Solvers and Game Designers by Nature

Therapists are constantly looking for new approaches to engage persons living with dementia/MCI in different therapeutic and leisure activities (usually on a tight budget and a busy schedule). They are accustomed to thinking outside the box to develop novel solutions to difficult problems. For instance, the idea of using an animal character to guide a "tour" around the tropical environment to modulate exercise intensity came from a therapist when we asked: "How do you think we can make the rowing activity more fun and engaging for persons living with dementia/MCI?". As guided by the therapists, we are exploring novel ways of visualizing data to provide therapists and their clients with objective measures of exercise (to be presented in a forthcoming paper). This aspect is challenging as it is a blend of system capabilities and information that results in new forms of data that are readily understood by therapists. To design this, therapists need to envision how the gaming system could be used to augment and improve the conventional methods as well as what information they were not currently working with but would be helpful to have. In our case, inviting therapists as members of our research team created a sense of belonging, long-term commitment, and ownership of the project, which allowed everyone to feel more comfortable, honest, and direct when discussing ideas or exchanging opinions. In short, having therapists as co-designers of our exergame was a very fruitful and enriching experience.

Limitations Found When Older Adults Use VR Technology

In addition to the lessons learned, limitations presented through the use of VR technology must be addressed. The *weight* and

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cost of the headsets have continuously decreased over the last decades, making VR headsets increasingly accessible and comfortable. Further, limitations arise from the physical hardware of headset itself, as HMDs can be bulky both in size and in weight. Improper fitting of HMDs can cause further discomfort and strain on the neck muscles and indeed feelings of discomfort and dislike of wearing a headset have been previously reported in the literature [83]. We have used Oculus Quest 1 and 2, which weigh approximately 500 g, and have provided participants with a detailed manual as well as one-on-one support with the setup process prior to and during the data collection to help minimize strain and correct placement of the headset.

Technology know-how, ranging from limited to no previous experience to expert users [84-86], is a barrier for uptake of VR in older adults as well as other populations. Once a user has gained access to the device, further limitations may appear. For example, to have agency and to be able to explore a virtual environment, the user must be able to use hand controllers to interact with their surroundings. As previous research has found that hand controllers can be complicated for some older adults, especially those living with MCI or dementia, this can limit their interaction with the environment [67]. Therefore, the use of haptic gloves or other controller-free interfaces has been recommended as they may be more intuitive to use [83,87]. Indeed, our playtesting sessions with community-dwelling older adults indicated some issues when using the controllers.

Cybersickness is also a concern, with symptoms of nausea, sweating, salivation, apathy, headache, abdominal discomfort, disorientation, postural instability, oculomotor disturbance, and eyestrain being the most commonly reported [88-91]. In VR, the dynamic environments are designed to induce a high degree of immersion enabling an illusory perception of self-motion, known as vection. However, because a user is usually stationary (eg, standing of sitting), the vestibular and proprioceptive organs receive minimal afferent input which can cause sensory conflict, leading participants to experience cybersickness. Given that cybersickness has been associated with detriments in user performance, safety, immersion, presence, and acceptance [39,88,91-94], it is necessary to examine how this may impact the participants who partake in our exergame intervention. Although our pilot project did not lead to any reports of cybersickness, we were provided with feedback regarding the directionality of rowing being incongruent with reality, which may lead to future participants experiencing cybersickness.

Finally, there is a *risk of injury* from one's external environment when using an immersive HMD virtual environment [95-97]. During this period, users of VR have limited, if any, visibility of the real world as well as limited real-world aural stimulation as many virtual environments include visual and sound cues that are designed to be immersive and distract attention away from the real world. These factors can lead to collisions with real-world objects that can cause injury. Suggestions to mitigate such an outcome range from engaging in VR in a safe area with protected railings to sitting while playing [95]. As such, Seas the Day has been designed to be played while seated and while remaining within the guardian setup.

Limitations and Future Work

Our process has several limitations. While the research was designed to include end users in several playtesting sessions throughout the project, the COVID-19 outbreak critically limited our access to both persons living with dementia/MCI and exercise professionals working with this population. Collecting information from a homogeneous group of fragile older adults during a global pandemic situation involves multiple challenges such as (1) the constantly changing regulations and governmental policies in developed countries and (2) the individual measures adopted by LTC homes to protect the residents. The recruitment of persons living with dementia/MCI was carried out by exercise professionals in the LTC homes, whereas the recruitment of the community-dwelling older adults for the pilot was by a snowball sampling method. Both recruitment processes have limitations related to the little control researchers have over the participants and their demographics as well as the potential lack of representativeness of the recruited participants. Besides, due to the qualitative nature of the HCD process, the sample size is normally low due to the in-depth analysis required to create engaging game mechanics using playtesting methods and comprehensive player-centric models.

Nevertheless, the feedback collected during the playtesting sessions carried out before the COVID-19 pandemic allowed collecting rich information on player's preferences regarding visuals, interaction issues in the virtual environment, and perceptions about the use of VR technology. Additionally, we were able to engage community exercise professionals who had a history of working in LTC homes. We also managed to engage community-dwelling older adults to co-develop the deployment protocol, which was invaluable in helping us to refine the protocol for deploying the system and related testing for at-home exercise training programs. Our HCD process did not intend to create generalizable models (eg, user personas, empathy maps) of persons living with dementia/MCI [3] and their preferences for playing VR games. We intended to collect usable information that could inform our game design process and provide insights into which game elements were more suitable to elicit the required movements (Table 2) while keeping the fun of exergaming.

As the game was initially created to be played by persons living with dementia/MCI, some community-dwelling older adults found the game was not very challenging, especially as they became more accustomed to it. While there is nothing impeding healthy older adults to get benefits from playing *Seas the Day*, the challenges and game design process were tailored to those with cognitive impairment, therefore it is not surprising that healthy older adults may find the game and game activities easy to accomplish. Therefore, generatability of the findings should be carefully considered because we have playtested the game with 2 groups of very different older adults (community-dwelling and persons living with dementia/MCI). This research represents a first stage in this project. Future work includes evaluating the effectiveness of the VR system in 2 populations: persons living with dementia/MCI in LTC assisted by exercise therapists (once COVID-19 allows it) and community dwelling-older adults at home.

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We will also continue to develop the technology; the next stage of our research will focus on the development of intelligent algorithms to create adaptive gaming experiences that include physiological (eg, cardiovascular [98]) and kinematic (eg, motor control [99]) data to modulate gameplay. In addition, our game development will focus on creating new game scenarios to provide a more diverse, multithematic, and enjoyable virtual farming experience.

Conclusions

This research provides insights into how HCD can be used to actively involve multiple stakeholders (including end users, researchers, and industry partners) in designing and developing VR exergames that are tailored to older adults with cognitive impairment. The results of our process demonstrate a replicable model of interaction that blends the needs and preferences of end users with those of exercise providers. The value of including end users and exercise therapists' feedback throughout the game design process results in an enriched game design with elements familiar to and preferred by end users that are potentially effective in eliciting desired exercise movements that produce measurable health outcomes. Also, the inclusion of an appropriate industry partner that specializes in VR content development was crucial to producing a set of exergames with characteristics that are closer to a finalized product (Multimedia Appendix 3).

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Conflicts of Interest

None declared.

Multimedia Appendix 1
VR equipment sanitizing protocol.
[PDF File (Adobe PDF File), 713 KB - games_v10i1e29987_app1.pdf]

Multimedia Appendix 2
Cognitive and physical assessments.
[PDF File (Adobe PDF File), 545 KB - games_v10i1e29987_app2.pdf]

Multimedia Appendix 3
Seas the day is an interactive experience created to foster wellbeing in persons living with dementia using virtual reality. A collaborative design process involving exercise professionals, persons living with dementia, kinesiologists, the VR Vision design and development team and researchers in human factors from the University of Waterloo.
[MP4 File (MP4 Video), 132145 KB - games_v10i1e29987_app3.mp4]

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Abbreviations

ADLs: activities of daily living
HCD: human-centered design
HMD-VR: head-mounted displayed-virtual reality
LTC: long-term care
MCI: mild cognitive impairment
ROM: range of motion
SWOT: strengths, weaknesses, opportunities, and threats
VR: virtual reality

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Original Paper

A Reusable Multiplayer Game for Promoting Active School Transport: Development Study

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Abstract

Background: Most children and adolescents in Sweden do not meet the recommended daily physical activity levels of the World Health Organization. Active school transport (AST) and gamification are potential methods for increasing children's daily physical activity. We previously developed a game named Tic-Tac-Training for promoting active transport at workplaces; however, the game has not been applied to AST.

Objective: The objectives of this study are to investigate how Tic-Tac-Training functions to promote AST among schoolchildren in northern Sweden, improve the game to be more suitable for schoolchildren, and construct a road map for future development based on children's ideas.

Methods: First, we developed Tic-Tac-Training using the Scrum agile software development method. Second, we conducted a questionnaire-based formative evaluation of the game with schoolchildren (n=16; 9/16, 56% male; 6/16, 38% female; and 1/16, 6% other aged 11-12 years) in Luleå, Sweden. Third, we conducted focus group interviews with 33 children (13/33, 39% male and 20/33, 61% female aged 12-13 years) to gather ideas for gamifying AST. We mapped the interview results to the Octalysis gamification framework and established a road map for future development.

Results: The formative evaluation revealed several issues, including a lack of interesting game features, lack of support for continuous engagement, disliked competitive features, and lack of incentives for discourse and participation. New features such as rewards, collectibles, and levels were implemented based on the results. The focus group interviews revealed additional ideas for gamifying AST, such as using avatars, in-game currency and trading, and context-sensitive tasks.

Conclusions: The results have several potential impacts on how reusable, gamified AST interventions can be developed and what kind of gamification elements schoolchildren in northern Sweden wish to see. These results can interest game researchers and teachers who wish to apply gamification in school contexts. Finally, we aim to continue developing the game based on the road map.

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KEYWORDS

gamification; active school transport; physical activity; formative evaluation; architecture; mobile phone; web browser

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Introduction

Physical Activity and Active School Transport

Considerable health benefits are associated with increased physical activity, such as cardiorespiratory and muscular fitness and a positive effect on weight status [1-3]. Furthermore, there is evidence concerning the positive impact of physical activity on cognitive abilities and prosocial behavior [4]. However, most children and adolescents worldwide do not reach the recommendation of daily physical activity from the World Health Organization [1,5].

A solution is to use active transportation daily, which has substantial positive impacts [6]. Moreover, physically active children and adolescents are more likely to adopt healthy behaviors, and a physically active lifestyle in childhood often transfers to adulthood [7-9]. Overall, adequate physical activity in childhood can lead to healthier lives in adulthood through avoidance of adverse health effects related to obesity and through continuity of regular physical activity behavior [10]. The health benefits of walking and cycling for transport entail a significant reduction in risks for cancer mortality, cardiovascular disease, and obesity morbidity [11,12]. Although active transport involves risks such as traumatic accidents and exposure to poor air quality [13,14], the health benefits of cycling are significantly larger than the risks of cycling when compared with car driving [3,15,16]. There is also climate protection and environmental benefits accrued to active transport–based physical activities [17] and the possibility of decreasing traffic around schools [18].

Despite the numerous benefits of active transport to increase physical activity, only 57% of children aged 6-15 years in Sweden use active transport to school during spring and fall, with an even lower frequency of 48% during winter [19]. The trend of decreasing the use of active transport among children and adolescents is global, and it is expected to continue if interventions are not made to change this trend [20-22]. Increasing daily routines for physical activity, such as using active school transport (AST), is also a prioritized area in the global plan of the World Health Organization for increasing physical activity [23].

This study focuses on AST, in which nonmotorized methods are applied to transportation between homes and schools. Thus, AST can increase much-needed daily physical activity among children. However, adopting AST can be challenging given that motorized transportation has many attraction points, such as convenience, weather independence, and avoiding trip chaining [24]. In contrast, AST requires physical exertion and is affected by weather conditions, the latter of which can be a significant factor in northern Sweden. Moreover, parents' concerns, such as the availability of infrastructure, distance, time, traffic safety, and compatibility with other activities requiring transportation, form additional barriers that AST solutions must overcome [25,26]. Despite these challenges, successful AST in winter is possible as long as the motivational aspects of AST (eg, promoting togetherness and involvement) are adequately realized [27].

Gamification of Physical Activity and AST

Gamification refers to applying elements of games, such as rules of playing, badges, points, and leaderboards, in nongame contexts. Games have been shown to possess strong motivators that drive a person's desire to engage in unappealing activities [28] such as cycling during snowy winter conditions [27] and using active transport instead of motorized transport [29]. Moreover, several notable models and frameworks such as Octalysis [30], Mechanics-Dynamics-Aesthetics [31], and Hexad [32] have been proposed to assist researchers and practitioners in applying gamification to diverse areas. In addition, widely spread commercial games such as Pokémon GO have been shown to positively influence the physical activity and health of both child and adult players [33-35].

Recent studies have suggested using gamification to promote physical activity among children and adolescents to encourage and motivate behavior change toward a physically active lifestyle. Quintas-Hijos et al [36] explored the use of gamification in the context of physical education in fifth and sixth grade. The results affirmed that gamification provided a greater overall positive feeling, fun, creative inspiration, autonomous learning, motivation, and digital leisure alternatives. Corepal et al [37] carried out a gamified intervention at a secondary school in Northern Ireland. The StepSmart Challenge was an intervention for adolescents to change their physical activity behavior through team and individual competition using motivation and incentives. Another study used weekly challenges among students where they earned badges, trophies, and rewards after the intervention to improve cardiorespiratory fitness and reinforce positive physical activity behavior [38]. In another study, Lindberg et al [39] developed and evaluated a sensor-driven board game in which players competed against each other by solving physical and pedagogical missions to complete moves on a large game board. The results indicated increased learning efficiency, player engagement, and exertion. Finally, Comeras-Chueca et al [40] conducted a systematic review of the use of active video games for overweight and obese children and adolescents. Their findings showed that active video games have clear positive effects on BMI and body fat percentage, but their effects on muscular fitness, fat-free mass, waist circumference, and motor competence remain unclear.

In addition to supporting children's physical activity, gamification has been applied to promote AST with notable benefits [41-44]. Coombes and Jones [41] found evidence that children who engaged in gamification that encouraged them to walk and cycle to school using tracking technology with a reward scheme increased their AST time and physical activity level. Specifically, there was an increase in weekly active travel and a positive association between moderate to vigorous physical activity during school commuting times and the number of days children used the gamified system. In another study built on gamification elements, the participants recorded their walking and cycling travels by tapping "Beat Boxes" (radio-frequency identification scanners installed at various locations in the game area) and received points and incentives [43]. The results of this study showed increased physical activity levels among the participants. Another study on the same project

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showed that collective rewards, social influence, and exploration were key motivating factors for engagement with the intervention [44].

In 2020, we presented a novel distributed multiplayer game, Tic-Tac-Training, for promoting active transport at workplaces [45]. Tic-Tac-Training is an adaptation of the Tic-Tac-Toe game in which players compete against other teams by completing various tasks related to active transportation and sustainable working habits. The game can be customized by defining the tasks that the players are to complete. This way, the game system could be applied to a wide range of contexts, such as AST for children.

Context of the Study

This study focuses on northern Sweden, particularly the municipality of Luleå, which has a population of 77,832, of which 7492 were pupils attending grades 1-9 in the academic year 2019-2020 [46]. The municipality has a wide network of bicycle and pedestrian roads and strong expertise in maintaining the roads in winter conditions (eg, plowing and spreading sand and salt), making motorized and nonmotorized transportation feasible throughout the year.

Despite the feasibility of nonmotorized transportation, the number of children using AST has been low. The situation has recently improved owing to efforts to promote AST in schools. The fifth (SR) and sixth (AKL) authors implemented a previous intervention to promote AST based on empowerment and nondigital gamification [47]. To scale the intervention, a digital gamified AST tool would be vital.

This study is part of the multidisciplinary project Sustainable Innovations for Children Transporting Actively. One of the project's aims is to create new knowledge about applying games to engage children in behavior change in favor of AST. In addition, the project co-designs curriculum-based learning activities with teachers, pupils, and parents to motivate and engage AST.

Aim and Contributions

We aim to investigate how the Tic-Tac-Training game is suitable for promoting AST among schoolchildren, how its suitability can be improved, and what gamification elements schoolchildren would like to have in the AST game. Consequently, we make the following contributions: (1) a description of the game and its technical implementation, (2) a formative evaluation with schoolchildren in Luleå to test the suitability of the game concept for AST, (3) a refinement of the game by adding features based on the formative evaluation results, (4) a presentation of other AST gamification ideas gathered from schoolchildren and mapping of the ideas to the Octalysis gamification framework [30], and (5) a road map for the next iteration of development of Tic-Tac-Training based on these ideas.

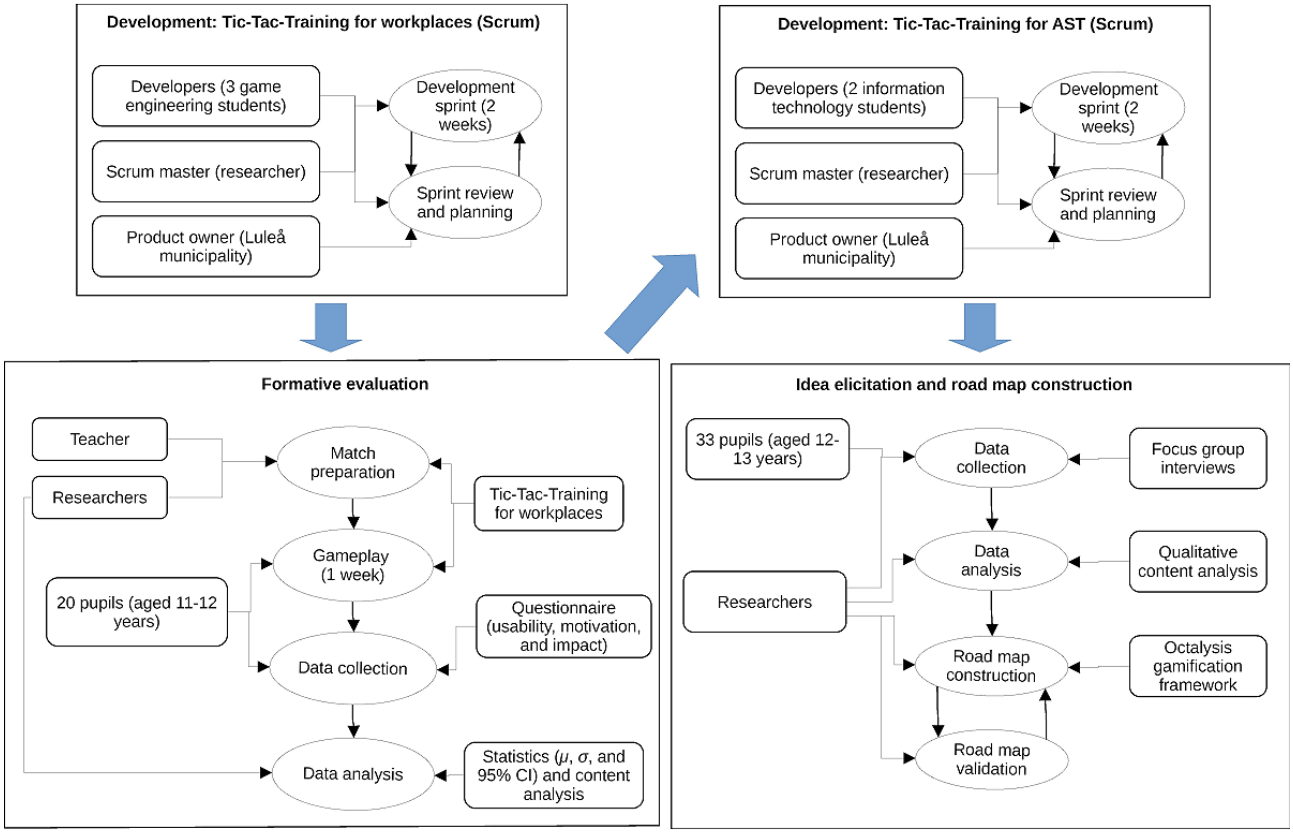
Methods

Research Design

This study followed a mixed methods approach, comprising both quantitative and qualitative methods. The core part of the study is an iterative, user-centered development of the Tic-Tac-Training game building on the contributions of end users, university students, and elementary school pupils. In addition, we conducted a formative evaluation of the game using a questionnaire, as well as focus group interviews to explore the pupils' experiences and ideas for the gamification of AST. The overall research design of this study is shown in Figure 1. The 4 stages of research are explained in detail in the following sections followed by an ethics statement.

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Figure 1. Research design. AST: active school transport.



Game Development: Tic-Tac-Training for Workplaces

Tic-Tac-Training was originally developed for workplaces with a user-centered design method whereby the designers iteratively constructed a series of design prototypes in the context of the Luleå municipality [45]. The workplace version of Tic-Tac-Training was implemented using the Scrum agile development method [48] whereby biweekly scrum sprint review and planning meetings were arranged between the developers (3 university students in game engineering), the scrum master (the first author), and the product owner (Luleå municipality and the third author).

Formative Evaluation

The purpose of the formative evaluation [49] was to measure the perceptions of a group of elementary school pupils in Luleå of the Tic-Tac-Training game, which would guide the iteration of the game development process. In particular, we sought to understand how children react to a game created to promote active transport at workplaces by exploring the aspects of usability, motivation, and expected impact.

Participants

In total, 20 voluntary participants were recruited among sixth-grade pupils by a teacher at a Luleå-based school in February 2020. The number of participants was deemed to be sufficient for a formative evaluation to identify most shortcomings and problems; in the classic usability testing guideline, 5 participants are recommended as an adequate number, and 15 is found to be an optimal number of participants for a user test in a medium to large project [50]. The ages of the participants were between 11 and 12 years, with the gender distribution of the questionnaire respondents being 56% (9/16) male, 38% (6/16) female, and 6% (1/16) who chose *other* as their gender. As the participants were minors, we obtained permission from their parents.

Data Collection Instrument

We developed a questionnaire (Multimedia Appendix 1) comprising demographic information (school, age, and gender) and three sections comprising 5-point Likert scale questions: usability, motivation, and impact. In addition, open fields were provided to the participants to motivate their answers and for them to provide comments freely. The usability section measured the overall usability of the game using questions that were adopted from the System Usability Scale [51] and Net Promoter Score [52]. The motivation section gauged the enjoyment factors, if any, in the gameplay. The impact section measured the impacts of the game on areas such as physical movement, environment, and fellowship in the class. The questionnaire was developed in Swedish, and we asked a teacher to validate the language before the questionnaire was administered. Finally, the questionnaire did not contain any personally identifiable information about the participants.

Match Preparation

Researchers and a teacher created a total of 24 tasks in Swedish. The tasks covered various activities such as cycling, walking,

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playing outdoors, and convincing adults at school to perform AST. Instructional videos were created for the teacher to learn about the game and its features, including a tutorial on creating a match. The teacher created an account for herself in January 2020 and was promoted to the match creator role by the game administrator. The teacher then created a match for her pupils using the previously created tasks.

Data Collection and Analysis

The gameplay and data collection took place in February 2020. We first obtained permission from the participants' parents for their children to participate in the formative evaluation. The teacher then provided the pupils with instructions to create a player account, after which she configured and started a 1-week–long match for the pupils with 5 teams of 4 pupils each. The teacher explained how the gameplay worked and answered the pupils' questions. The teacher was asked to contact the researchers if any technical problems or questions arose that she was not able to answer. After the gameplay ended, the pupils were asked to fill in the questionnaire delivered through Google Forms. In total, 16 pupils replied to the questionnaire. The questionnaire data were analyzed using descriptive statistics (mean, SD, and CIs) of the Likert data and simple content analysis of the open-field data.

Game Development Method: Tic-Tac-Training for AST

On the basis of the formative evaluation findings, 2 university students in information technology continued the development by adding new features that would make the game more suitable for AST. The same Scrum method [48] was used as described above. The 2 students were different from the original group of student developers.

Idea Elicitation and Road Map Construction

In 2017, 2 classes with 40 children aged 12-13 years participated in the nondigital AST intervention by the fifth and sixth authors. After the intervention, 33% (13/40) male and 50% (20/40) female children gave their informed consent to participate in focus group interviews with 4-7 students in each group. They were asked to discuss their experiences with participating in the intervention concerning photos they had taken during the intervention period; the results were published elsewhere [27]. In addition, we asked the participants to discuss their ideas and thoughts about developing a digital game to support the AST intervention; these data are presented in this study.

The focus group interview data were transcribed and analyzed using qualitative content analysis [53] by the fifth and sixth authors to identify gamification ideas. Once the ideas were recorded, the first author analyzed them through the lens of the Octalysis gamification framework [30]. This framework is well-known in the field of gamification and comprises 8 *core drives* into which various gamification elements can be placed. The first author mapped the children's ideas to the core drives and then, based on the ideas, derived concrete feature suggestions for each core drive that could be implemented in the next iteration of development. The other authors validated the mappings and feature suggestions, resulting in the final feature road map.

Ethics Statement

This study was conducted in accordance with the ethical principles within Swedish law for research and the Declaration of Helsinki of the World Medical Association. This study was approved by the Regional Ethical Board of Umeå, Sweden (2018-10-31M). The participating students and their parents provided informed consent. All students were informed about the possibility to participate or not, as well as that they could decide to withdraw their participation at any time.

Results

Tic-Tac-Training for Workplaces

In this section, we describe the details of the implementation of the workplace version of Tic-Tac-Training before presenting the formative evaluation results. First, we describe the game concept followed by the game's architecture and implementation details.

Game Concept

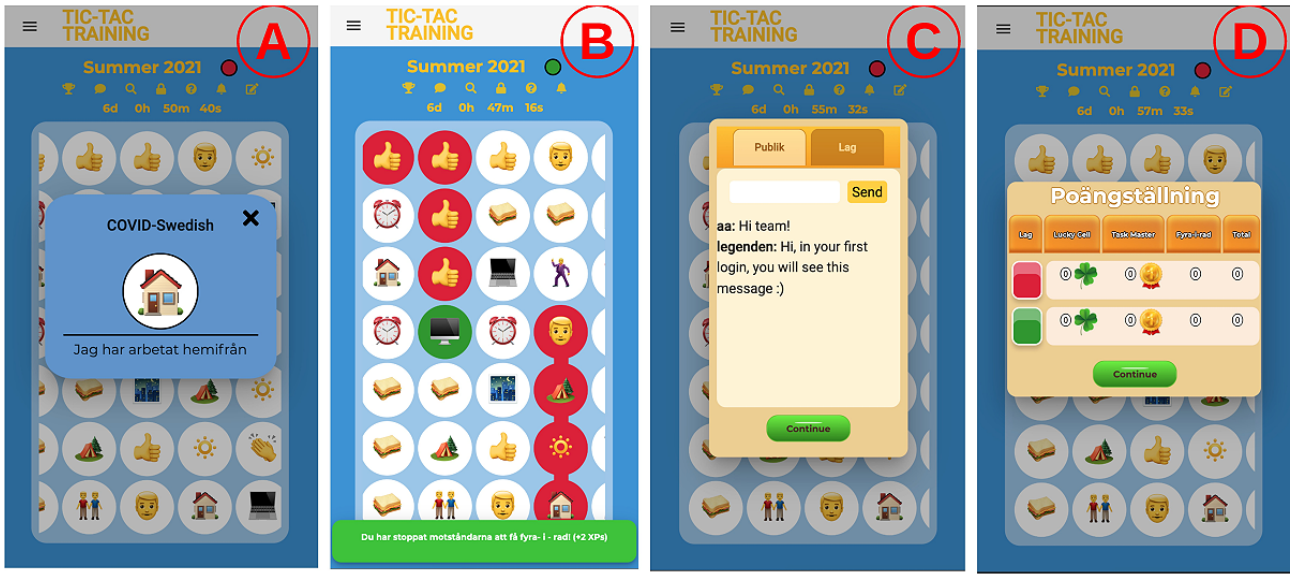
Basic Gameplay

The purpose behind developing Tic-Tac-Training was to motivate people to become physically more active. The game was designed to offer competitive and collaborative gameplay by expanding upon the basic concept of the Tic-Tac-Toe board game. Unlike Tic-Tac-Toe, players play in teams without turns and earn points by completing various tasks assigned to the game board cells. Before completing the task, players can open the description box of the task to understand the requirements (Figure 2A). Completing 4 cells in a diagonal, horizontal, or vertical row yields the team a point. The players can also block other teams. These cases are illustrated in Figure 2B. A match ends when the time runs out or when one of the ending conditions is met (see *Match and Task Creation*).

The player profile contains basic information about the players, such as their name, nickname, email address, picture, and a short description. When the player selects a match after log-in, it is opened with a match timer and several tools such as (1) a chat room where the player can communicate with their team as well as with other teams (Figure 2C), (2) a leaderboard where players can see their team's position relative to other teams (Figure 2D), and (3) a task filter that allows the player to highlight only the desired tasks on the game board.

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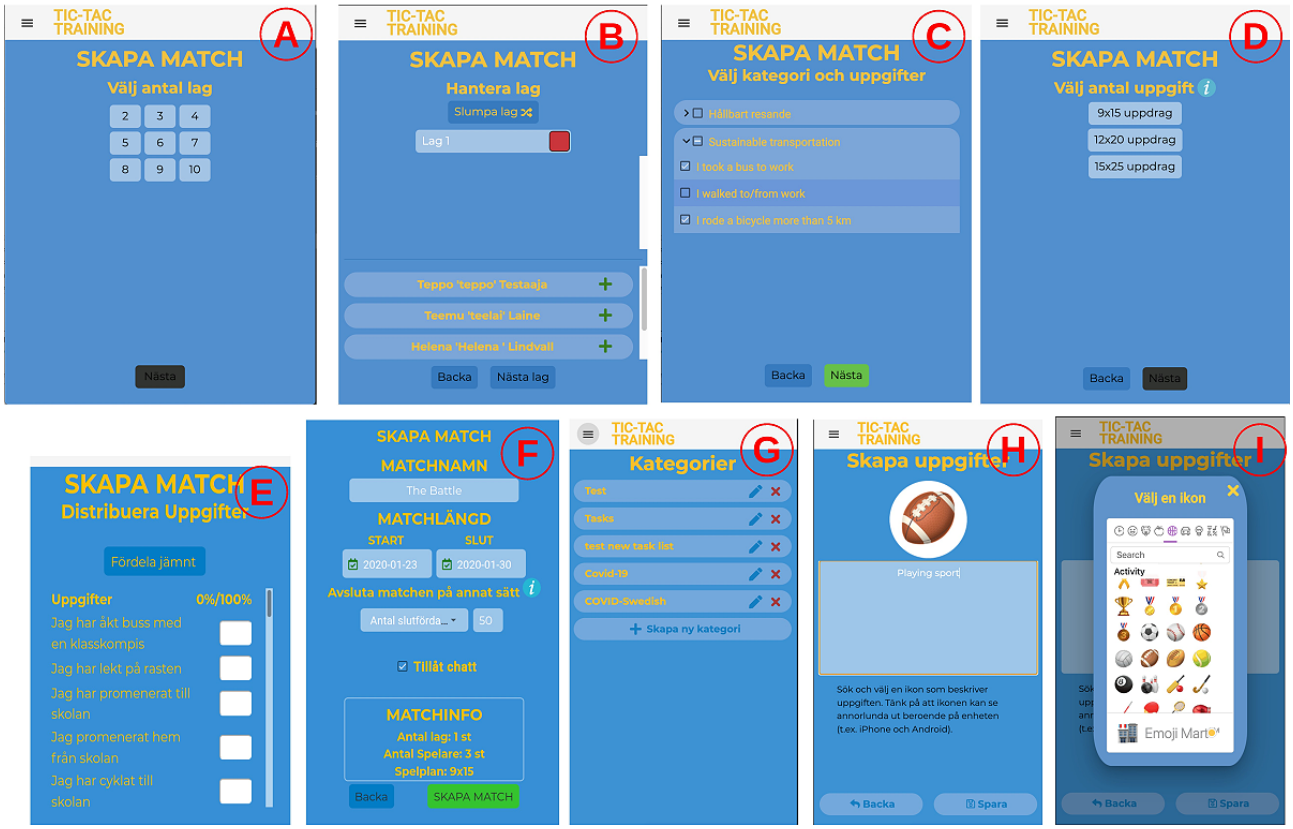
Figure 2. Tic-Tac-Training gameplay screens. (A) Task details, (B) game board where the green team blocked the red team, (C) in-game chat, (D) match statistics.



Match and Task Creation

A match can be created and modified by a match creator (eg, a teacher). The basic match settings are the number of teams (Figure 3A); team members, colors, and names (Figure 3B); tasks for the match (Figure 3C); game board size (Figure 3D); tasks and their distribution on the game board (Figure 3E); and match name, duration, end condition, and whether to enable chat (Figure 3F). A match can be set to expire after some time when the number of completed rows reaches the set target or when the number of completed cells reaches the set target. Finally, the match creator can modify some match settings (eg, team compositions and match-ending conditions).

Figure 3. Tic-Tac-Training match and task creation screens. (A) Selecting how many teams will play; (B) assigning players to teams; (C) selecting tasks for the match; (D) selecting the game board size; (E) selecting distribution of the tasks; (F) choosing match name, period, ending condition, and chat; (G) managing task categories; (H) creating a new task; (I) choosing an icon for a new task.



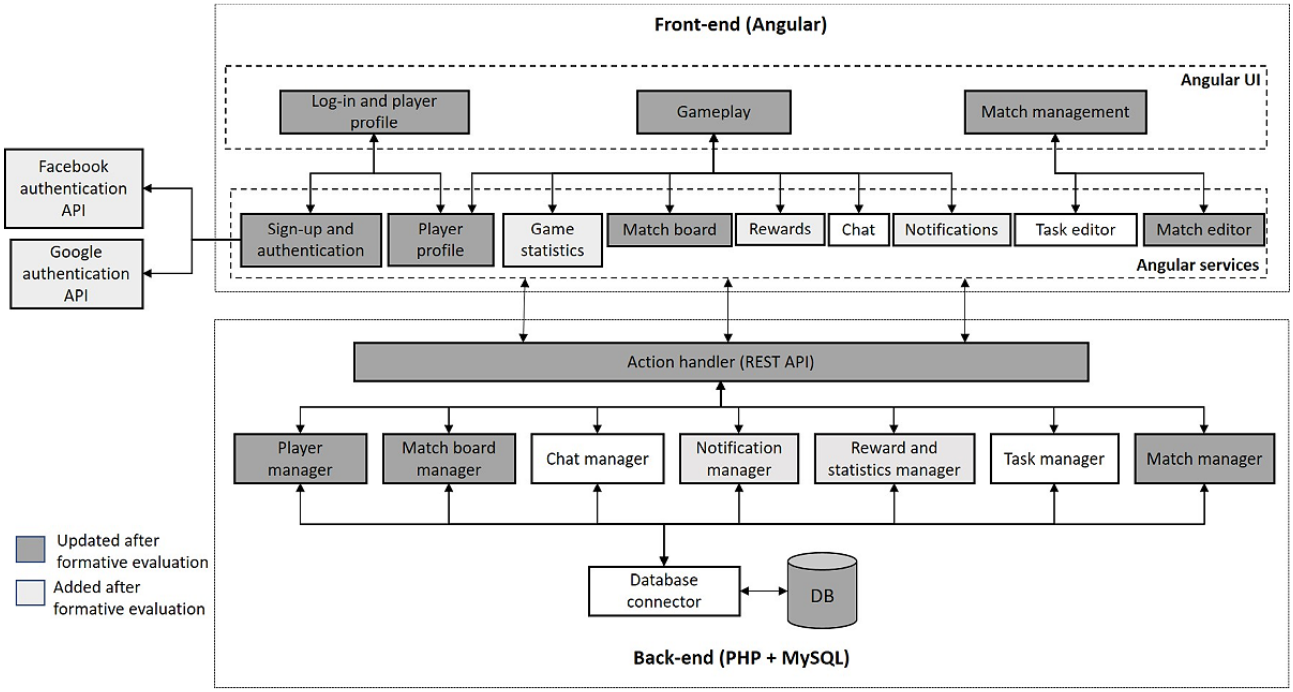
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The match creator creates match tasks by first selecting a suitable task icon from a searchable list of emojis (Figure 3I) and then adding a description for the task (Figure 3H), such as *Ride bicycle to school*, *Take a walk during lunch break*, or *Run two kilometers*. Moreover, the created tasks can be grouped into categories (Figure 3G), enabling the selection of several tasks at once during match creation. Finally, all the created categories and tasks can be reused in matches and optionally shared with other match creators.

Architecture and Implementation

Tic-Tac-Training was developed on a client–server architecture where the web-based client can be accessed with a web browser. Figure 4 depicts the game architecture we implemented using Angular, PHP Hypertext Preprocessor, and MySQL technologies. Firebase (via the AngularFire library, Google Inc) was used to store chat messages and notifications, and Facebook and Google application programming interfaces (APIs) were used for optional log-in services. We divided the game features into Angular services accessed by the user interface (UI) components in the front-end architecture. For example, the UI components related to gameplay use Match Board (for overall gameplay management), Rewards (for Lucky Cells, Task Masters, and overall game statistics), Game Statistics, Chat, Notifications, and Player Profile (for accessing player information during a match). The Login and Player Profile UI allows players to register and log-in as well as view and edit their profiles. The Angular services communicate with the back-end managers over a Representational State Transfer API. The back-end Action Handler works as a front controller that delegates requests to appropriate managers that perform various database operations on the game data.

Figure 4. Tic-Tac-Training architecture based on Angular, PHP Hypertext Preprocessor, and MySQL. API: application programming interface; DB: database; PHP: hypertext preprocessor; REST: Representational State Transfer; UI: user interface.



The UI is responsive to web browsers on desktop computers, tablets, and smartphones. We implemented the UI using HTML templates that we dynamically updated from the Angular components. In addition, we implemented a notification system based on the Web Notification API.

Formative Evaluation

This section reports 16 schoolchildren's perceptions of Tic-Tac-Training for workplaces. The results of our analysis are presented according to the questionnaire sections: usability, motivation, and impact.

Usability

The items on the game's usability, presented in Table 1, were mostly agreed with. For example, most participants agreed that the game was easy to use (1; μ=3.87; σ=1.03). In addition, they agreed that it was easy to understand how the game worked (2; μ=3.56; σ=1.26). Further support for adequate usability was evident in the following statements that most participants disagreed with: the game was too complicated (3; μ=1.75; σ=0.86), the game was difficult to use (6; μ=1.94; σ=1.34), they would need someone's help to use the game (7; μ=1.75; σ=1.00), the game was hard to learn to play (9; μ=1.69; σ=1.08), and the game was too troublesome (11; μ=2.37; σ=1.50). Given that the usability results were generally positive, it was surprising to us that the participants somewhat disagreed that they would like to play the game again (10; μ=2.56; σ=1.50). Aligned with this, the statement of the Net Promoter Score—*I can recommend the game to others* (4)—was also somewhat disagreed with (μ=2.37; σ=1.36).

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Table 1. Responses to the usability statements (derived from the System Usability Scale [51] and Net Promoter Score [52]).

Item number	Statement	μ (95% CI)	σ
1	The game was easy to use.	3.87 (3.32-4.42)	1.03
2	It was easy to understand how the game worked.	3.56 (2.89-4.23)	1.26
3	The game was too complicated.	1.75 (1.29-2.21)	0.86
4	I can recommend the game to others.	2.37 (1.65-3.09)	1.36
5	I am satisfied with the game as a whole.	3.31 (2.77-3.85)	1.01
6	The game was difficult to use.	1.94 (1.23-2.65)	1.34
7	I think I need someone's help to use the game.	1.75 (1.22-2.28)	1.00
8	I think most people would learn to use the game quickly.	3.69 (3.08-4.3)	1.14
9	It was hard to learn to play the game.	1.69 (1.11-2.27)	1.08
10	I would like to play the game again.	2.56 (1.76-3.36)	1.50
11	The game was too troublesome to use.	2.37 (1.57-3.17)	1.50

Motivation

The motivational items that promoted active transport and collaboration with classmates received the most agreement from the participants, as shown in Table 2. Specifically, the participants agreed that they wanted to play the game because it was good for the environment to walk and cycle (18; μ=4.06; σ=0.93), it was good for the body to move (17; μ=3.44; σ=1.37), and they could collaborate with classmates (13; μ=3.44; σ=1.20). In addition, the game tasks were found to be motivating to most participants (14; μ=3.06; σ=1.18). There were significant disagreements among the participants on the motivations regarding competing against others (12; μ=1.94; σ=1.12) and having the opportunity to talk, discuss, and make plans to play as a team (15; μ=2.44; σ=1.41). The fact that the game was part of the participants' schoolwork was motivating only to a slight majority of the participants (19; μ=3.31; σ=1.35).

Table 2. Responses to the following motivation statements: "I enjoyed playing the game because...."

Item number	Statement	μ (95% CI)	σ
12	...we could compete.	1.94 (1.34-2.54)	1.12
13	...of the collaboration with classmates.	3.44 (2.8-4.08)	1.20
14	...of the tasks in the match.	3.06 (2.43-3.69)	1.18
15	...of the opportunity to talk, discuss, and make plans for how we would play.	2.44 (1.69-3.19)	1.41
16	...of notifications in the game (eg, when some team got four-in-a-row).	2.69 (1.92-3.46)	1.45
17	...it is good for the body to move.	3.44 (2.71-4.17)	1.37
18	...it is good for the environment to walk and cycle.	4.06 (3.56-4.56)	0.93
19	...this was part of school work.	3.31 (2.59-4.03)	1.35

Impact

Finally, the formative evaluation analyzed the participants' responses regarding the perceived impacts of playing the multiplayer Tic-Tac-Training game. The results are presented in Table 3. The participants disagreed that the game contributed to increasing fellowship in the class (20; μ=2.26; σ=1.34). In addition, they disagreed that the game contributed to walking and cycling more (23; μ=2.56; σ=1.37), moving more (21; μ=2.38; σ=1.46), and improving the environment (22; μ=2.81; σ=1.38).

Table 3. Responses to the following impact statements: "The game has contributed to...."

Item number	Statement	μ (95% CI)	σ
20	...increased fellowship in the class.	2.25 (1.54-2.96)	1.34
21	...my increased movement.	2.38 (1.6-3.16)	1.46
22	...improvement of the environment.	2.81 (2.07-3.55)	1.38
23	...my increased walking and cycling.	2.56 (1.83-3.29)	1.37

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Analysis of the Formative Evaluation Results

The results of the formative evaluation revealed several points for improvement in Tic-Tac-Training when repurposing it for schoolchildren. First, although usability was generally deemed to be adequate, most of the participants did not want to play the game again or recommend it to others. Some hints as to why this result was achieved can be seen in the following excerpts that were captured from the open answers of the participants when we asked them to motivate their responses to the usability questions:

> *It was just buggy sometimes.* [Male, 11]
>
> *It was just boring.* [Female, 11]
>
> *Boring game.* [Male, 11]
>
> *Bad game.* [Female, 11]

The game had some technical and usability glitches discovered during the test that may have triggered discontent among the participants. The perceptions of the game being boring and bad can be attributed to the fact that the game was originally developed for another kind of audience. The game was toned down in comparison with games that children typically play, which often include colorful visuals and diversity in terms of game mechanics, such as rewards, collectibles, level-ups, and badges. Another factor that could have influenced the participants' opinion of not wanting to play the game again and their unwillingness to recommend the game to others is that they played only 1 match, which may not have been enough to form a deeper understanding of and connection with the game. Moreover, the game provided little support for maintaining interest between matches; each match was considered a new incarnation of the match board and the teams, with nothing for the player to build upon when playing multiple matches. If the game better supports the player's profile development through points, levels, collectibles, and other mechanics, it might motivate the player to play again.

One of the core game mechanics of Tic-Tac-Training is competition between teams—competition was one of the aspects that adult players at a workplace wished to have in the game [45]. However, the participants received this game mechanic poorly; they were more motivated by collaboration with their classmates. Thus, we can conclude that the game should be playable in a noncompetitive, collaborative manner by schoolchildren. This is aligned with the results of a study on Pokémon GO suggesting that collaboration conquers competition among children [54].

The participants were not motivated by the notifications produced by the game of important events. A reason for this could be that some players missed the incoming notifications. This could have happened because (1) after a notification was dismissed, it was difficult to find it again; (2) notifications were only shown on devices that supported them (eg, Safari on Apple devices did not work with the notification system at the time of evaluation); (3) the game sent notifications seldom, such as when a team completed 4-in-a-row; and (4) if the player selected to decline notifications when the game was opened for the first time, all notifications were blocked. Moreover, the players had no way to choose which notifications to show or hide. This lack of control could have affected their overall motivation toward the feature.

Although the participants enjoyed collaborating with their classmates, they disagreed about the opportunity to talk, discuss, and make plans for playing. This is aligned with our observation that the game chat was not used much by the teams. We suspected that the players, being from the same class, had existing communication channels that they used.

Table 4 summarizes the shortcomings that our analysis revealed, along with the proposed updates to make the game more appropriate for AST. These updates were implemented in Tic-Tac-Training from April 2020 to August 2020, as detailed in the next section.

Table 4. Primary shortcomings identified in the formative evaluation and proposed updates.

Shortcomings	Proposed updates
Boring game	Increase the diversity of game mechanics through rewards, collectibles, and levels; update the user interface to be more appealing
Lack of support for continuous engagement	Introduce level-ups and badges that are earned only by actively participating in matches; show diverse statistics that are updated based on played matches
Disliked competition and lack of fellowship	Implement a game mode that is only based on collaboration without competition between teams
Demotivating or unnoticed notifications	Update the notification system by (1) adding more different types of notifications of various game events, (2) allowing the player to choose which notifications to receive, and (3) sending the most important notifications by email
Lack of incentives for discourse and participation	Inform the players about the existence and purpose of the chat; show statistics that motivate players to contribute to their team; allow players to use social media accounts to log-in, thereby connecting the game to their existing social media profiles

Tic-Tac-Training for AST

We developed new features to overcome the identified shortcomings, improve the overall player experience, and promote teamwork. We developed scoring, level, ranking, and reward systems to keep players motivated and engaged in long-term gameplay. We designed a reward system with two reward types: Lucky Cell and Task Master. The Lucky Cell reward is earned by capturing cells with the tag *lucky cell* (Figure 5A), which are randomly distributed on the game board. The Task Master reward is given to the first player who completes a certain number of tasks (Figure 5B). The match creator defines the type of tasks for the Task Master. All the available rewards are listed in the *Information* box of the match

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(Figure 5G), and the player is notified immediately after they win a reward.

We also implemented a scoring, level, and ranking system with 20 levels and 5 ranks (badges; Figure 5C). Players are awarded a new rank after every 5 levels. Players gain levels and ranks by collecting experience points (XPs) from various game activities (Figure 5H), either as individuals (eg, Lucky Cells, Task Masters, and capturing cells) or as a team (eg, 4-in-a-row and winning a match). The player's profile presents the current rank, level, and XPs (Figure 5D).

Figure 5. Tic-Tac-Training new features: gameplay. (A) Lucky Cell reward, (B) Task Master reward, (C) level progression view, (D) player statistics, (E) notification settings, (F) notification history, (G) information about rewards in a match, (H) information about how experience points can be earned in a match.



We redesigned the UI to be more colorful, consistent, and appealing to the children (Figure 5). We used consistent colors, dialog boxes, notifications, buttons, and icons to reduce the learning curve. Moreover, we used animations in notifications and pop-up windows to draw the user's attention and make the game look more dynamic. In addition, whenever the player completes a row, blocks a row, obtains a reward (Figure 5A and B), obtains a level-up, or captures a cell, the game responds with a short pop-up message showing the earned XPs. The XP information and progress bars (Figure 5C and D) aim to motivate continuous gameplay.

To improve the notification system, we added support for email to deliver important notifications (eg, match begins or ends) and created new types of notifications, such as for when a 4-in-a-row is taken, a cell is taken, another team's 4-in-a-row chance is blocked, the player's team's 4-in-a-row chance is blocked, a match is started, a match is ended, a player achieves a Lucky Cell or a Task Master, and a player achieves a new rank. The player can opt in or opt out of notifications (Figure 5E) and view the notification history (Figure 5F) that summarizes all activities in a match.

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As the competition was disliked by the evaluation participants, we implemented a 1-team match mode where the players collaborate to meet the ending conditions as soon as possible. This mode serves as a basis for future tasks that are based on collaboration.

Finally, we implemented log-in through Facebook or Google accounts. Deeper social media integration (eg, contact lists and discussion forums) remains to be implemented. We anticipate that integrating social media accounts into the game will make it more convenient for players to play and create new possibilities for future feature expansion and interconnectivity with other systems.

Children's AST Ideas and Road Map for Future Development

In addition to developing new features based on the formative evaluation, we asked another group of pupils (13/33, 39% male and 20/33, 61% female) what features they would like to see in the AST game. We then mapped the gathered ideas to the eight core drives of gamification proposed by the Octalysis gamification framework [30]—meaning, empowerment, social influence, unpredictability, avoidance, scarcity, ownership, and accomplishment—and created a road map of future features for Tic-Tac-Training. The results are presented in Multimedia Appendix 2 [30].

Discussion

Principal Findings

We presented the conceptual and technical details of the Tic-Tac-Training game, which was designed to promote active transport at workplaces. The original game was based on competition between teams and offered little incentive for continuous gameplay over multiple matches. By analyzing the subjective perceptions gathered through a formative evaluation with schoolchildren in northern Sweden, we discovered that this approach is not well-suited for schoolchildren as they generally prefer collaboration to competition and have different opinions from those of adults regarding what a good game should be like. Thus, based on the formative evaluation results, we developed a new version of the game with new features that aim to make the game more interesting and appealing to schoolchildren, incentivize long-term engagement in gameplay, and increase collaboration. In addition, we collected ideas for the gamification of AST in general from another group of schoolchildren through focus group interviews and mapped the findings to the Octalysis gamification framework. On the basis of these ideas, we derived a road map for future Tic-Tac-Training features.

Voluntary Engagement and Motivation

In the formative evaluation, we asked the participants for their opinions on the expected impact of the game on fellowship, physical activity, and the environment, which are the underlying themes of the game. The results were mostly negative as shown in Table 3. A possible explanation for this is that the participants played the game only once; a longitudinal study could reveal different results and detailed reasons. Another possible explanation is that the game failed to motivate the participants to play the game *minds-on*, and the participants considered it merely a task that the teacher gave them. This explanation is supported by a participant's comment: "Our teacher made us play it" (Male, 11). An important lesson can be learned here: players may see the impact of an intervention more clearly if they are convinced to voluntarily engage in it in the long term. Exploring voluntary engagement in serious games in depth is a topic for another study. However, gamification has been shown to support a myriad of factors that can promote intrinsic motivation and engagement [28]. Moreover, motivational theories can help explain the presence or absence of essential motivational components in the game. For example, the components of the self-determination theory [55]—autonomy, competence, and relatedness—were not fully supported by the original version of Tic-Tac-Training that the schoolchildren played. The game supported limited autonomy by allowing players to make arbitrary moves on the game board. Support for autonomy could be increased by allowing players to customize their profiles and avatars, and create their matches. Moreover, adding XPs and levels can be seen as ways to promote competence, and collaboration features such as team play, 1-team matches, and chats support relatedness. A future longitudinal evaluation may show how well the new features of Tic-Tac-Training will support voluntary engagement and motivational theories such as the self-determination theory and whether there are any changes to the perceived impacts gathered in the formative evaluation.

Social Media Connection: Opportunities and Threats

One of the new features added to Tic-Tac-Training was linking social media accounts such as Facebook and Google through the OAuth authorization protocol. This linkage provides a basis for further use of social media in the game through importing friend lists, integrating social media–based discussions, and even integrating the game onto a social media platform such as Facebook. Such social media integration was also suggested by children who gave ideas to gamify AST. The ability of the game to connect to a popular social media platform increases its potential for large-scale adoption. This introduces threats such as privacy and safety in web-based environments that one cannot ignore. Most social media accounts have age limits for children, but it is not uncommon for children under the age limit to become avid users of social media. For example, according to a report by Ofcom, 30% of children aged 5-7 years and 44% of children aged 8-11 years used social media in the United Kingdom in 2020 [56]. Using publicly available information makes it possible to build detailed profiles of people that can be used for criminal purposes [57]. Furthermore, social media can become a context for cyberbullying [58]. When integrating social media accounts into Tic-Tac-Training, the same precautions must be taken as with social media use in general. To this end, many social media privacy guides exist, such as the social media privacy guides offered by Internet Matters [59], a nonprofit organization dedicated to promoting children's safety in web-based environments.

Gamification Potential

The road map of the new Tic-Tac-Training features presented in Multimedia Appendix 2 forms the basis for the next

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development steps. The ideas mapped well to the core drives of gamification [30]; only one of the drives, unpredictability, was left without ideas from the children. Overall, the collected gamification ideas indicate that schoolchildren have the capacity to develop diverse ideas based on their knowledge of and experience with different games. This supports previous observations that children possess assets as co-designers of games, such as creativity, relationships, and emotional impacts [60]. Although it is unnecessary to support all core drives for a game to be successful, supporting many of them can help the game reach different player types within the same age group who have different preferences about playing games. There exist several models for player types that can be useful for understanding differences between players, such as Killers, Achievers, Explorers, and Socializers by Bartle [61]; the 4 temperaments by Keirsey [62]; the Demographic Game Design 2 model by Bateman et al [63]; and the Hexad model by Marczewski [32]. A future iteration of Tic-Tac-Training could use one or more of these models to identify each player's type and adjust the gameplay accordingly. For example, the task types could be automatically customized to use the types of game mechanics that the player enjoys.

As the features proposed in the road map are derived from children's ideas, we expect that they can help increase the game's motivation, appeal, and engagement factors among Swedish schoolchildren. In particular, having an evolvable avatar in the game seems important to many schoolchildren. Having a personalizable avatar supports the autonomy component of the self-determination theory [55] as the player voluntarily controls their avatar and its evolution. The competence component is promoted when the player develops the avatar's skills by completing tasks and collecting gameplay data (eg, via sensors). Autonomy and competence are identified as basic psychological needs through which intrinsic motivation can be nurtured [55]; thus, a future version of the game has increased potential for intrinsic motivation. However, this is mere speculation until the road map features are implemented and their effects are measured in a future study.

As demonstrated in Multimedia Appendix 2, the use of avatars was a way to establish a deeper meaning for the gameplay. Developing and caring for an avatar motivates continuous gameplay, an important factor in supporting behavior change over time. Another potential gamification element related to establishing a more profound meaning is the use of narratives. Although they were not present in the children's ideas, narratives and storytelling are key motivators in many games [28]. Moreover, research has shown that narratives can help increase physical activity among children [64].

Another road map idea that the children frequently brought up was the inclusion of an in-game currency that can be used to purchase items and develop the avatar. This idea is familiar, with many free-to-play mobile games offering in-game purchases of items and skills with real or in-game currency. The ability to earn in-game currency connects to competence as it is a direct result of successfully completing tasks, whereas making purchases in the game world supports the player's autonomy. If the purchases were shared with others (eg, by decorating the player's avatar and sharing it with other players), relatedness in the self-determination theory would also be supported. The demand for relatedness was also evident in the ideas of creating and sharing content (eg, photographs) and interacting with other players through social media.

Limitations

Despite a number of contributions, this study has several limitations. First, although 16 is deemed to be a sufficient number of participants for identifying problems in a user test [50], the results cannot draw deeper conclusions on the impacts of the game. Second, the sample comprised only Swedish pupils in sixth grade. Although the context of the study was Sweden, having a more diverse set of participants from different countries and age groups would make the results more generalizable. We hypothesize that the results can be applicable at least in other northern regions of the Nordic countries as they are in many ways similar to Luleå, but this remains to be tested. Third, the updated version of the game was not evaluated to measure the effects the new features had on schoolchildren's perceptions of the game. The formative evaluation was conducted in February 2020, before the global COVID-19 outbreak. Because of the pandemic and restrictions, we did not have a chance to evaluate the new features in this study.

Conclusions and Future Work

The study's primary objectives were to investigate the game's suitability for promoting AST in schoolchildren, improve the game according to the results, and prepare a road map for future development based on ideas gathered from schoolchildren. We achieved these objectives by contributing to implementing the Tic-Tac-Training game, its formative evaluation and consequential upgrade, and additional gamification ideas elicited from schoolchildren. The study results are generalizable to other locations similar to the study's context: a midsized city with harsh winter conditions and a well-maintained pedestrian and bicycle road network.

The results have potential impacts on how gamified AST interventions can be developed and what kind of gamification elements schoolchildren in the Swedish context wish to see in such interventions. The study results can be of interest to game researchers, developers, and teachers who wish to apply gamification to AST or other school subjects. For example, following the road map of features, a future game developer targeting elementary school contexts might design the gameplay around collaboration, avatars, rewards, and achievements. Finally, the proposed architecture can be useful for developers who wish to create reusable, collaborative game platforms on cross-platform web technologies.

However, the results are not conclusive in terms of verifying whether the new version of Tic-Tac-Training sufficiently addresses the issues discovered in the formative evaluation. Therefore, in future work, we plan to conduct a longitudinal mixed methods evaluation with the current version of the game once the COVID-19 pandemic is over. This evaluation will occur in multiple schools in Sweden and possibly other countries, such as Finland and the Republic of Korea, and will involve children from grades 3 to 9. In addition, we will start

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implementing the road map features and developing more collaborative games for AST. Finally, based on a body of literature and our experiences, we seek to develop a model for designing collaborative gamification interventions for AST.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Formative evaluation questionnaire (translated).
[DOCX File , 525 KB - games_v10i1e31638_app1.docx]

Multimedia Appendix 2
Tic-Tac-Training development road map.
[DOCX File , 18 KB - games_v10i1e31638_app2.docx]

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Abbreviations

API: application programming interface
AST: active school transport
UI: user interface
XP: experience point

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Original Paper

Effect of the Nintendo Ring Fit Adventure Exergame on Running Completion Time and Psychological Factors Among University Students Engaging in Distance Learning During the COVID-19 Pandemic: Randomized Controlled Trial

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Abstract

Background: The COVID-19 outbreak has not only changed the lifestyles of people globally but has also resulted in other challenges, such as the requirement of self-isolation and distance learning. Moreover, people are unable to venture out to exercise, leading to reduced movement, and therefore, the demand for exercise at home has increased.

Objective: We intended to investigate the relationships between a Nintendo Ring Fit Adventure (RFA) intervention and improvements in running time, cardiac force index (CFI), sleep quality (Chinese version of the Pittsburgh Sleep Quality Index score), and mood disorders (5-item Brief Symptom Rating Scale score).

Methods: This was a randomized prospective study and included 80 students who were required to complete a 1600-meter outdoor run before and after the intervention, the completion times of which were recorded in seconds. They were also required to fill out a lifestyle questionnaire. During the study, 40 participants (16 males and 24 females, with an average age of 23.75 years) were assigned to the RFA group and were required to exercise for 30 minutes 3 times per week (in the adventure mode) over 4 weeks. The exercise intensity was set according to the instructions given by the virtual coach during the first game. The remaining 40 participants (30 males and 10 females, with an average age of 22.65 years) were assigned to the control group and maintained their regular habits during the study period.

Results: The study was completed by 80 participants aged 20 to 36 years (mean 23.20, SD 2.96 years). The results showed that the running time in the RFA group was significantly reduced. After 4 weeks of physical training, it took females in the RFA group 19.79 seconds (P=.03) and males 22.56 seconds (P=.03) less than the baseline to complete the 1600-meter run. In contrast, there were no significant differences in the performance of the control group in the run before and after the fourth week of intervention. In terms of mood disorders, the average score of the RFA group increased from 1.81 to 3.31 for males (difference=1.50, P=.04) and from 3.17 to 4.54 for females (difference=1.38, P=.06). In addition, no significant differences between the RFA and control groups were observed for the CFI peak acceleration (CFIPA)_walk, CFIPA_run, or sleep quality.

Conclusions: RFA could either maintain or improve an individual's physical fitness, thereby providing a good solution for people involved in distance learning or those who have not exercised for an extended period.

Trial Registration: ClinicalTrials.gov NCT05227040; https://clinicaltrials.gov/ct2/show/NCT05227040

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KEYWORDS

exergaming; cardiac force index; running; physical activity; sleep quality; mood disorders; digital health; physical fitness; Nintendo Ring Fit Adventure; COVID-19 pandemic

Introduction

The global COVID-19 outbreak has changed people's lifestyles [1], forcing them to self-isolate or engage in distance learning. These conditions have resulted in physical inactivity and sedentary behavior, thus introducing health risks [2,3]. Although research on the effects of COVID-19 on physical inactivity is still in the early stages [4], it is expected that people's sedentary behavior will increase due to long hours of working from home. Some researchers have indicated that the metabolic equivalent of prolonged television or computer use is approximately 1.0 to 1.5 metabolic equivalent of task [5]. The Physical Activity Guidelines Advisory Committee Scientific Report published in 2018 revealed that sedentary behavior was directly related to mortality and morbidity associated with cardiovascular disease as well as the incidence of type 2 diabetes, colorectal cancer, and lung cancer [6,7]. Therefore, a physical training program that can be performed at home is necessary.

With technological development and innovation, exergaming has become a new option for fitness training, education, and health maintenance [8]. Exergaming is defined as a type of exercise that integrates different modes of digital games into physical activities. It offers a new way to perform physical activity at home without space restrictions being an issue. Moreover, exergaming has proved a successful business model [9]. Studies have shown that exergaming not only helps players perform light-to-moderate–intensity exercises [9,10] but also enhances players' self-efficacy and willingness to engage in physical activities [11]. In 2007, Nintendo used Wii Fit (Nintendo Co, Ltd) in the rehabilitation of patients with Parkinson disease and stroke [12,13]. In addition, some research indicated that exergames demonstrated a positive effect on sleep quality shown by the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI) score and mood disorders shown by the 5-item Brief Symptom Rating Scale (BSRS-5) score [14,15], whereas other studies found that exergaming could alleviate the symptoms of chronic low back pain [8]. Despite the existence of studies on the effect of exergaming on health maintenance

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or psychological improvement, it is still necessary to conduct extensive investigations on the changes or improvements of physical fitness among students after performing exergames.

In this study, the physical condition during exercise was monitored using a new indicator developed by Hsiao et al, namely a novel cardiac force index (CFI); CFI = weight × activity/heart rate per second (HR), which was calculated and monitored using a noninvasive device. The authors reported that this index was positively correlated with running performance [16]. Subsequently, another study suggested that the CFI was positively correlated with the G tolerance of pilots [17]. The purpose of this study was to observe changes in the CFI after performing exergames. In addition, this study modified the original CFI formula and converted the index into centimeters per beat (CMPB), which was presented as the distance of body movement during the running per heartbeat and was expressed in centimeters [18].

Therefore, assuming that the Ring Fit Adventure (RFA; Nintendo Co, Ltd) exergame is an effective and useful tool, this study aimed to explore the following: (1) whether RFA could improve physical fitness and reduce the completion time for a 1600-meter run; (2) whether RFA could improve sleep quality and mood disorders; and (3) whether the new CMPB index could provide results similar to those of the CFI and be suitable for estimating run time.

Methods

Study Design

This randomized prospective study lasted 4 weeks. The participants were voluntarily recruited and divided into an intervention and a control group. Taiwan's Ministry of Education has formulated health-related physical fitness standards for adolescents aged 7 to 23 years [19]. Its safety and reliability have been verified [19], and therefore, we selected a 1600-meter running test. Before the start of the study, the participants were provided with a comprehensive explanation of the research content, and those who were willing to participate provided written informed consent. In addition, all the data were collected, analyzed, and stored anonymously. The study was approved by the Trial Committee of the Tri-Service General Hospital in Taiwan (approval number: C202005175; trial registration number: NCT05227040).

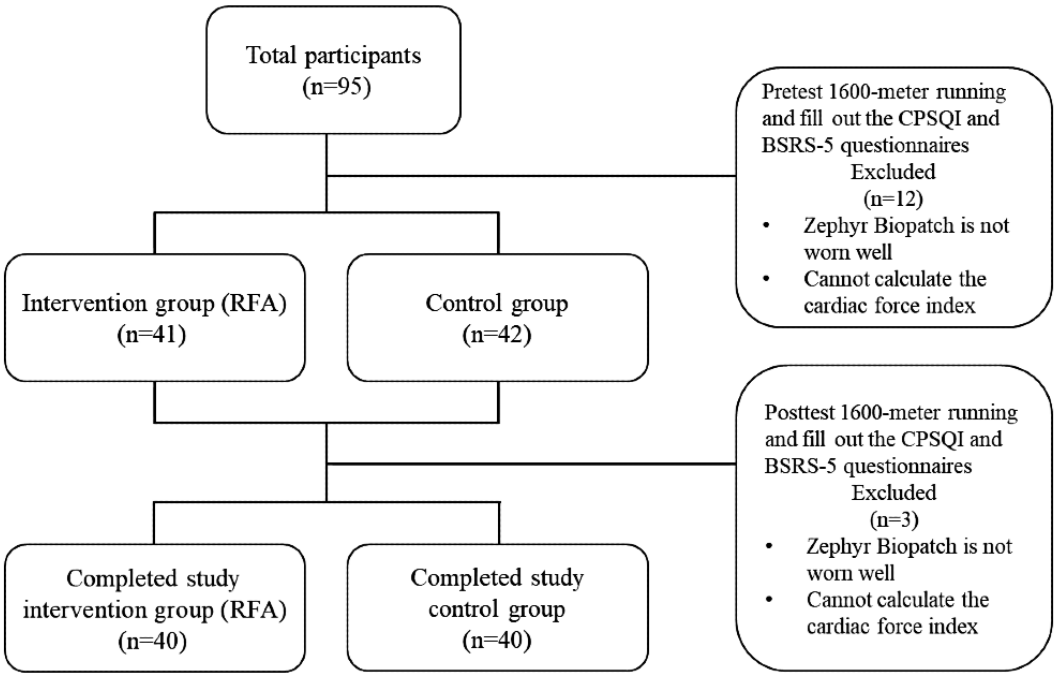
Participants

The study period was from January to April 2021. The inclusion criteria were as follows: (1) students who were over 20 years old and did not have chronic diseases; (2) students who were able to complete the 1600-meter outdoor run before and after the intervention; (3) students who understood and agreed with the research purpose and signed the consent form; and (4) students who used wearable devices correctly.

Sample and Randomization

This randomized prospective study was conducted with 1 experimental group and 1 control group. A total of 95 participants were recruited for this study. However, 12 participants were excluded from the pretest because their CFI could not be calculated (Based on the Zephyr BioPatch Monitoring Device for Human Performance manual, the values of the HR confidence value lower than 20% indicated data were unreliable, and they were automatically deleted) [20]. Randomization was conducted using the simple random sampling method. After 4 weeks, during the posttest running test, the CFI of 3 participants could not be fully calculated, and hence, these participants were excluded. Finally, a total of 80 participants in the intervention group and control group completed the study (Figure 1).

Figure 1. Flowchart showing enrollment of study participants. BSR-5: 5-item Brief Symptom Rating Scale; CPSQI: Chinese version of the Pittsburgh Sleep Quality Index; RFA: Ring Fit Adventure.



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Intervention

Participants in the RFA group were required to exercise for 30 minutes 3 times per week (in adventure mode) (Figure 2) for 4 weeks. The initial exercise intensity was set according to the instructions given by the virtual coach during the first game and was gradually adjusted according to the game instructions. The research team continued to track the RFA group subjects and encouraged the completion of 4 weeks of physical activity training.

In contrast, no intervention was introduced to the control group participants, who maintained their regular habits during the study period.

Figure 2. Adventure mode screen of Nintendo Ring Fit Adventure.



RFA of Nintendo Switch

RFA is a role-playing fitness exergame that uses a Ring-Con attached to a Joy-Con. The controller is equipped with high-precision sensors that can detect and digitize the player's movements. Ring-Con is a resistance training device that allows users to jump over obstacles or attack objects by stretching or squeezing them. In addition, an infrared sports camera monitors the changes in the player's heart rate. The game determines the optimal exercise intensity for the player and makes fine adjustments based on physiological feedback [8]. With an adjustable exercise intensity, RFA may be suitable for all age groups.

During battle scenes, players are required to defeat the enemies using a combination of different physical activities. Although the amount of exercise depends on the specific exercise intensity chosen by the player, it is generally set at 4 to 6 metabolic equivalents [21]; a previous study found that the exercise intensity of Wii Sports was between 3 and 5 metabolic equivalents [22].

Measurements

CPSQI Score

The Pittsburgh Sleep Quality Index can be used to assess an individual's sleep quality at a 1-month interval and extract quantitative and qualitative information about sleep based on sleep quality data [23]. The CPSQI developed by Tsai et al in 2005 showed superior validity, consistency (Cronbach α=.75-.85) [24,25], and test-retest reliability (0.85 for the 14- and 21-day intervals).

The scale consists of 7 factors (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep-promoting medication, and daytime dysfunction). The total score of the scale ranges between 0 and 21 and is obtained by summing the individual scores. A higher score indicates poorer sleep quality. Generally, people with a CPSQI score greater than 5 are considered to have poor sleep quality [24].

5-item BSRS-5 Score

Studies have indicated that the BSRS-5 is an effective tool that can screen the onset of mental illness and suicidal ideation [26,27]. The BSRS-5 can also be used to investigate the mood disorder of an individual within a week [28]. The scale includes five items: (1) having trouble falling asleep; (2) feeling tense or high-strung; (3) feeling easily annoyed or irritated; (4) feeling depressed or being in a low mood; (5) feeling inferior to others; and an additional question on suicidal ideation. Participants are required to answer these questions on a 5-point Likert scale (0-4) [26] and then the total score is calculated as the sum of the individual scores. A score >6 indicates the onset of mental illness or mood disorder. In addition, participants who have a score >2 on suicidal ideation are recommended to seek professional consultation or mental health care [29].

CFI Measurement

The CFI is used to measure the heart condition during exercise; it is patented in the United States (US 9566010 B2) [30] and Taiwan (I546051) [31] and can be used to calculate the amount of work done by the heart for body movement per heartbeat per second. When combining this index with acceleration, the individual status can be analyzed during physical activity; this index is a feedback indicator for monitoring exercise intensity and load [16]. CFI=weight × activity/heart rate [16]. The CFI can also be converted to CMPB (cm/beat), namely the distance (in cm) the body can move during each heartbeat. The index can be used to indicate changes in distance during each

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heartbeat, and centimeter is a common unit, which is very convenient for people to understand [18].

Wearable Device

We used a Zephyr BioPatch loaded with the Zephyr BioHarness 3.0 module (Zephyr Technology Corporation). In addition, the Ambu BlueSensor T, an electrocardiogram (ECG) patch (Ambu A/S, Ballerup) [32], was attached to the participants' apical area. In addition, when attached to the BioPatch (Figure 3), it could measure the potential changes in the skin through the bilateral ECG patches and consequently record the heart rate and respiratory rate.

The Zephyr BioPatch is a device approved by the US Food and Drug Administration for medical and clinical applications [20,33]. It can provide reliable heart rate measurements [34]. Zephyr BioHarness 3.0 is noninvasive and consists of a 3-axis gyroscope and an accelerometer to distinguish between the x-, y-, and z-axes. Moreover, it can measure and estimate basic physiological parameters, such as the heart rate, respiratory rate, acceleration, maximum oxygen consumption, and temperature. The data can be displayed in real time through Bluetooth and are stored in the memory of the device, allowing access for statistical analysis [20,33].

Figure 3. Zephyr BioPatch wearable device.



Data Collection

Before the pretest and posttest, the participants' basic demographic information, including age, sex, height, weight, neck circumference, waist circumference, smoking status (yes or no), alcohol consumption status (yes: 2 to 3 times a week or at least once a week; or no), milk intake (yes or no), whether the participants consumed 3 servings of vegetables and 2 servings of fruit per week, exercise habits (4 to 6 times a week, 1 to 3 times a week, or none), sleep quality (CPSQI), and mood disorder (BSRS-5 score), was collected.

Prior to the 1600-meter outdoor run, participants were required to wear the Zephyr BioPatch loaded with the Zephyr BioHarness 3.0 module. In addition, the Ambu BlueSensor T [32] was attached to the participants' apical area (Figure 3).

After the participants completed the 1600-meter run, the BioHarness 3.0 module was removed from the BioPatch, and the physiological data were extracted. The data, which were binned per second, were then calculated and saved in Excel sheets (Microsoft Corporation). Due to the large amount of data, the method described by Hsaio et al was adopted for data processing [16]. Subsequently, a member of the research team further reviewed the physiological data collected by the BioHarness 3.0 module and calculated the CFI and CMPB values. CFI is an established method for monitoring heart function and workload during physical activity [16]. Its advantages include being noninvasive, wireless, and the ability for real-time monitoring through mobile devices [16].

The definitions of the BioHarness 3.0 parameters are listed below [16,18]:

1. CFI peak acceleration (CFI_PA): It was the peak acceleration per second divided by the number of heartbeats per second, both of which were estimated and measured by BioHarness 3.0.

2. Heart rate: It is defined as the number of heartbeats per second measured by the sensors during exercise. With BioHarness 3.0, the heart rate data were recorded in beats per minute (bpm), and the result was the average value of the data over 1 second.

3. CFI_PA while walking (CFI_PA_walk): This was the peak acceleration per second divided by the number of heartbeats per second while the participant was walking.

4. CMPB while walking (CMPB_walk): It was the movement in centimeters per second divided by the number of heartbeats per second while the participant was walking.

5. CFI_PA while running (CFI_PA_run): This was the peak acceleration per second divided by the number of heartbeats per second while the participant was running.

6. CMPB while running (CMPB_run): This was the average value of the CMPB_run calculated using the start of the run to the end of the run (movement in centimeters per second divided by the number of heartbeats per second while the participant is running).

Statistical Analysis

The Windows version of the SPSS 28.0 software (IBM Corp) was used for the statistical analysis. According to descriptive statistics, categorical data are expressed in numbers and percentages, whereas continuous variables are expressed as averages and SDs. We conducted independent sample *t* tests and chi-square tests to confirm group differences.

Subsequently, the paired *t* test was conducted to analyze the differences between the completion time for the 1600-meter

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run in seconds, CFI, CMPB, CPSQI, and mood disorders between the pretest and posttest. We determined that the data may not be normally distributed, and therefore, we additionally used the Wilcoxon signed rank test for analysis.

Alternatively, generalized estimating equations (GEEs) were adopted to predict important factors influencing the running time. The significance level was set at 2-tailed $P<.05$.

Results

Participant Demographics

The study was completed by 80 participants aged 20 to 36 years (mean 23.2, SD 2.96 years), and both groups were composed of 40 individuals. The RFA group comprised 16 males and 24 females, with an average age of 23.75 (SD 3.58) years; the control group included 30 males and 10 females, with an average age of 22.65 (SD 2.08) years. None of the participants were smokers; 51 participants (64%) exercised 1 to 3 times a week.

In addition, there were no significant differences in the participants' age, BMI, neck circumference, waist circumference, smoking status, and alcohol consumption status; there were also no differences regarding whether they drank milk, consumed 3 servings of vegetables and 2 servings of fruit per week, and the exercise habits between the RFA and the control groups. The detailed demographics of the participants are listed in Table 1.

Table 1. Demographics of the participants in each group (N=80)[a].

Variable	Total	RFA[b] group	Control group	χ^2/t (*df*)	*P* value
Age (years), mean (SD)	23.20 (2.96)	23.75 (3.58)	22.65 (2.08)	–1.68 (78)	.1
BMI (kg/m^2), mean (SD)	21.96 (2.69)	21.80 (2.77)	22.13 (2.63)	0.54 (78)	.59
Neck circumference, mean (cm) (SD)	33.96 (2.76)	33.40 (2.68)	34.50 (2.75)	1.80 (78)	.08
Waist (cm) mean (SD)	74.53 (7.95)	73.67 (7.77)	75.38 (8.12)	0.96 (78)	.34
Gender, n (%)				10.02 (1)	.002
Female	34	24 (70.6)	10 (29.4)		
Male	46	16 (34.8)	30 (65.2)		
Smoking status, n (%)				N/A[c]	N/A
Yes	0	0 (0)	0 (0)		
No	80	40 (50)	40 (50)		
Alcohol, n (%)				0.35 (2)	.84
2-3 times a week	3	1 (33.3)	2 (66.7)		
At least once a week	6	3 (50)	3 (50)		
None	71	36 (50.7)	35 (49.3)		
Drinking milk, n (%)				3.41 (1)	.07
Yes	30	21 (42)	29 (58)		
No	50	19 (63.3)	11 (36.7)		
Eating at least 3 servings of vegetables and 2 of fruits, n (%)				0.56 (1)	.46
Yes	72	35 (48.6)	37 (51.4)		
No	8	5 (62.5)	3 (37.5)		
Exercise habits, n (%)				0.91 (2)	.64
4-6 times a week	15	6 (40)	9 (60)		
1-3 times a week	51	26 (51)	25 (49)		
None	14	8 (57.1)	6 (42.9)		

[a]The age, BMI, neck circumference, and waist circumference were used in the *t* test and the rest of the variables were used in the chi-square tests.

[b]RFA: Ring Fit Adventure.

[c]N/A: not applicable.

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Intervention Outcomes

Comparison of Running Time

After 4 weeks of the intervention, the time taken by the RFA group to complete the run (in seconds) decreased significantly from 611.75 seconds to 591.96 seconds for females (difference=–19.79; *P*=.03) and from 489.5 seconds to 466.94 seconds for males (difference=–22.56; *P*=.03) (Table 2).

In contrast, the time taken by the control group to complete the run (in seconds) increased from 483.6 seconds to 491.83 seconds for males and decreased from 598.3 seconds to 583.8 seconds for females. However, the differences between the preintervention and postintervention periods were not significant.

Heart Performance Indices

After 4 weeks of the intervention, CFIPA_run increased from 13.95 to 15.02 in females (difference=1.07, *P*=.11) and 16.54 to 17.38 in males (difference=0.845, *P*=.22). CMPB_run increased from 83.68 to 90.09 in females (difference=6.41, *P*=.11) and increased from 99.21 to 104.28 in males (difference=5.07, *P*=.22) (Table 2). In addition, no significant differences between the RFA and control groups were observed for CFIPA_ walk, CMPB_ walk, CFIPA_ run, or CMPB_ run.

Psychological Factors

In terms of mood disorders, the average score of the RFA group increased from 1.81 to 3.31 for males (difference=1.50, *P*=.04) and from 3.17 to 4.54 for females (difference=1.38, *P*=.06) (Table 2). The sleep quality score (CPSQI) increased from 4.81 to 5.56 (difference=0.75, *P*=.19) for males and from 5.75 to 6.21 (difference=0.46, *P*=.38) for females, but there was no statistically significant difference. In addition, no significant differences between the control groups were observed for sleep quality (CPSQI) or mood disorders.

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Table 2. Comparison of run time, cardiac force index, and psychological factors after 4 weeks of intervention.

Group	Pretest	Posttest	Difference	*P* value[a]
RFA[b] group				
Females				
Running seconds, mean (SD)	611.75 (92.92)	591.96 (87.39)	–19.79 (37.93)	.03
CFIPA[c]_ walk, mean (SD)	6.28 (1.25)	6.22 (1.75)	–0.06 (1.72)	.55
CMPB[d]_ walk, mean (SD)	37.66 (7.49)	37.29 (10.51)	–0.67 (10.35)	.55
CFIPA_ run, mean (SD)	13.95 (3.59)	15.02 (4.77)	1.07 (3.24)	.11
CMPB_ run, mean (SD)	83.68 (21.56)	90.09 (28.64)	6.41 (19.45)	.11
Sleep quality, mean (SD)	5.75 (3.40)	6.21 (2.64)	0.46 (2.23)	.38
Mood disorder, mean (SD)	3.17 (2.71)	4.54 (4.08)	1.38 (3.06)	.06
Males				
Running seconds, mean (SD)	489.50 (65.53)	466.94 (54.17)	–22.56 (36.11)	.03
CFIPA_ walk, mean (SD)	6.37 (0.81)	6.07 (1.07)	–0.30 (1.05)	.28
CMPB_ walk, mean (SD)	38.24 (4.85)	36.44 (6.43)	–1.80 (6.33)	.28
CFIPA_ run, mean (SD)	16.54 (2.84)	17.38 (2.82)	0.845 (1.95)	.22
CMPB_ run, mean (SD)	99.21 (17.07)	104.28 (16.93)	5.07 (11.69)	.22
Sleep quality, mean (SD)	4.81 (2.56)	5.56 (2.71)	0.75 (1.95)	.19
Mood disorder, mean (SD)	1.81 (2.90)	3.31 (3.98)	1.50 (2.71)	.04
Control group				
Females				
Running seconds, mean (SD)	598.30 (79.38)	583.80 (92.06)	–14.50 (39.96)	.24
CFIPA_ walk, mean (SD)	6.50 (1.03)	6.98 (2.93)	0.48 (2.76)	.65
CMPB_ walk, mean (SD)	39.01 (6.16)	41.87 (17.58)	2.86 (16.59)	.65
CFIPA_ run, mean (SD)	13.32 (3.24)	14.12 (4.66)	0.81 (2.37)	.14
CMPB_ run, mean (SD)	79.90 (19.46)	84.74 (27.94)	4.85 (14.21)	.14
Sleep quality, mean (SD)	3.90 (3.57)	3.80 (2.10)	0.70 (2.32)	.34
Mood disorder, mean (SD)	5.80 (2.57)	6.50 (2.91)	–0.10 (3.54)	.86
Males				
Running seconds, mean (SD)	483.60 (47.92)	491.83 (51.97)	8.23 (40.05)	.33
CFIPA_ walk, mean (SD)	7.17 (1.20)	7.15 (1.85)	–0.02 (1.50)	.45
CMPB_ walk, mean (SD)	43.03 (7.23)	42.90 (11.10)	–0.12 (9.00)	.45
CFIPA_ run, mean (SD)	18.48 (4.37)	18.81 (3.45)	0.33 (2.43)	.21
CMPB_ run, mean (SD)	110.89 (26.22)	112.85 (20.70)	1.95 (14.59)	.21
Sleep quality, mean (SD)	5.93 (2.74)	5.37 (2.77)	–0.57 (2.50)	.26
Mood disorder, mean (SD)	2.90 (3.04)	4.07 (2.91)	1.17 (4.09)	.15

[a] obtained from the Wilcoxon signed rank test.

[b]CFIPA: cardiac force index peak acceleration.

[c]CMPB: centimeters per beat.

[d]RFA: Ring Fit Adventure.

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Predicted Physical Factors Affecting the Completion of the 1600-Meter Run

We used linear regression to select the variables with a significance level at $P<.05$. A prediction model was established using GEEs, and the BioHarness 3.0 parameters were introduced to identify factors that affected the time taken by the 80 participants to complete the run. The explanatory power of the model was 66.3% (R^2=0.663). The results indicated that sex, exercise habits, alcohol consumption status, CMPB_ run, age, and BMI were important factors that affected the time taken for completing the run. If variables such as the group, sex, age, sleep quality, mood disorder, BMI, neck circumference, and waist circumference were controlled, those who exercised 4 to 6 times per week took 48.02 seconds less to complete the run (95% CI –85.65 to –10.38), and compared to nondrinkers, those who consumed alcohol 4 to 6 times per week took 45.83 seconds more to complete the run (95% CI 6.64 to 85.01). Furthermore, each additional unit of CMPB_ run corresponded to a decrease of 0.89 seconds in run time (95% CI –1.37 to –0.4) (Table 3).

Table 3. Predicted physical factors affecting the completion of the 1600-meter run.

Variable	Beta (95% CI)	*P* value
Group		
RFA[a]	–6.24 (–32.04 to 19.57)	.64
Control	N/A[b]	N/A
Gender		
Male	–96.10 (–125.25 to –66.94)	<.001
Female	N/A	N/A
Exercise habits		
4-6 times a week	–48.02 (–85.65 to –10.38)	.01
1-3 times a week	–25.88 (–57.20 to 5.45)	.11
None	N/A	N/A
Alcohol consumption		
2-3 times a week	45.83 (6.64 to 85.01)	.02
At least once a week	–1.66 (–42.28 to 38.96)	.94
None	N/A	N/A
Age	3.68 (0.02 to 7.34)	.05
Sleep quality	2.13 (–0.86 to 5.13)	.16
Mood disorder	–1.58 (–4.20 to 1.03)	.24
CMPB[c]_ run	–0.89 (–1.37 to –0.40)	<.001
BMI	10.02 (3.17 to 16.87)	.004
Neck circumference	1.54 (–1.89 to 4.98)	.38
Waist	–0.23 (–1.37 to 0.91)	.69

[a]RFA: Ring Fit Adventure.

[b]N/A: not applicable.

[c]CMPB: centimeters per beat.

Discussion

Principal Findings

To our knowledge, this is the first study assessing the effect of a Nintendo RFA exergame on running completion time of adults after an intervention. As a study that incorporated a popular exergame (RFA) into the intervention implemented among students, in addition to assessing physical fitness and changes in the time it took to complete a run, this study also investigated the changes in the participants' sleep quality and psychological factors related to mood disorder.

In the RFA group, after 4 weeks of intervention, the completion time for the 1600-meter run decreased significantly for male and female participants, which was consistent with the findings of a previous study [11]. For example, a meta-analysis of studies conducted with children and adolescents found that previous exergames, such as Wii Fit and Dance Revolution, demonstrated similar physiological benefits [11].

Another 3-group randomized controlled trial of obese teenagers aged between 15 and 19 years reported that those who were encouraged to cooperatively play Wii Fit for 40 to 60 minutes per day lost substantially more weight and had an elevated self-identity [35,36]. In addition, similar exergames on Xbox

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Kinect (Microsoft Corp) exhibited a positive effect on physical fitness and emotional cognition [37] and were proven to enhance the dynamic balance of the lower limbs [38]. Both these benefits were attributed to the fact that Xbox Kinect required users to actively move in a given space by making the tasks dynamic [39] and introduced training programs that promoted visual feedback and dynamic balance [40].

Furthermore, a study provided preliminary evidence that Wii Fit could encourage people to exercise, thereby alleviating fatigue and reducing their body weight, waist circumference, anxiety level, and overall pain intensity [41]. Among traditional training programs, high-intensity interval training and similar methods use short-term high-intensity exercises to increase cardiorespiratory fitness and maximum oxygen consumption [42]. Moreover, a relatively short exercise time can effectively improve aerobic metabolism [43,44].

However, it remains unknown whether individuals can sustain such exercises over an extended period. In contrast, by combining exercise with digital games, emerging exergames can integrate physical activities with cognitive tasks and facilitate players to engage in physical activity according to visual, audio, and sensational feedback [45]. In addition, its user stickiness is strong owing to the introduction of multiple levels. Although this study did not include elderly individuals as part of the study population, similar research indicated that their experience with exergames was positive [46]. Exergames could also be used for rehabilitation purposes, as a study suggested that rehabilitation through Wii Fit achieved satisfactory therapeutic effects [47]. A recent study that adopted RFA as an intervention found that after 8 weeks, the chronic low back pain of participants was effectively alleviated [8]. The high level of movement they provide and the reduced cost of interactive modern technology have made exergames increasingly popular [48]; therefore, their application in health promotion is considered a future trend [49].

Influence of Exergames on Psychological Factors

The existing studies on the effects of exergames on social and psychological factors, such as sleep quality and mood disorders, are somewhat limited. Our research indicated no significant changes in sleep quality after the intervention. The CPSQI adopted in this study is a psychometrically reliable measure of sleep quality and sleep disorders in patients with primary insomnia [25]. Although a study found that 6 weeks of Xbox Kinect training could improve the sleep quality of elderly individuals and alleviate their anxiety symptoms [50], this study did not reach a similar conclusion.

Alternatively, the BSRS-5 scale used in this study to measure mood disorders can be used to assess psychological symptoms, including anxiety, depression, hostility, interpersonal sensitivity, and difficulty falling asleep [26,28,51]. The modified BSRS-5 was found to rapidly detect mood disorders in a previous Taiwanese study and showed high validity and reliability among the general public as well as patients with mental or medical diseases [26]. In this study, although the BSRS-5 scores of males (1.81 to 3.31) and females (3.17 to 4.54) in the RFA group increased considerably after the intervention, they did not reach the category of mild mood disorder (BSRS-5 score>6). At present, no studies have used the BSRS-5 to explore the effectiveness of exergames. Although a study suggested that exergames could alleviate anxiety symptoms [41], a different questionnaire was used.

Therefore, more relevant research may be required to provide further evidence. The increased mood disorders in this study were likely because the pretest was performed immediately before the Lunar New Year Festival, whereas the posttest was performed after the holiday and before the midterm examinations, during which the participants were possibly more stressed. Some researchers also pointed out that during the COVID-19 pandemic, even low-threshold and mild psychological reactions could provoke intense mood disorder reactions [52].

Predicted Physical Factors Affecting the Completion of the 1600-Meter Run

This study proposed a new index, CMPB, based on the original CFI. CMPB refers to the distance (in cm) the body can move during each heartbeat, which makes it easier for the public to understand. Our study showed that sex, exercise habits, alcohol consumption status, CMPB_run, age, and BMI were important factors that affected an individual's performance in the 1600-meter run. A previous study found that the older the person, the longer the run completion time [16], which was consistent with our findings. In addition, our study included exercise habits as a variable and found that compared to those who did not have an exercise habit, participants who regularly exercised 4 to 6 times a week required substantially less time to complete the 1600-meter run, which was consistent with the result of another study [53].

Moreover, we found that compared to nondrinkers, participants who consumed alcohol 2 to 3 times a week took significantly longer to complete the run, which was consistent with the findings of a previous study that focused on the correlation between alcohol consumption and exercise [54,55]. Furthermore, our study showed that each additional unit increase in CMPB_run reduced the time required to complete the run, and the difference was statistically significant. This was in line with the results of a CFI study [16], which indicated that CMPB could provide good predictions similar to those of CFI. However, further research is required to support this conclusion.

Finally, our study used the novel Zephyr BioPatch device. As a result, the participants were no longer required to wear a strap on the lower edge of the chest for the Zephyr BioHarness 3.0 module to take measurements, which previously prevented women from participating [16]. Therefore, the CMPB indicator allowed measurements to be taken among female participants and thus identify sex-specific differences.

Strengths and Limitations

This study had several strengths. First, the study found that RFA provided an opportunity for indoor exercise during the COVID-19 pandemic [56]. In addition, users' constant engagement in training and activities could be encouraged by different elements in the game. Second, aside from running performance, this study also investigated the effect of RFA on sleep quality and mood disorders. Third, a new index, CMPB,

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was proposed based on the original CFI. Hence, the CMPB allows for easier comprehension and shares the same important factors in predicting the time required to complete the run.

However, this study had some limitations. First, the participants were limited to military students (college, master, and doctoral students) in northern Taiwan. Second, the study did not explore potential interfering elements, such as lifestyle habits and environmental factors. In addition, healthy participants may have contributed to a plateau effect, as their performance was already close to an optimal level [14].

Conclusions

This study found that training using RFA could maintain or improve users' physical fitness. Therefore, RFA provides a good solution for people who engage in distance learning for a prolonged period or those who do not have sufficient time for exercise. Exergames not only serve as an alternative for exercising at home but also show the potential to evolve with societal changes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1155 KB - games_v10i1e35040_app1.pdf]

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Abbreviations

BSRS-5: 5-item Brief Symptom Rating Scale
CFI: cardiac force index
CFI_PA_walk: cardiac force index of peak acceleration while walking
CMPB_walk: centimeters per beat while walking
CFI_PA_run: cardiac force index of peak acceleration while running
CMPB_run: centimeters per beat while running
CPSQI: Chinese version of the Pittsburgh Sleep Quality Index
GEE: generalized estimating equation
RFA: Ring Fit Adventure

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Original Paper

Data-Driven Classification of Human Movements in Virtual Reality–Based Serious Games: Preclinical Rehabilitation Study in Citizen Science

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Abstract

Background: Sustained engagement is essential for the success of telerehabilitation programs. However, patients' lack of motivation and adherence could undermine these goals. To overcome this challenge, physical exercises have often been gamified. Building on the advantages of serious games, we propose a citizen science–based approach in which patients perform scientific tasks by using interactive interfaces and help advance scientific causes of their choice. This approach capitalizes on human intellect and benevolence while promoting learning. To further enhance engagement, we propose performing citizen science activities in immersive media, such as virtual reality (VR).

Objective: This study aims to present a novel methodology to facilitate the remote identification and classification of human movements for the automatic assessment of motor performance in telerehabilitation. The data-driven approach is presented in the context of a citizen science software dedicated to bimanual training in VR. Specifically, users interact with the interface and make contributions to an environmental citizen science project while moving both arms in concert.

Methods: In all, 9 healthy individuals interacted with the citizen science software by using a commercial VR gaming device. The software included a calibration phase to evaluate the users' range of motion along the 3 anatomical planes of motion and to adapt the sensitivity of the software's response to their movements. During calibration, the time series of the users' movements were recorded by the sensors embedded in the device. We performed principal component analysis to identify salient features of movements and then applied a bagged trees ensemble classifier to classify the movements.

Results: The classification achieved high performance, reaching 99.9% accuracy. Among the movements, elbow flexion was the most accurately classified movement (99.2%), and horizontal shoulder abduction to the right side of the body was the most misclassified movement (98.8%).

Conclusions: Coordinated bimanual movements in VR can be classified with high accuracy. Our findings lay the foundation for the development of motion analysis algorithms in VR-mediated telerehabilitation.

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KEYWORDS

motion analysis; principal component analysis; telerehabilitation; virtual reality

Introduction

Stroke Telerehabilitation

Stroke is continuously cited as a leading cause of disability in adults. Every year, 795,000 Americans experience stroke, and 649,000 survive it [1]. Approximately 610,000 of these cases are the first attacks, indicating that the population of stroke survivors is rapidly increasing [1]. Stroke survivors commonly experience neuromuscular disorders that profoundly disrupt their lives. It is estimated that 74% of stroke survivors require assistance with activities of daily living, costing billions of dollars annually [1,2]. Beyond loss of mobility, stroke-induced disability takes a societal toll; many stroke survivors can no longer contribute to the workforce and lose their functional role in their community [2]. They often enter a downward spiral that is associated with a steep decline in their psychological and cognitive well-being, affecting their families and social circles [1,3,4].

Motivated by these economic and societal needs, rehabilitation medicine aims to reintegrate individuals with disabilities into society. This process typically involves multiple visits to outpatient clinics, where therapists treat patients with arduous exercises. The more frequently and intensely they exercise, the sooner the patients would recover muscle strength and function [5]. Nonetheless, outpatient clinics are often underequipped and understaffed. As a result, patients have to wait for long periods for appointments and do not receive sufficient care, significantly hindering their recovery [6]. To address this issue, the notion of telerehabilitation has emerged.

In the ideal telerehabilitation paradigm, patients are prescribed home-based exercises involving electronic devices that measure their movements [7-9]. Data on motion are then sent to a physician, who would, in turn, remotely assess motor performance and recommend the next steps in the rehabilitation regimen. Through this process, patients are expected to exercise at their own convenience at home, readily receive professional feedback, and ultimately maximize their rehabilitation outcomes. Multiple telerehabilitation systems have been introduced in the past 20 years, demonstrating and yielding outcomes comparable with those of traditional in-clinic rehabilitation [9-12].

Despite the promising prospects, the advantages of telerehabilitation are often not realized, as patients fail to adhere to their prescribed regimen in the absence of a physical therapist [13,14]. One of the primary factors pinpointing a lack of adherence is a lack of motivation [13,14]. To address this critical limitation, innumerable efforts were invested in gamification of telerehabilitation [15-17]. Notably, the Java Therapy, one of the first examples of a telerehabilitation system, incorporated *therapy games* in between *status tests* that measure rehabilitation progress [18]. Similarly, games that involve chasing rabbits [19], catching falling fruit [20], and even competitive air hockey [21], were developed to make physical exercise more enjoyable.

Citizen Science–Based Telerehabilitation

Although games effectively improve engagement in telerehabilitation, incorporating citizen science into the activity was proposed instead [22]. In citizen science, members of the general public carry out research tasks in projects led by professional scientists [23,24]. These tasks involve data collection or data analysis and do not require any particular expertise or commitment [23,24]. Citizen science is a compelling means for improving engagement in telerehabilitation for a few reasons. Similar to games, the motivations underlying participation in citizen science are primarily intrinsic [25,26]. Some citizen science projects incorporate gaming elements, such as point systems, scoreboards, or competitions, to promote long-term participation [27,28]. Unlike in games, citizen scientists choose to contribute to a project not only because it is enjoyable or fun but also because they are interested in the research topic, they have a desire to learn more about it, and they would like to promote it [29-31]. In essence, citizen science is intellectually stimulating and encourages learning. Moreover, citizen science has the potential to empower patients to help scientists despite their disability, increase their self-esteem, and provide them with a sense of belonging to a community [24,32]. Finally, as it is important for leading scientists to collect or analyze data meticulously, there is rarely a time constraint for making a contribution such that users can contribute at their own pace.

In a recent study, we presented a low-cost telerehabilitation system that delivers exercise in the context of citizen science [33]. The system consisted of a Microsoft Kinect sensor and an inertial measurement unit mounted on a wooden dowel. Users would manipulate the dowel in front of the Kinect sensor to perform actions on a standard computer monitor or television screen. More specifically, the actions involved the annotation of 360° images of a highly polluted canal in Brooklyn, New York, United States. The system was dedicated to bimanual exercise, in which users would manipulate the dowel with both hands. The system also featured a classification algorithm that identified the movements performed by the user, which achieved a high accuracy of 93.1%.

In this study, we adapted the Kinect-based interface to virtual reality (VR) and focused on the classification of upper limb movements in a preclinical setting. We recorded the interactions of 9 healthy users with the Oculus Rift (Oculus VR), a popular VR gaming system. The Oculus Rift consists of a head-mounted display, 2 Touch controllers, and 2 tracking sensors. Inertial measurement units are embedded in the head-mounted display and Touch controllers such that the system is able to record the orientation of the head and the hands. The devices were also seeded with an array of infrared lights, which, in conjunction with the tracking sensors, enable high-fidelity motion tracking through the Oculus trademarked Constellation Tracking [34]. The VR setting offered more degrees of freedom in motion relative to our Kinect-based system, whereby users could rotate their entire bodies to interact with the interface. Therefore, to adapt the software and classification algorithm, we applied a

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kinematic framework that infers the position and orientation of the Touch controllers relative to the head-mounted display.

Our choice to explore human movement in VR was motivated by 2 main reasons. First, the major barriers that prevent the widespread adoption of rehabilitation technologies are cost and user friendliness. Rehabilitation devices are often custom-made, cost prohibitive, and require technological proficiency that extends beyond the typical knowledge of the general public [35]. On the other hand, gaming controllers such as the Oculus Rift are safe and intuitive to use and are more affordable than rehabilitation robots, thereby offering a viable means for home-based telerehabilitation. Gaming controllers can also objectively measure the motor performance through their embedded sensors. Specifically, the Oculus Rift tracks movements of the headset and Touch controllers with high spatial and temporal resolution, thereby providing rich data on the user's motions. It was validated in controlled experiments and deemed sufficient for motion analysis in medical applications [36,37].

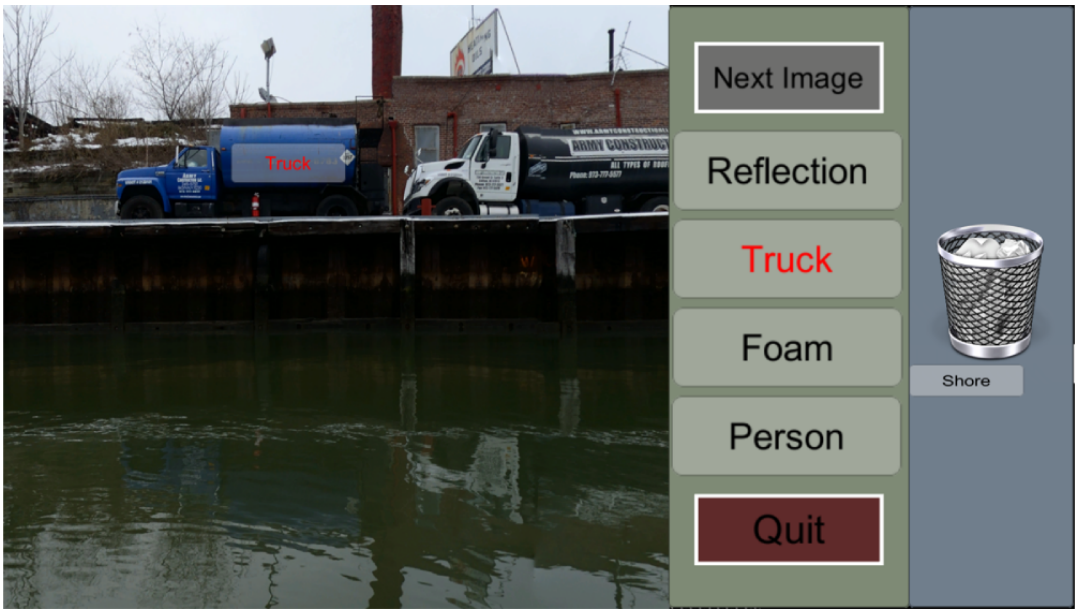
Second, VR is the most immersive medium available today. The technological apparatus of VR grants the user the experience of *presence*, where the user accesses a novel environment and interacts with it as if the computer ceased to exist [38,39]. In the context of rehabilitation, immersive VR environments are largely used to improve patients' engagement and adherence to the rehabilitation regimen, which will accelerate their recovery in return [6,16,40]. The literature suggests that patients undergoing rehabilitation augmented with VR could substantially improve their motivation and motor functions [40,41]. For example, Dockx et al [42] compared 281 older adults' perceptions of fall prevention training over a period of 6 weeks when delivered with and without VR. All participants who exercised in the VR condition reported higher engagement and perceived benefits and were more likely to recommend the intervention to others than those who did not use VR in their training. In another study, AlMousa et al [43] tested a game with 5 patients with stroke and compared their satisfaction when playing in VR and in a traditional setting. All patients agreed that the VR modality was highly motivating and expressed interest in including it in their rehabilitation. Finally, in a study involving 4 patients with spinal cord injury, Palaniappan and Duerstock [44] showed that VR improved motor performance, whereby patients' upper limb range of motion was greater.

We created an interactive interface in which users could participate in an environmental citizen science project. In this particular application, users contributed to the environmental monitoring of the highly polluted Gowanus Canal in Brooklyn, New York, United States. Users could explore 360° images of the canal, select labels from a list of 4 labels, and allocate them onto objects of interest, such as potential pollutants and notable landmarks (Figure 1).

The interface was dedicated to bimanual training of patients with stroke, whereby users interacted with the interface by performing coordinated movements with both arms. Many rehabilitation strategies, such as constraint-induced movement therapy [45,46], task-oriented training [47], and continuous passive movement [48], have various advantages. Bimanual training is highlighted as a potent clinical approach for the recovery of coordinated movements with both physiological and practical advantages [49] Research has shown that passive movement of paretic limbs can recover voluntary motion by imparting electrical impulses to the contralateral primary motor cortex (sometimes referred to as *spillover*) [50-52] and project them to the affected muscles [53-55]. Furthermore, it has been argued that bimanual skills are abundant in activities of daily living and therefore practicing them will help patients regain independence more quickly [56-59].

We pursued a simple, yet effective, data-driven approach to automatically assess bimanual movements in VR.

Figure 1. Screenshot of the user interface. A 360° image of a polluted canal can be explored in the virtual environment. In the green panel on the right, there is a list of 4 labels (*Reflection*, *Truck*, *Foam*, and *Person*) and a trash bin. The *Next Image* button above the labels allows the user to analyze a new image. Below the list, a *Quit* button is situated. By pressing it, the user will exit the application. The user has selected the label *Truck* (highlighted in red) and intends to allocate it onto the image. The label *Shore* has been disposed of and appears below the trash bin.



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Motor Assessment Using Machine Learning

Machine learning offers an important avenue for automatically identifying and categorizing human behavior. In machine learning, a computer uses data to predict an outcome without explicitly knowing the relationship between the data and the outcome [60,61]. The input of a machine learning algorithm consists of features that describe instances of data. When a supervised machine learning approach is used, knowledge of the outcome must be available during training. In this case, a set of instances is fed to the machine, encapsulating their features and associated outcomes [61,62]. For example, Begg and Kamuzzaman [63] used machine learning to distinguish between the gait of the young and older adults. The authors fed their machine learning algorithm with data on the gait of 12 young and 12 older individuals, where their gait was summarized through multiple features, such as stride length, walking speed, forces applied by the feet, and ankle angles. They used a supervised machine learning approach (support vector machine [SVM]) and therefore provided the machine with the true class of the participant: young or older. Following training, the SVM classifier achieved an accuracy rate of 91.7% in the classification of the age group of the participant.

In a similar study, Novak et al [64] aimed to identify gait initiation and termination using wearable inertial measurement units. The authors recorded 10 participants walking with inertial sensors on their legs and trained a tree classifier to distinguish between gait phases. The algorithm exceeded 80% accuracy and was robust with respect to the gait speed. Semwal et al [65] trained a multilayer perceptron to identify disordered gait. The authors defined features for walking, running, jogging, and jumping from vision-based and sensor-based data and achieved accuracy rates ranging from 85% to 92.5%.

Despite its success with gait analysis, the use of machine learning to assess upper limb movement has not been extensively studied. Such an assessment is more challenging as the repertoire of arm movements is wider than that of the lower limbs. In several studies, statistical pattern recognition algorithms have been used to quantify the motor performance of the upper limb from data collected by inertial sensors [66] and vision-based sensors [67]. Additional work to recognize upper limb movement was carried out using k-means clustering and convolutional neural networks [68,69]. Nonetheless, the efficacy of machine learning in upper limb rehabilitation remains underexplored.

Objective

We developed a machine learning algorithm that classifies the movements performed by the user to automate the assessment of motor performance. The proposed algorithm implements dimensionality reduction through principal component analysis (PCA), feature extraction, and ensemble classification. In all, 9 healthy individuals interacted with our interface, whereas data on their movements were recorded by the sensors embedded in the Oculus Rift devices. The classification of the movement was achieved with remarkably high accuracy and could reduce the time and cost of poststroke rehabilitation assessment by a therapist. Furthermore, the classification strategy can be extended to provide haptic feedback to the user to perform exercises correctly and safely.

Methods

VR Interface

The interface was developed in the Unity real-time game engine (Unity Technologies) for use with the Oculus Rift VR system. In the game, participants were presented with a random 360° image of the Gowanus Canal, overlaid by a heads-up display (HUD). The HUD served as the participants' main method of interacting with the application. It contained a button for navigation between images of the canal and a trash bin and a list of descriptive keywords that may or may not describe objects within the image.

Users were tasked with analyzing the images. Specifically, they could explore the 360° images, select labels from the list of keywords, and allocate them to objects of interest (Figure 1). If the users could not find an object that a label described in the image, they could eliminate the label by allocating it onto the trash bin (Figure 1). Once the user felt that the image was saturated with labels, they could analyze a new image by selecting the *Next Image* button.

To interact with the HUD, the users performed bimanual gestures (Figure 2). Specifically, users began from a baseline pose where they flexed their elbows and held the Touch controllers near their shoulders. To move the cursor to the left, they extended both arms to the left side of their body, simultaneously performing horizontal abduction of the left shoulder, horizontal adduction of the right shoulder, shoulder flexion, elbow extension, and forearm pronation (Figure 2A). Similarly, to move the cursor to the right, they performed horizontal shoulder abduction in the opposite direction, extending both hands to the right side of their bodies (Figure 2D). To move the cursor upward, users raised the Touch controllers by flexing their shoulders and extending their elbows (Figure 2B). To move the cursor downward, they extended both the elbows and lowered the Touch controllers (Figure 2E). Finally, to select a button, they flexed both shoulders simultaneously and extended their elbows, pushing the Touch controllers away from their body (Figure 2C and Figure 2F). These movements used most joints of the upper limb and were commonly prescribed to patients [70,71]. If a user wanted to move the cursor diagonally along the screen, they would instead move it horizontally and vertically.

To enable the user interface, we used a kinematic framework using data on the position of the head-mounted display and Touch controllers, measured by the infrared camera sensors. We considered 4 reference frames for the inertial, global space, denoted as {G} and the 3 noninertial reference frames associated with the head-mounted display, right hand Touch controller, and left hand Touch controller, denoted as {H}, {R}, and {L}, respectively (Figure 3).

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Figure 2. Implementation of the user interface. The user is able to perform actions on a computer through (A and D) horizontal abduction and adduction of the shoulders, (B and E) flexion and extension of the shoulders, and (C and F) flexion and extension of the elbows.

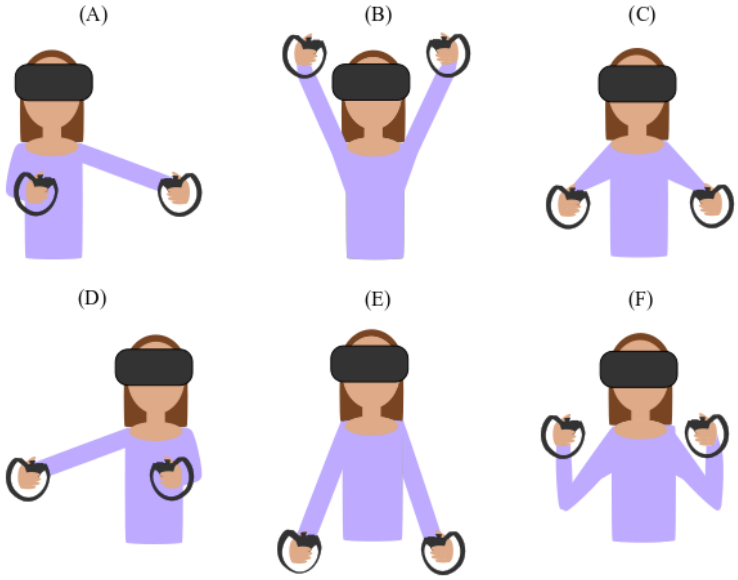
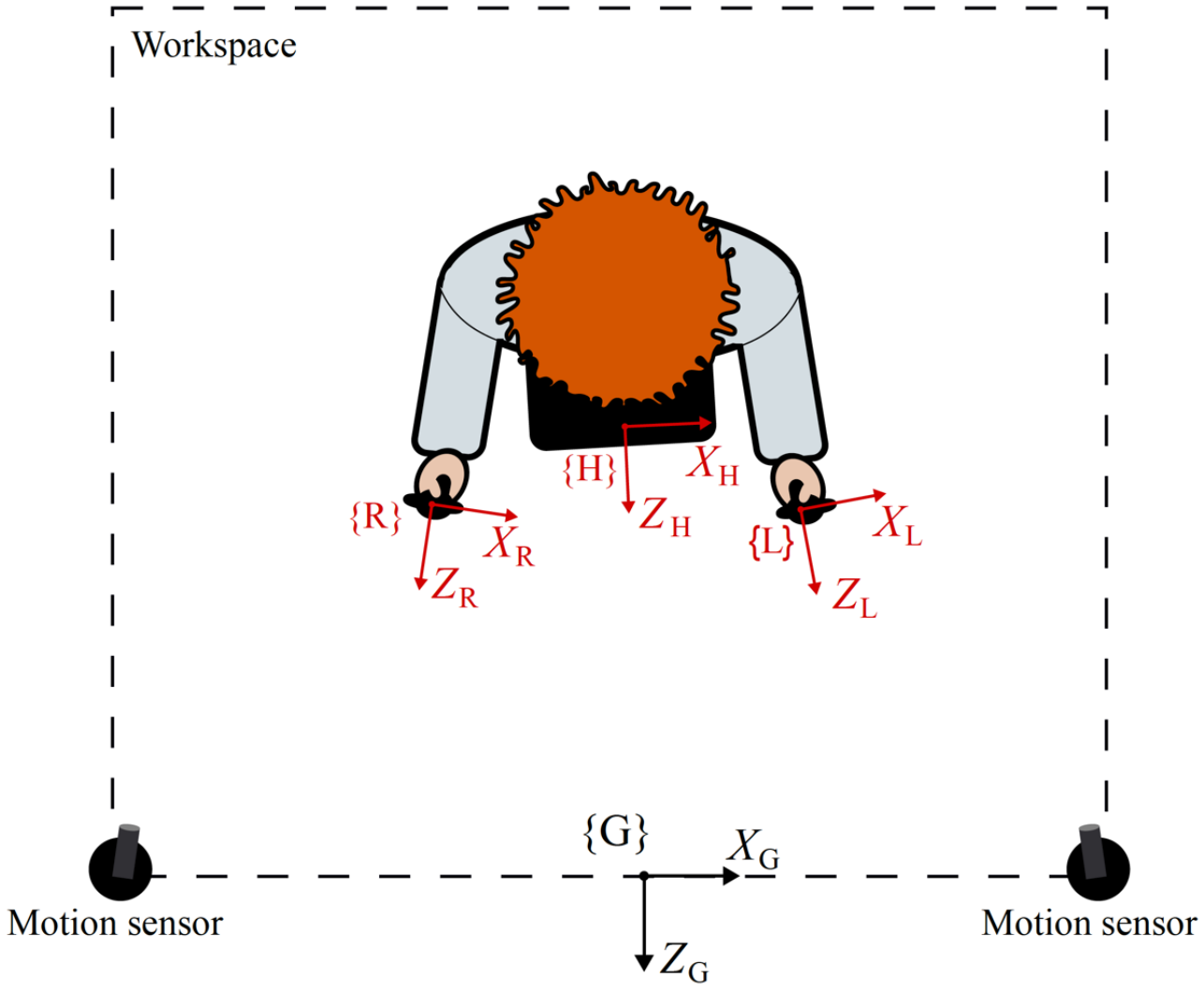


Figure 3. Illustration of a typical Oculus Rift workspace from a top view. Two sensors are placed at the edge of the workspace. The global frame, {G}, uses the coordinate system (X_G, Y_G, Z_G). The local frames for the head-mounted display and the right and left Touch controllers are drawn in red and denoted as {H}, {R}, and {L}, respectively.



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Throughout the game, a midway point between the Touch controllers, P^{G}_{h} (Figure 4A), was computed in real time as follows:



where P^{G}_{h} is a vector in the form of $[X\ Y\ Z]^{T}$ that expresses the position of the midpoint h in the global frame {G} (T being matrix transposition); , , and  are the positions of a point along the *X*-, *Y*-, and *Z*-axis of global frame {G}, respectively; and subscripts R and L represent the right and left Touch controllers, respectively. The cursor on the screen responded to the fixed values of P^{G}_{h}. For example, if X^{G}_{h} was greater than a certain threshold value, the cursor would move to the left on the screen. Similarly, if X^{G}_{h} was smaller than a certain negative threshold value, the cursor would move to the right. Considering that patients may take longer to complete their movements, we did not impose any time constraints on these controls.

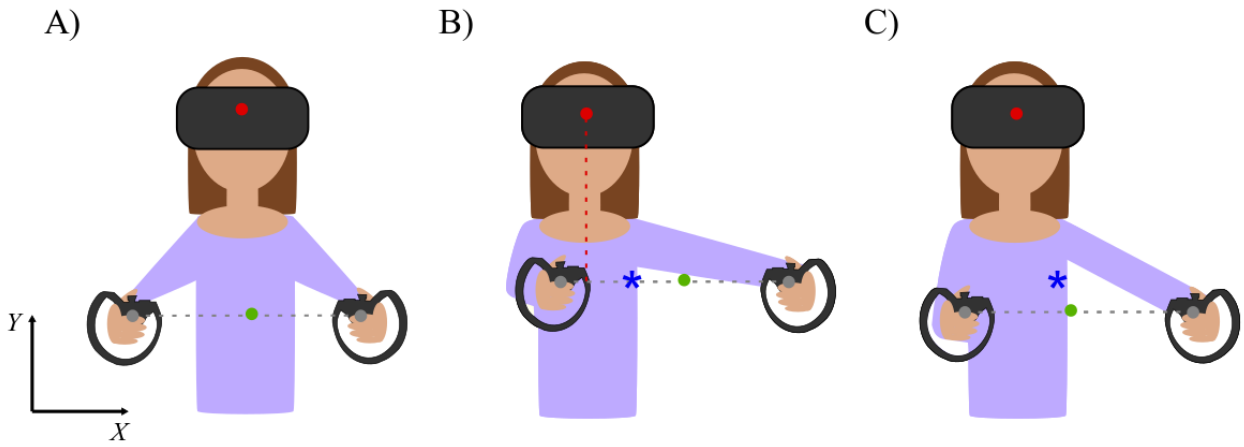
To accommodate for impaired movement with a compromised range of motion, a calibration phase was added to determine the aforementioned threshold values. During calibration, the participant performed each of the movements 5 times consecutively. The software computed an average of the user's range of motion  during the 5 iterations as follows:



where n=1, 2,..., 5 is the iteration of the movement, $P^{G}_{h,n}$ is the time series of the position of the midpoint between the right and left Touch controllers during iteration n; and $P^{G}_{H,n}$ is the time series of the position of the head-mounted display during iteration n. The application set a threshold point at a distance of 0.25 along the *X*-, *Y*-, and *Z*-axis of the head-mounted display (Figure 4B). At any time when P^{G}_{h} exceeded 0.25, the cursor began moving on the screen along the axes that satisfied this condition (Figure 4C). Thus, users who had a limited range of motion had to move their arms at a shorter distance to induce movement of the cursor on the screen.

Finally, acknowledging that physical therapy can be physically and mentally taxing, we enabled a *Home* page menu such that patients could press a button to pause the software and rest. This feature is particularly important for telerehabilitation of stroke, as many patients may feel pain or fatigue, discouraging them from engaging in the exercise [14].

Figure 4. Illustration of the calibration threshold along the *X*-axis. (A) Throughout the game, the instantaneous position of the point between the Touch controllers (marked with a green circle) is computed. (B) Its maximum position relative to the position of the head-mounted display along the *X*-axis (marked with a red circle) is computed during the calibration phase. A threshold is set at 25% of that displacement, represented by the blue star. (C) During the game, every time the average controller point exceeds the threshold, the cursor will begin moving on the screen in the corresponding direction.



Data Collection

This study was carried out in accordance with the relevant guidelines and regulations set by the New York University's Institutional Review Board, the University Committee on Activities Involving Human Subjects (study number: FY2019-2828). Informed consent for participation was obtained from all participants.

In all, 9 members of the university community were recruited and escorted to a private room. They were introduced to the project and VR system. Upon signing a consent form, the participants stood in a 3 meter × 3 meter cleared space and wore the head-mounted display. They viewed a short presentation about the Gowanus Canal and the notion of citizen science and underwent a calibration phase.

The calibration was designed such that the participants began with a baseline pose with their elbows bent and hands held near their respective shoulders. The participants first performed horizontal shoulder abduction toward their right side. Instructions on the screen explicitly asked the participants to extend their arms as far as possible to the right and return to the baseline pose, repeating this movement 5 times. Then, the participants performed horizontal shoulder abduction toward their left side and returned to the baseline pose 5 times. In the same manner, the participants performed shoulder flexion by raising both hands, elbow extension by lowering both hands, and simultaneous shoulder flexion and elbow extension by

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pushing both hands forward in this order. The participants repeated each movement 5 times consecutively and returned to the baseline pose after each excursion.

After calibration, the participants completed a tutorial teaching them how to use the HUD. They then analyzed images of the Gowanus Canal for as long as they wished. The movements of the participants were recorded throughout the experiment. The data set consisted of the time series of the positions of the head-mounted display and Touch controllers in 3D and their orientations in Tait-Bryan angles. Measurements were logged at a sampling rate of 89 measurements per second.

Data Analysis

Kinematics in the VR Setting

Data were processed and analyzed in MATLAB (MATLAB R2020a; The MathWorks, Inc). We aimed to infer the participants' movement during their interaction with the VR system from data on the positions and orientations of the head-mounted display and Touch controllers. In VR, the interface is not constrained to a fixed planar screen, and participants' interactions extend to 3D whereby the user can walk and turn their body around. Therefore, to infer the participants' movements, the positions of their hands relative to their heads are more informative than their positions in absolute space.

We began with a kinematic description of the positions and orientations of the Touch controllers relative to the head-mounted display through matrix manipulation [72]. The reference frame of the head-mounted display was expressed with respect to the global frame using the rotation matrix:



where a superimposed hat identifies unit vectors for the reference frames, such that the columns of the matrix are the unit vectors of {H}, expressed in {G}'s coordinate system. Similarly, the reference frames of the Touch controllers with respect to the global frame were expressed as ${R^{G}}_{R}$ and ${R^{G}}_{L}$ for the right and left controllers, respectively.

Taking the devices' rotation matrices, the frame of reference of the right Touch controller relative to the head-mounted display was calculated as



and the left Touch controller's was calculated as



where the inverse is equivalent to the transpose of the matrix [72]. To fully describe the instantaneous relative positions and relative orientations of the devices, we applied the homogeneous transform [72] at each time step, such that



where ${P^{G}}_{H}$ is the instantaneous position of the head-mounted display in the global frame, ${P^{G}}_{H}$ is the instantaneous position of the head-mounted display in the right hand controller frame, ${R^{G}}_{R}$ is the rotation matrix of the right Touch controller frame relative to the global frame, ${P^{G}}_{R}$ is the position of the right Touch controller in the global frame, and 0 on the bottom left entry of the matrix represents a row vector of 3 zeros. We applied the transformation to instantaneous measurements at each time step and generated a time series containing the positions and orientations of the Touch controllers relative to the head-mounted display.

Assessing Motor Performance

For a comparison of patients' movements with movements of healthy ones, we quantified the participants' motor performance using several metrics: (1) range of motion, computed as the maximum distance of each of the Touch controllers from the headset, along each of the anatomical planes [22,73]; (2) mean speed, computed as the average of instantaneous speeds [22,73]; (3) smoothness, computed as the mean speed divided by the maximal instantaneous speed [22,73]; and (4) path length, measured as the sum of distances between pairs of consecutive data points during movement [22,74].

Feature Selection

We pursued a data-driven methodology to classify the movements performed by the participant based on the Touch controllers' position and orientation relative to the head-mounted display. Only data from the calibration phase were used in the analysis, as the sequence of movements performed by the participants during this period was known and could be specified in supervised training. The data that were collected in the remainder of the session while participants interacted with the citizen science software could be used in future endeavors to assess motor performance and engagement over longer periods, once automatic classification is implemented. We also included the instantaneous head-mounted display and Touch controllers' linear and angular velocities in the global frame for analysis. Specifically, we computed the devices' linear, denoted as , , and , where (·) is the noninertial reference frame under examination and angular velocities about their *X*-, *Y*-, and *Z*-axis in the global reference system, denoted as , , and . We also computed the Touch controllers' positions and orientations relative to the head-mounted display, denoted as , , and , and , , and , respectively. In general, we denoted  as the generic coordinate of point B, in coordinate system {A}. For notational convenience, when the trailing subscript is a reference frame, B represents the position of the origin of frame {B}. For example, ${X^{H}}_{R}$ is the position of the right Touch controller, along the *X*-axis of the head-mounted display. Similarly, ${\gamma^{G}}_{R}$ is the angular velocity of the right Touch controller about the *X*-axis in the global frame. Overall, the data set included 30 variables, as summarized in Table 1.

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Table 1. Summary of the variables used for principal component analysis. The variables γ, β, and α refer to the Tait-Bryan angles of the Oculus head-mounted display and Touch controllers about the *X*-, *Y*-, and *Z*-axis, respectively.

Device and variable notation	Variable description
Head-mounted display	
${X^G}_H, {Y^G}_H, {Z^G}_H$	Linear velocity in {G}
${\gamma^G}_H, {\beta^G}_H, {\alpha^G}_H$	Angular velocity in{G}
Right Touch controller	
${X^H}_R, {Y^H}_R, {Z^H}_R$	Position in {H}
${\gamma^H}_R, {\beta^H}_R, {\alpha^H}_R$	Orientation in {H}
${X^G}_R, {Y^G}_R, {Z^G}_R$	Linear velocity in {G}
${\gamma^G}_R, {\beta^G}_R, {\alpha^G}_R$	Angular velocity in {G}
Left Touch controller	
${X^H}_L, {Y^H}_L, {Z^H}_L$	Position in {H}
${\gamma^H}_L, {\beta^H}_L, {\alpha^H}_L$	Orientation in {H}
${X^G}_L, {Y^G}_L, {Z^G}_L$	Linear velocity in {G}
${\gamma^G}_L, {\beta^G}_L, {\alpha^G}_L$	Angular velocity in {G}

Next, we automatically identified instances of movement (versus nonmovement) in the time series of each variable and segmented them. Specifically, we used finite differences between the positional data for the Touch controllers with respect to time and defined the time series [75]:



Intervals of movement were taken as the instances where Ω exceeded 0.077 meters/second and lasted for longer than 0.2 seconds (Figure 5). These threshold values were derived empirically and were unique to the participant. To identify instances where a distinct pose occurred, pairs of consecutive intervals and the time series between them were selected as segments. Overall, 25 segments were identified, one each for each movement.

PCA was performed to identify salient variables in each movement. Within segments n=1, 2,..., 25, each of the 30 time series was normalized with respect to its own SD in the segment. The normalized time series, $s_{n,i}$ was represented by a column vector containing variable i=1, 2,..., 30 in segment n. For each segment n, we generate covariance matrix K_n, whose entries i, j are given by



where i=1, 2,..., 30, j=1, 2,..., 30, and  is the average value of the components of vector s_n. As there are 30 variables, there are 30×30 possible ordered variable pairs to compute the covariance for, which is the size of the symmetrical matrix K_n.

The principal components of each covariance matrix K_n were determined from the dominant eigenvalues $\lambda_i s$ [76]. To identify these eigenvalues, we defined a spectral gap as the largest difference between consecutive eigenvalues sorted in descending order (Figure 6A). The eigenvalues that preceded the gap were deemed to be dominant. Then, we examined the contribution of eigenvector v_i's components, the so-called *principal component loadings*, to these principal components. We sorted the absolute values of these loadings in descending order and recognized a gap as the largest difference between consecutive values. The loadings that appeared before the gap were retained, and the associated variables were used as salient variables that summarize the entire principal component (Figure 6B).

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Figure 5. Example of movement segmentation. The time series reflects the first 5 movements a participant performed during the calibration phase. The colored intervals are the ones identified as instances of movement in the segmentation process. Purple intervals correspond to outward movements where the participant extended their arms, and blue intervals reflect subsequent abduction when the participant returned to baseline pose. Gray regions are segments where the participant assumed the baseline pose.

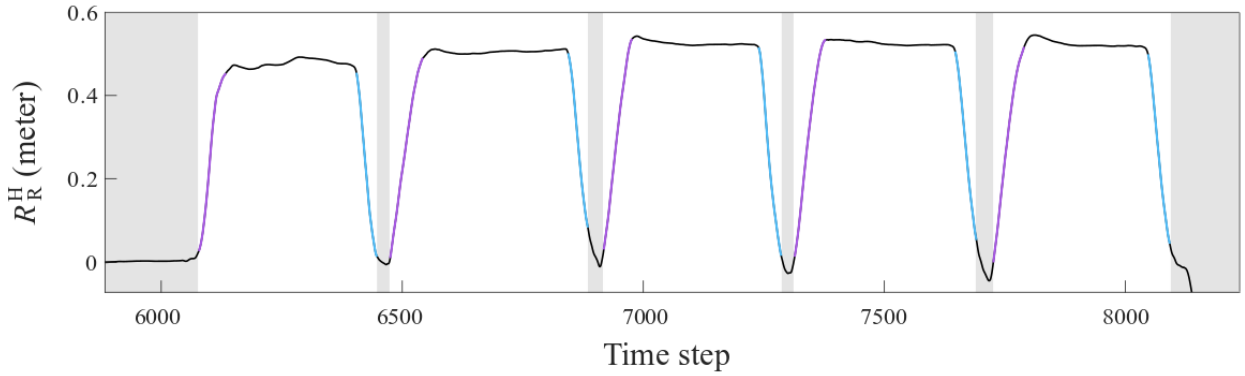
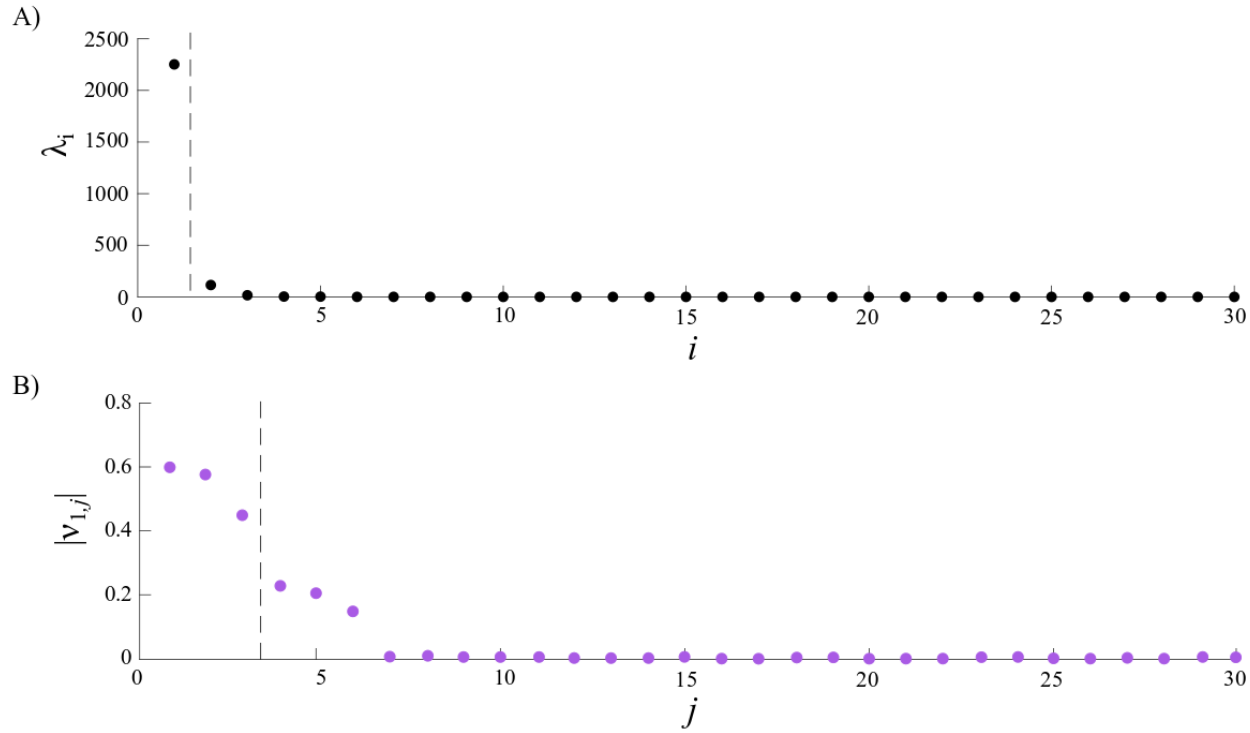


Figure 6. Example of the spectrum of a covariance matrix, corresponding to shoulder abduction to the right. The covariance matrix quantified the covariance of the 30 variables in the first segment, corresponding to shoulder abduction to the right side. (A) The array of 30 eigenvalues (λ_is) of the covariance matrix is sorted in descending order. The spectral gap where the largest difference between 2 consecutive eigenvalues appears (marked with a vertical dashed line) indicates that the eigenvector v_i, which is associated with the largest λ_i, is sufficient for capturing most of the variance in this first segment. (B) The absolute values of the components of v_i are sorted in descending order as well to identify the principal components. Here, the largest difference appears after 3 components, suggesting that the 3 variables associated with the first 3 components (in this case, γ^H_L, α^H_L, β^H_L) are principal for variation in the segment.



The salient variables we identified in the PCA were used to create discriminating statistics for training a classification algorithm. In the training, given the true class of a movement that was performed, the algorithm would unveil different relationships between the features that distinguish one movement from another [61,62].

Importantly, we observed that only the orientations of the Touch controllers relative to the head-mounted display were prominent during movement. Thus, their means and SDs were selected as the features. We also included the mean positions of the Touch controllers relative to the head-mounted display as features to further support the distinction between the poses. Nonetheless, we acknowledged that movements may be better discriminated using features that encapsulate the interactions between the variables. Therefore, we used correlation coefficients as additional features that relate 2 variables at a time. The correlation coefficients between γ, β, and α of one Touch

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controller and their counterparts in the other Touch controller were added to the analysis, yielding 21 features in total.

Movement Classification

We implemented a supervised machine learning classification that identifies which movement a user performs at any given time. To observe the evolution of features over time in a future clinical study, we chose to perform classification in a moving-window paradigm. Within this paradigm, we evaluated the actual movement and associated features within a window of several time steps, shifted the window forward in time by a single step, evaluated the features again, and so on. The length of the moving window was set to 13 time steps, equivalent to 0.15 seconds.

First, we established the true classes within each frame to train the algorithm. We visually inspected the time series of the calibration (where we knew what movement was performed), identified which movement was performed (if any) at every time step, and labeled it as such. Beginning from the first time step, we determined the true class of the window that covered the subsequent 13 time steps based on their mode. That is, the window's true class matched the class of the majority of time steps (7 or more). Henceforth, the window was moved to the following time step and the subsequent true class was determined. In this manner, we created a time series for the true class of frames. To determine the true class of a movement within a 13–time step frame, we also computed the set of 21 features and recorded them for the same frame. Thus, we created 21 additional time series, each representing the evolution of a feature.

Next, we trained a classification algorithm using MATLAB's Classification Learner app. We compounded the moving frames' true classes and features across participants into a single table and selected it as the data set variable. The frames' true classes were set as response variables, and all features were set as predictors. We applied a K-fold cross-validation with K=5, such that 80% of the calibration data from all participants were used for training and the remaining 20%, for validation. Finally, we selected bagged trees as the model type.

Bagged trees is an ensemble method based on decision trees [77]. A basic decision tree splits the input data into subgroups with a similar response to a binary criterion. The subgroups are partitioned recursively until the model is able to predict the output based on the class that has the majority representation. A bagged trees classifier performs bootstrapping and aggregation, that is *bagging*, on a multitude of decision trees. Specifically, the bagged trees algorithm generates decision trees by resampling the data set with replacement and determines the response class based on the simple majority of the trees' predictions. Thus, this classification method mitigates the high variance often observed in them [78,79].

Because the trees are produced by bagging, all features are considered for a splitting event. It is possible to score the importance of each feature by estimating the *out-of-bag* error. That is, instances that were not sampled when a tree was generated were used to make a prediction. The mean error of the prediction was then computed. The features that yielded the largest decrease in mean error were considered to be the most important.

Results

Data Collection

Data were collected from 9 healthy participants who interacted with the interface. On average, the participants interacted with the interface for 368.26 (SD 92.74) seconds, generating time series of 32,776 (SD 8254) time steps on average. A total of 294,983 measurements were collected, of which 142,916 time steps (1605.80 seconds) were recorded during the calibration phase.

Motor Performance

The participants' range of motion, mean speed, peak speed, and path length were computed (Table 2). The range of motion, mean speed, and smoothness for each movement in one arm were comparable with those of its symmetrical counterpart. However, during shoulder adduction and shoulder flexion or extension upward, considerable variation was measured among participants with respect to smoothness; SDs were >25% of the mean value, or even greater than the mean value, as in the case of the left hand during shoulder flexion or extension upward. Finally, in all movements, the path length was larger than the range of motion, indicating that the participants did not follow a straight line along the anatomical axes.

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Table 2. A summary of participants' motor performance for each arm, computed from data from the right and left Touch controllers. The values represent the mean (SD) across the participants.

Movement and hand	Range of motion (meters), mean (SD)	Speed (meters/second), mean (SD)	Smoothness, mean (SD)	Path length (meters), mean (SD)
Shoulder adduction to the right				
Right	0.61 (0.11)	0.86 (0.25)	2.47 (1.16)	0.72 (0.17)
Left	0.39 (0.06)	0.60 (0.13)	1.95 (0.58)	0.48 (0.08)
Shoulder adduction to the left				
Right	0.38 (0.05)	0.60 (0.10)	2.27 (1.43)	0.46 (0.08)
Left	0.61 (0.16)	0.94 (0.25)	4.39 (3.96)	0.74 (0.18)
Shoulder flexion or extension upward				
Right	0.60 (0.08)	0.86 (0.20)	3.43 (3.33)	0.64 (0.10)
Left	0.59 (0.08)	0.86 (0.20)	3.16 (3.64)	0.63 (0.10)
Shoulder flexion or extension downward				
Right	0.66 (0.06)	1.02 (0.30)	1.94 (0.21)	0.82 (0.13)
Left	0.66 (0.06)	1.03 (0.29)	1.95 (0.21)	0.81 (0.12)
Elbow flexion or extension upward				
Right	0.45 (0.05)	0.79 (0.19)	1.81 (0.29)	0.51 (0.08)
Left	0.45 (0.05)	0.78 (0.18)	1.81 (0.33)	0.50 (0.07)

Dimensionality Reduction

PCA disclosed the salient variables that best characterized each movement performed by the participants. Examination of the spectra of the covariance matrices revealed that the spectral gap was located between the largest and second largest eigenvalues for all instances of movement. Therefore, only 1 principal component was required to capture variations in movements.

Unexpectedly, among the 30 variables we considered, only the orientations of the Touch controllers were pertinent for the analysis. We found that shoulder abduction to the right side of the body and to the left side of the body were both associated with changes in the Tait-Bryan angles about the *X*- and *Z*-axis of the Touch controllers in the head-mounted display frame: γ^H_R, α^H_R, γ^H_L, and α^H_L. Shoulder flexion while raising the hands was dominated by variations in all 6 Tait-Bryan angles γ^H_R, β^H_R, α^H_R, γ^H_L, β^H_L, and α^H_L. Only changes in α^H_L and γ^H_L strongly characterized elbow extension while lowering the Touch controllers. Finally, appreciable variations in α^H_R and α^H_L were most prominent during elbow extension while pushing the Touch controllers forward. Changes in γ^H_L, β^H_L, γ^H_R, and β^H_R were also detected in this motion. The PCA results are summarized in Table 3.

Table 3. Summary of the principal component analysis results. The variables γ, β, and α refer to the Tait-Bryan angles of the Touch controllers about the *X*-, *Y*-, and *Z*- axis, respectively.

Movement	Salient variables
Shoulder abduction to the right	γ^H_R, α^H_R, γ^H_L, α^H_L
Shoulder abduction to the left	γ^H_R, α^H_R, γ^H_L, α^H_L
Shoulder flexion or extension upward	γ^H_R, β^H_R, α^H_R, γ^H_L, β^H_L, α^H_L
Shoulder flexion or extension downward	γ^H_L, α^H_L
Elbow flexion or extension upward	γ^H_R, β^H_R, α^H_R, γ^H_L, β^H_L, α^H_L

Feature Selection

We created features based on the variables identified as salient using PCA. We considered the mean values and SDs of the Touch controllers' Tait-Bryan angles. We also included the Touch controllers' mean displacement relative to the head-mounted display to distinguish between static poses. We used correlation coefficients as additional features to capture the interactions between the variables. Specifically, we computed the correlation coefficients for the following three pairs: (γ^H_R, γ^H_L), (β^H_R, β^H_L), and (α^H_R, α^H_L). Overall, 21 features were selected (Table 4).

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Table 4. Summary of the features and variables used in the training of the classification algorithm.

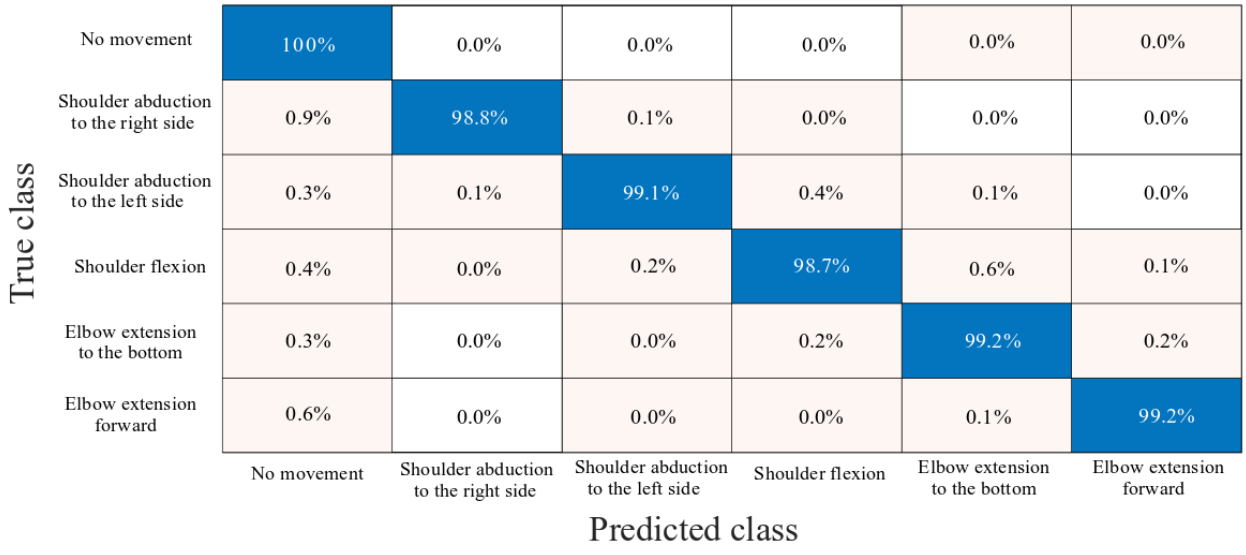
Features	Variables
Mean	• X^H_R, Y^H_R, Z^H_R • γ^H_R, β^H_R, α^H_R • X^H_L, Y^H_L, Z^H_L • γ^H_L, β^H_L, α^H_L
SD	• X^H_R, Y^H_R, Z^H_R • γ^H_R, β^H_R, α^H_R
Correlation coefficient	• (γ^H_R, γ^H_L), (β^H_R, β^H_L), (α^H_R, α^H_L) • X^G_L, Y^G_L, Z^G_L

Movement Classification

Our classification model achieved an accuracy of 99.9%, where most misclassifications resulted from falsely classifying instances of movement as nonmovements (Figure 7). The true positive rate was highest for elbow extension to the bottom and for elbow extension forward, with 99.2% of instances classified successfully in both. The algorithm performed the worst in the classification of shoulder flexion forward, where the true positive rate reached 98.7%.

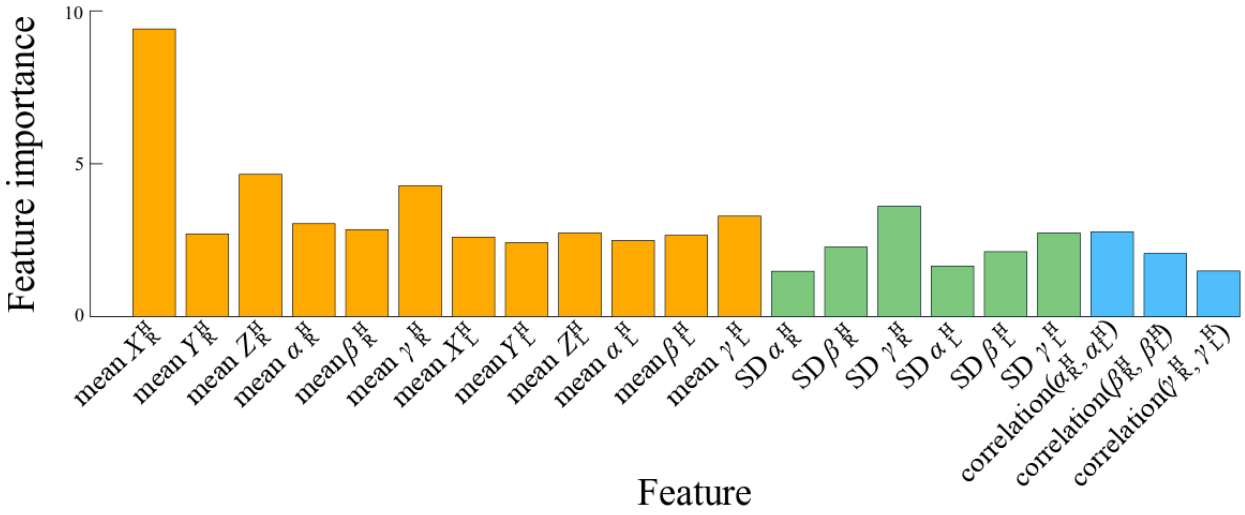
Out-of-bag analysis revealed that the mean value of X^H_R was the most important variable for the classification of movement, followed by the means of Z^H_R and β^H_R (Figure 8). The correlation between α^H_R, and α^H_L contributed the most to the classification among the correlation values. Among the SDs, γ^H_R contributed the most to the classification. Nonetheless, correlation coefficients and SDs seemed to modestly impact the classification. The mean value of γ^H_L was the least important, and α^H_R had the smallest contribution to classification among the SD values.

Figure 7. Confusion matrix summarizing the true positive rates of the classification algorithm. Blue entries denote instances of correct classification, whereas red entries denote instances of incorrect classification. The intensity of the color correlates with the true positive rate. Since the true positive (negative) rates for misclassification are very low, they appear in light pink.



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Figure 8. Feature importance based on out-of-bag error estimation, where importance is measured as the sum of decreases in error throughout all of the decision trees generated. Orange bars represent variable mean values, green bars represent their SDs, and blue bars represent the correlation of variable pairs.



Discussion

Principal Findings

As the world's population is aging, the incidence of stroke and other neuromuscular diseases is increasing, and the demand for affordable and convenient physical therapy is rising [80]. Sensor and communication technologies are readily available for delivery and monitoring of home-based therapy; however, human interaction is a critical design aspect in this context: telerehabilitation programs are carried out without clinical supervision, so that patients must motivate themselves to perform exercises with sufficient intensity and frequency.

Lack of motivation has led to the study and development of exergames [17,81], where physical activity facilitates games. Although the effectiveness of these interventions has been demonstrated [81,82], it may be further maximized by incorporating cognitively challenging elements, learning, and sociality [83] as older adults, who comprise most patients, show a propensity toward these features [83]. As such, citizen science presents itself as an intellectually stimulating motivational framework with greater appeal to patients. By framing physical exercise in citizen science, patients would be able to learn about ongoing research, bring about scientific discoveries, and support a cause they care about—all while adhering to their rehabilitation regimen.

A second, yet equally important aspect in the design of telerehabilitation systems is minimizing health care providers' time commitment such that they can diagnose and monitor multiple patients rapidly and simultaneously. However, this undertaking can become especially challenging when human behavior is abnormal [84]. Machine learning offers a viable means of automating the classification of human movements. Multiple examples exist where machine learning algorithms successfully detect and analyze different behaviors with high accuracy, as well as deviations from those behaviors, whether the application was for safe driving [85], gaming [86], or physical therapy [63-65]. Through machine learning algorithms, devices can learn from new data such that they can update their control strategies and dynamically adapt to the user's behavior over time. This feature is particularly useful for telerehabilitation applications, as patients recover motor function and move differently [84,87].

In this study, we present the use of machine learning to identify and classify bimanual movements in VR. We demonstrate the approach in the context of a citizen science software that is dedicated for telerehabilitation. Commercial gaming systems are advantageous for home-based rehabilitation because they are relatively small, affordable, and user-friendly [88]. VR gaming systems are particularly favored as they confer high levels of immersion and increase user engagement [16,40,41,89]. In telerehabilitation, recovery is often hindered by patients' lack of motivation to perform prescribed exercises [83]. Thus, the motivational aspects of home-based interventions are crucial to their success. To address this challenge, we also incorporated citizen science content into the application, such that the user could contribute to an authentic scientific project and help clean a polluted canal [32]. The task leverages human intellect as an intrinsic motivator and has a strong potential to improve patients' sense of self-worth [32,88,90].

In all, 9 participants interacted with the citizen science system through a set of 5 predefined bimanual gestures. Bimanual training effectively improves rehabilitation outcomes through several physiological mechanisms [52,53,59]. This clinical approach could also target a wider range of patients with varying levels of impairment. Specifically, for the Oculus Rift system, a rigid link can be designed and 3D-printed for the Touch controllers such they are affixed to one another [91]. The custom-made link could enable passive exercise of the affected limb in patients with moderate to severe impairment, whereby the intact limb mediates coordinated movement of the paretic side. In a future study, we will seek to measure movements of participants with and without such fixture and compare its effect on motor performance.

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One of the novelties of our approach lies in the application of a movement classification algorithm to a VR exercise for telerehabilitation. Although the movements we incorporated into game control are carried out along the 3 orthogonal anatomical planes and appear to be easily distinguishable, they require coordinated flexion or extension of the shoulder and elbow joints, as well as pronation of the forearms. For example, extending the right arm to the right side of the body involves simultaneous flexion of the shoulder, lateral rotation of the shoulder, extension of the elbow, and pronation of the forearm. Owing to these degrees of freedom, backward kinematics to determine the angles of these joints would require more information beyond the position of the Touch controllers relative to the head-mounted display. To further support this notion, our PCA results showed that the Tait-Bryan angles of the Touch controllers relative to the head-mounted display, and not their positions, are salient during movements. Most variations in these angles likely resulted from simultaneous movement of the shoulder and elbow joints and pronation of the forearm.

The variation of features based on relative angles is expected to become extremely important for the classification of movements when our approach is implemented on data from patients with stroke. Stroke can lead to a wide range of movement abnormalities, including spasticity, segmentation, and compensation. However, the latter is best known for sabotage rehabilitation efforts. In the face of reduced mobility, patients with stroke tend to recruit body parts that are not normally involved in certain movements to add degrees of freedom to their kinematics. For example, patients with stroke commonly use their trunk during reach movements to compensate for the limited range of motion of their upper limbs [92,93]. By reinforcing these strategies, patients perpetuate the nonuse of the affected limb and do not recover their function. Fortunately, compensatory movements would be easily detected through our algorithm, whereby the angles of the Touch controllers relative to the headset will not vary significantly.

The algorithm was used to classify the movements the participant performed toward a genuine telerehabilitation paradigm, where one's motor performance is monitored remotely by a clinician. The algorithm classified bimanual movements objectively and reliably, reaching 99.9% accuracy. The 0.1% inaccuracy was mainly related to lack of sensitivity with respect to the presence of a movement. In other words, the algorithm erroneously classified movements as instances of no movement. This misclassification likely resulted from the use of a moving-window scheme. The moving window covers 13 time steps. During the algorithm training, the instantaneous true class of a window was defined as the mode of the true classes of the time steps it covered. For example, if the window covered 2 time steps of shoulder flexion and 11 time steps of no movement, its true class was *no movement*. At the beginning and end of each movement segment, the window covered 7 time steps of one class and 6 time steps of another class. The true class was then arbitrarily defined as 1 of the 2 classes. The accuracy of our approach may be further improved by refining this scheme and eliminating false negatives or by applying an alternative method to assign the true class of a moving window.

Future research could explore the use of alternative dimensionality reduction techniques. Our selection of features was based on the results of PCA, which informed us about which variables characterized each movement. However, this method may be inappropriate. In symmetrical movements performed by the participant, PCA showed that variables in only 1 arm were prominent. For example, when a participant performed shoulder abduction to the right side of the body, 2 angles of the left Touch controller and only 1 angle of the right Touch controller were dubiously deemed salient. Potentially, nonlinear dimensionality reduction methods such as Isomap, diffusion maps, and principal manifolds could better identify sets of variables that distinguish one movement from another [94-96].

The methodology presented herein can be extended to several research directions. First, multiple classification schemes can be applied in tandem to distinguish between static and dynamic poses. This will be especially useful for measuring metrics that are important for clinical evaluation, such as movement accuracy [97], smoothness [73,98], and coordination [99].

We measured some motor performance metrics using data collected by the VR system. We observed symmetry in motor performance when comparing the right and left arms. In patients with paresis, we expected significant differences in motor performance between each side of the body. Specifically, movements of the affected arm would present stiffness and be segmented early in recovery, measured through lower mean speed, reduced range of motion, and longer path lengths, which will change over time as muscle function is recovered in the affected arm. We also found considerable variation among healthy participants with respect to smoothness. It is tenable that this metric reflects the individualistic nature of user interaction with the VR interface, whether it involves abrupt initiation of movements or the sequential use of different sets of upper limb joints. As such, smoothness should be examined over the course of a movement rather than as a single score. To further support this notion, Rohrer et al [73] showed that the smoothness of pathological movements is characterized by a series of peaks and dips, which become shorter and shallower along recovery.

In addition to the quality of movements, one might consider the use of cognitive cues in the analysis to treat low motivation. Posture and movement have been previously demonstrated to be closely related to engagement [100,101]. For example, restlessness may be reflected by the frequently moving body weight between the legs. Similarly, arousal can be expressed by head rotation and extensive hand movements [102]. The combined use of biometrics, such as heart rate, skin conductance, and pupil dilation, may also provide important insights into human behavior [103-105]. Incorporating such psychophysiological sensory information could open the door for multifaceted interventions in telerehabilitation [106], although this path will require the use of additional sensors and requires further research.

Finally, the classification algorithm can be enhanced to detect and minimize compensatory movements. Compensatory movements are nonphysiological movements that patients with disabilities perform with their bodies to compensate for their

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limited range of motion. Essentially, the patients use muscles that are not normally involved in the movement, thereby adding degrees of freedom to it. Most commonly, patients tend to displace their torso during reaching tasks to compensate for their inability to move their upper limbs [92,107,108]. Although such nonphysiological movements improve patients' function instantly, they are energetically inefficient, hinder functional recovery, and pose a risk of injury [109,110].

Recently, Cai et al [111,112] explored the effectiveness of machine learning in detecting compensatory movements in patients with stroke. In their experimental setting, users sat on a chair covered with a pressure distribution mattress and interacted with a tabletop robotic manipulator [112]. Data were collected on their motion from the mattress and from a VICON 3D motion capture system [112]. Users' postures and compensation were classified by an SVM algorithm, which achieved an accuracy >96%. Although the sensors used in this study are different in nature from those of commercial VR gaming systems, the results are encouraging and suggest that our approach is feasible. Work to assess our approach is currently under way, and head-mounted display-based features are expected to aid in the detection of compensatory movements.

Limitations

Our findings strongly support the viability of machine learning in the accurate assessment of movements in telerehabilitation with commercial VR systems. Nonetheless, the several limitations of this study must be acknowledged. First, this study was conducted on healthy participants only. Patients with stroke exhibit a wide range of movement disorders, including loss of mobility, loss of balance control, spasticity, chorea, and adoption of maladaptive movements [113-116]. It is unknown whether these disorders can be detected and correctly characterized from sensor data, let alone be tracked and monitored over time. We are currently collecting controlled clinical data from patients with stroke and intend to challenge these questions once the study is concluded.

The second limitation concerns the focus of our system on bimanual training with the Oculus Rift. Although this setting is practical, affordable, and has the potential to improve engagement in telerehabilitation, it is still subject to the limitations of machine-mediated patient–physician interactions. During in-clinic meetings, a physician can assess the physiological, behavioral, and emotional status of a patient simultaneously. For example, physicians may evaluate skin tactile feedback during grip [117] or the patient's ability to balance while performing gross motor movements [118]. This cannot be accomplished in a telerehabilitation setting without teleconferencing with a physician or encumbering the patient with multiple wearable sensors, which would likely require special training and the aid of another person. Nonetheless, many of these in-clinic assessments may be feasible in telerehabilitation by means of machine learning. Emotion recognition from physiological [119,120] and behavioral [121,122] signals has already been demonstrated. Similarly, research has been carried out to predict patients' ability to balance [123] and infer pain levels from kinematic features [124] and detect compensatory movements [125]. Thus, machine learning methodologies may successfully quantify other aspects of rehabilitation from data originating from a single modality, thereby providing health care providers with more information to monitor patients remotely.

Another nontrivial limitation of our study is the essence of machine learning as a black box [60,126-129]. In recent years, it has become widely accepted to trust machine learning predictions without fully understanding the model from which they are derived. The transparency of machine learning models is paramount to users' trust in machines [60]. In medical applications, rather than perceiving decisions as arbitrarily made, an understanding of their rigor and potential sources of errors must be gained for good clinical decision-making. Furthermore, machine learning algorithms are vulnerable to adversarial attacks [127-129]. Minimal perturbations can significantly impact the output of algorithms and remain unnoticeable to human inspectors [127]. Thus, in future work, we will probe the model and apply perturbing strategies to interpret it [60].

Conclusions

This study is a first step in our endeavor to incorporate machine learning into VR-mediated telerehabilitation. We classified bimanual movements using a bagged trees classifier and achieved high performance. Work to expand on our findings and hone our approach is underway, including experiments with patients with stroke, development of an interpretable model, and detection of compensatory movements.

Acknowledgments

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Authors' Contributions

RBV, ON, PR, and MP designed the study. ON, PR, and MP secured the funding. RBV, KH, and MP designed the experimental system. RBV and KH developed the experimental system and conducted the experiments. RBV, MRM, and MP developed an approach to perform motion analysis. RBV analyzed the data. RBV and KH wrote the first draft of the manuscript. MP supervised the study. All authors reviewed and approved the final submission of the manuscript.

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Conflicts of Interest

None declared.

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Abbreviations

HUD: heads-up display
PCA: principal component analysis
SVM: support vector machine
VR: virtual reality

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Original Paper

Determining the Optimal Virtual Reality Exergame Approach for Balance Therapy in Persons With Neurological Disorders Using a Rasch Analysis: Longitudinal Observational Study

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Abstract

Background: Virtual reality (VR) exergames have gained popularity in the rehabilitation of persons with neurological disorders as an add-on therapy to increase intensity of training. Intensity is strongly dependent on the motivation of the patient. Motivation can be increased by delivering variation within training and challenging exercises. However, patients are often underchallenged, as exergame difficulty often does not match the patient's ability. A Rasch analysis can establish hierarchy of exergame items in order to assist the delivery of patient-centered therapy.

Objective: The aim of this study was to apply the Rasch model to create a hierarchical order of existing VR balance exergames and to relate these exergames to the abilities of persons with neurological disorders, in order to deliver challenge and variation.

Methods: A total of 30 persons with stroke and 51 persons with multiple sclerosis (MS) were included in the study. All participants performed a training program, lasting 3 weeks for persons with MS and 4 weeks for persons with stroke, in which they performed VR balance exergames with a movement recognition–based system (MindMotion GO; MindMaze SA). VR exercise scores, Berg Balance Scale scores, and clinical descriptive data were collected. Berg Balance Scale and device scores were analyzed with the Rasch model using a repeated-measures approach to examine whether the distribution of exercise scores fitted the Rasch model. Secondly, a person-item map was created to show the hierarchy of exercise difficulty and person ability.

Results: Participants completed a selection of 56 balance exercises (ie, items), which consisted of a combination of various balance tasks and levels (ie, exercises). Using repeated measures, this resulted in a count of 785 observations. Analysis showed strong evidence for unidimensionality of the data. A total of 47 exercises (ie, items) had a sufficiently good fit to the Rasch model. Six items showed underfit, with outfit mean square values above 1.5. One item showed underfit but was kept in the analysis. Three items had negative point-biserial correlations. The final model consisted of 47 exercises, which were provided for persons with low to moderate balance ability.

Conclusions: The VR exercises sufficiently fitted the Rasch model and resulted in a hierarchical order of VR balance exercises for persons with stroke and MS with low to moderate balance ability. In combination with the Berg Balance Scale, the results can guide clinical decision-making in the selection of patient-focused VR balance exercises.

Trial Registration: ClinicalTrials.gov NCT03993275; https://clinicaltrials.gov/ct2/show/NCT03993275

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KEYWORDS

digital therapeutics; virtual reality; exergaming; balance; stroke; multiple sclerosis; neurorehabilitation; Rasch analysis

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Introduction

Balance impairments are common in persons with neurological disorders and lead to decreased mobility, increased risk of falling, and accompanied injuries [1,2]. Consequently, balance abilities further degenerate, general mobility reduces, and dependence in activities of daily living increases [3]. This has a significant negative impact on patients' quality of life; therefore, improvement of balance is key during neurorehabilitation [4,5].

A high treatment dose is important for effective balance rehabilitation; this consists of a high amount of repetitions and challenging exercises [6]. Virtual reality (VR) exergames have gained popularity for delivering VR therapy with a high treatment dose during neurological rehabilitation [7,8]. VR exergames are games that require physical movements to perform exercises in a virtual environment with a therapeutic purpose (eg, to improve strength, balance, or flexibility) [9]. VR is effective for increasing the training dose and delivers good results when used in addition to, or as a partial substitute of, conventional therapy [10]. VR training has been suggested to be effective for improving balance outcomes and gait abilities in persons with neurological disorders, such as multiple sclerosis (MS) or stroke [11-13].

Motivation is an important factor in VR exergames because it influences the duration of play, leading to a higher number of repetitions performed and, thus, increased treatment dose. In previous work by our research group, it was shown that after an initial increase of motivation, over time, motivation in older adults who played exergames decreased in comparison to self-regulated exercises guided by paper forms [14]. An explanation for these results could be found in earlier studies regarding game development [15,16]. Motivation strongly depends on factors like personal calibration of gaming parameters to the player's motor skills and goals, such as adaption of the range of motion, playing position, or speed of movement. In addition, variation within and between games is important for motivation because insufficient variation reduces focus and physical activity levels [17]. The variation of difficulty is used to keep the player engaged over a prolonged time, but also to progress the task training throughout the rehabilitation process. Progression of task training is important to best stimulate motor learning. This is supported by the challenge point framework, which shows that the difficulty of a task should be adapted to the skill level of the player in order for them to be optimally challenged and to promote learning [18]. Specific parameters that create challenge in balance VR exergames can be speed of play or range of movement during weight shifting [19,20]. From these results, we can presume that in order to keep the patient motivated, it is crucial to challenge the patient by delivering a variation of exercises, whereby the difficulty of the exercise matches the abilities of the patient.

Within robotic upper-extremity therapy, adaption of the difficulty of VR exergames to challenge the player has already been investigated [21]. However, the adaption of the difficulty of VR exergames has been performed based on the performance of the player in specific chosen parameters. This is possible within systems that have similar parameters to adapt difficulty, such as the robotic-guided reaching task from Zimmerli et al [22], who optimized the difficulty of the task by controlling the time that is available for a patient to reach to a given target. However, for therapy programs containing balance exercises this is impossible, as balance exercises are built up out of many different parameters that vary strongly between exercises [23]. Hence, the difficulty adaption of balance exercises needs to be based not on the performance but on the ability of the patient.

A statistical framework that is used in scale development and hereby investigates the difficulty of items and the abilities of persons has already been found in rehabilitation research. La Porta et al [24] investigated the 14 items of the Berg Balance Scale using the Rasch model. The Rasch model was used to investigate the construct of the scale and to order the items of the balance scale from easy and successfully executable by all participants (ie, sitting on a chair) to difficult items that were not executable by all participants (ie, standing on one leg). The model looks at the ability of the person on one hand and at the difficulty of the item on the other hand, and combines both along the continuum of a latent trait [25]. The latent trait is the attribute that all items on the scale have in common and aim to assess. In this study, the abilities of the persons under investigation were those of persons with stroke and MS. The items under investigation were the VR exergames from the MindMotion GO system (MindMaze SA) that are aimed at improving sitting and standing balance. The Rasch model has been widely used to construct and revise measurement instruments and test their psychometric properties [24,26]. The applicability of the Rasch model to data with technology-guided rehabilitation exercises has not been investigated so far and is, thus, an innovative approach to use the model.

To determine if the Rasch model is applicable for delivering a continuum of participant ability and exergame difficulty based on the exergames scores, we evaluated the unidimensionality (ie, if all exergames evaluate the same latent variable) and fit (ie, item fit) of the exergames to the Rasch model. When a continuum of the VR exercises were created, we would investigate whether the exergames deliver enough variation and challenge to the specific participants by establishing the difficulty of each exergame, and we would evaluate whether these difficulty estimates cover the whole spectrum of our participants' balance abilities.

Methods

Recruitment

We aimed to include 30 persons with stroke and 50 persons with MS from the Valens Rehabilitation Clinic in Valens, Switzerland. Patients referred for in-patient rehabilitation were included if they met following criteria: (1) persons with a recent stroke or suffering from MS with an Expanded Disability Status Scale score between 3 and 6.5, meaning patients with moderate to severe disability who need assistance during walking, as confirmed by a neurologist; (2) above 18 years of age; (3) referred for a minimum of 3 weeks of in-patient rehabilitation; (4) reduced balance, based on a Berg Balance Scale score of less than 52 out of 56 points; and (5) signed informed consent.

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Persons were excluded from the study if they had comorbidities that could interfere with exergame performance, walking ability, and balance (eg, visual or cognitive impairments, psychiatric disorders, and musculoskeletal problems). To include participants with a range of balance deficits that would represent the neurological population, we aimed to include 50% of participants with a Berg Balance Scale score below 45 points (out of 56) and 50% with a Berg Balance Scale score equal to or above 45 points. This study was prospectively registered at ClinicalTrials.gov (NCT03993275).

Ethics Approval

Ethical approval for this study was obtained from the Ethics Committee of the Sudostschweiz (BASEC [Business Administration System for Ethics Committees] No. 2018-01248), according to the Declaration of Helsinki [27].

Device and Balance Exergames

VR exergames were performed with the MindMotion GO (MindMaze SA). The MindMotion GO is a medical device software system that supports the physical and cognitive rehabilitation of adults and children in rehabilitation centers and of adults at home (Figure 1). The MindMotion GO software is meant to be installed on computers that run the Windows 10 operating system and is used in combination with the Kinect motion sensing device (version 2; Microsoft). The device consists of a screen to visualize the VR exergame and a Kinect camera that traces 25 joints with a rate of 30 frames per second to capture body movements. The camera, together with appropriate motion tracking algorithms, can reliably measure lower-extremity movement in healthy controls and is valid for assessing spatiotemporal gait parameters and kinematic strategies of postural control [28-30]. The software translates human body movements into displayed avatar movements to execute the VR exergame. The software includes a library with rehabilitation exercises for the upper extremities, trunk, and lower extremities. To specifically train trunk control and balance in a seated or standing position, there are nine different VR exergames available. Exergames vary in difficulty, depending on the type of task, playing position, static or dynamic base of support, velocity, and the use of dual tasks and go-no-go responses. Figure 2 details the goals and various difficulty parameters of the different exergames.

In total, nine different games are available, of which three games can be played in both sitting and standing positions (Figure 2, grey) and six games can be played only in the standing position (Figure 2, orange and green). The difficulty increases over 10 levels. To collect sufficient data on all difficulty levels, only levels 2, 4, 6, 8, and 10 were used in the study. This resulted in 60 combinations of VR exergames and levels, henceforth called exercises.

Figure 1. A patient performing exercises with the device under investigation. Exercises in the standing position were performed without aid or physical support, and a chair was placed at arm's length of the participant for security.



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Figure 2. Details of the various exergames. Games are divided into static sitting and standing balance exercises, weight shifting in standing exercises, and dynamic standing balance exercises. Games are described using the following parameters, where a green checkmark indicates the game contains it, while a red X indicates it does not: high precision—high precision of movement is needed in order to steer the avatar well; speed predefined—the speed is constant within the game and cannot be influenced by the player; speed increase over levels—the predefined speed increases with higher level; obstacles in levels 2 & 4 or levels 6, 8, & 10—whether obstacles occur in these levels or not; moving obstacles—obstacles move from left to right or up to down, interfering with the players trajectory; high cognitive demand—the game contains elements such as go-no-go reactions or choices between collectables with different point counts. FBW: forward-backward step.



Design and Data Collection

We implemented a longitudinal observational design with repeated measures of exercise scores and balance ability scores over a duration of 3 weeks among persons with MS and 4 weeks among persons with stroke. After inclusion, descriptive data of trunk control, mobility, gait ability, fatigue, and cognition were collected, and baseline assessments of balance were performed. Once per week during each participant's general physical therapy session, balance was assessed with the 14-item Berg Balance Scale by an experienced physical therapist. Each item is rated on a scale from 0 to 4, resulting in a maximum score of 56 points. Rasch analyses support the validity of the Berg Balance Scale, and test-retest, interrater reliability, and intrarater reliability are considered adequate to good [24,31].

Participants performed the exercises in a sitting position if their Berg Balance Scale score was lower than 45 points and in the standing and sitting positions if their Berg Balance Scale score was equal to or above 45 points. Exercises were explained and participants completed a practice trial at the middle level of difficulty for 30 seconds. This result was not used for analysis. Participants played at a lower level if the score of the practice trial was below 50% and at a higher level when 50% or higher. Participants completed each exercise for 2 minutes. Exercise scores were used for analysis. Participants rated exercise difficulty on a 6-point Likert scale, ranging from 0 ("very easy") to 5 ("unable to perform"). Participants' ratings of exercise difficulty were used to adapt exercise choice. During each therapy session, participants completed six different exercises. A variation of exercises was completed throughout the therapy sessions to make sure that each participant completed as many different exercises as possible, while considering the safety of the participant. Training was guided by an assistant under the supervision of an experienced physical therapist who specialized in robotics therapy.

Statistical Analysis

Sample Size

A minimum sample size of 150 observations was needed to achieve stable item calibration within ±½ logits and 99% confidence [32]. To reach this number of observations but still be able to perform a feasible study design with equality between groups, persons with MS were included in the study for 3 weeks, whereas persons with stroke were included for 4 weeks. Multiple observations were accounted for according to the following rules: (1) at the start of the week, the first session was accounted for as observation 1; (2) as soon as a participant completed an exercise twice within the same week, this was a new observation; and (3) the exergame scores were analyzed with the scores on the Berg Balance Scale of that week. Thus, this resulted in multiple repeated observations of the same participant, creating data that were partially independent. However, Rasch analysis can confidently be performed with this type of data [33].

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Analysis

Descriptive statistics were used to describe the study participants. The main analysis was performed using the Rasch analysis. The Rasch model is a mathematical model that delivers the expected response probability that shows how likely it is that a person with a certain ability (ie, number of correct test items) can perform an item of a certain difficulty (ie, number of persons who succeeded on the item) in a correct manner. The item level represents the difficulty of an item, whereby the difficulty of items range from very easy to very difficult. The person level represents the ability of the person that undertakes the item. Both are expressed in the natural log of an odds ratio (ie, logits) [34]. The higher the logit value, the more difficult the item and the higher the ability of the person [35]. The probability of success depends on the difference between the difficulty of the item and the ability of the person [25]. The advantage is that the scale under investigation becomes an interval scale and, thus, an improvement of one logit has the same value among the continuum of the scale independent of the difficulty of the item. Therefore, the use of the Rasch model enables the choice of the right exercise for the person's ability so that they are able to pass it without it being too easy, thus creating enough challenge for the patient without developing frustration.

We used Winsteps (version 4.5.5) to evaluate the fit of the data to the Rasch model [36]. The partial credit model was used because the structure of game scores is not comparable across the different exercises [37]. To use the Rasch model in a correct manner, unidimensionality and item fit were investigated, which show if the various exergames all train the same latent trait. The main concepts of the Rasch model are explained in the following paragraphs.

Unidimensionality

Unidimensionality is given when all items (ie, exercises) under investigation measure only one single latent variable [25]. Unidimensionality was investigated with the principal component analysis of the residuals [38]. An eigenvalue of greater than 2 was indicative for a potential secondary dimension [39]. Hereby, we consider the amount of raw unexplained variance within the contrast for our large number of items. A contrast plot was used to evaluate unidimensionality while looking closer at deviating items or patterns. The disattenuated correlation coefficients were assessed to see if the data between possible different dimensions are related and measure the same latent trait. Values below 0.3 were considered problematic, and values above 0.7 that are close to 1 would indicate that items from different clusters measure the same trait [40].

Point-Biserial Correlation

In Rasch analysis, the item correlations are an immediate check that the response level makes sense, meaning that with increasing ability, item (ie, exercise) scores also increase. If the observed correlation is negative, the response collection was wrong. This can be due to several reasons (eg, a reversed survey item was overlooked). These items were removed from the final model.

Item Fit

Fit statistics quantify the difference between the theoretical expectation based on the Rasch model and the actual item performance of the raw data, thus indicating how good the data fitted the Rasch model. Larger residuals denote an item that does not fit the model. Item fit was investigated with the fit statistics, whereby outfit mean square values between 0.5 and 1.5 are productive for measurement [41]. Values above 1.5 were classified as showing underfit; this means that there was more noise in the performance of the item and, therefore, this item cannot be used to make adequate predictions [25]. Items that showed misfit, without a clinical reasonable explanation, were removed from the analysis.

Values below 0.5 were classified as showing overfit; this means that multiple items were strongly interdependent and, thus, redundant for measurement. This derives, for instance, from items that are strongly interrelated by nature (eg, the development in rehabilitation of standing, stepping, and walking); therefore, responses are too predictable from other exercises. In the case of scale development, removing redundant items increases efficiency without reducing precision. However, as we were not developing a measurement instrument, but a construct of exercises, redundant items could be left in the model, as they increase variation in the exercise program for participants.

Ordering of the Item Thresholds

Thresholds represent the point where the chance of having a score of 0 or 1, or 1 or 2, are equal. The item threshold shows if the order of scores for a certain exercise is logical in a way that a participant with the ability to succeed at the task at hand can succeed when the items undertaken get more difficult. As persons advance and their skills get better, it is important that the categories of scores represent advancing levels of the construct under investigation.

Distribution of Responses: Person-Item Map

The hierarchy of the exercise difficulty and participant's abilities is shown in a person-item map. In this map, the easiest items are on the lower right side of the map, and the participant with the lowest ability is displayed at the lower left side of the map. The map allows visual inspection of whether the range of exercises targets the range of participants' abilities.

Differential Item Functioning

Differential item functioning (DIF) displays the difference in difficulty of the items for persons with stroke and persons with MS. This is assessed through comparison of both groups, whereby persons with stroke and persons with MS should show the same ability on an item, that is, the same logit value (ie, same DIF measure).

Results

Overview

Descriptions of the persons with stroke and persons with MS can be found in Table 1. A total of 32 persons with stroke and 52 persons with MS were recruited. A total of 30 persons with

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stroke and 51 persons with MS completed the data collection step and were included in the analysis; 2 persons with stroke and 1 person with MS dropped out after baseline measurements. Severity of balance disorder as measured by the Berg Balance Scale was comparable between pathology groups (P=.35). A total of 785 observations were recorded to reach stable item calibration. Adherence to the training program was very good (99%). No serious adverse events occurred during training with the device. Two falls from the chair without injuries or other consequences were recorded during training; this is comparable to conventional balance training at the limits of balance. Four out of 60 exercises were not included in the analysis because they were performed only two or four times and, thus, not enough data were available (Tables 2 and 3). In total, 56 exercises were included in the analysis, together with the 14 Berg Balance Scale items. The analysis consisted of two rounds to develop the final model (Table 2). The final model included 47 exercises (Table 4).

Table 1. Descriptions and clinical measures of the participants.

Characteristic	Participants with stroke (N=30)	Participants with multiple sclerosis (N=51)
Age (years), median (IQR)	64.50 (55.50-76.75)	55.00 (46.00-60.00)
Gender, n (%)		
Male	22 (73)	13 (25)
Female	8 (27)	38 (75)
Type of stroke, n (%)		
Ischemic	27 (90)	N/A[a]
Hemorrhagic	3 (10)	N/A
Type of multiple sclerosis, n (%)		
Primary-progressive multiple sclerosis	N/A	13 (25)
Secondary-progressive multiple sclerosis	N/A	19 (37)
Relapse-remitting multiple sclerosis	N/A	19 (37)
Hemiparetic or weaker body side, n (%)		
Left	12 (40)	26 (51)
Right	16 (53)	24 (47)
Bilateral	2 (7)	1 (2)
Time poststroke (days), median (IQR)	14.00 (11.25-20.75)	N/A
Time since multiple sclerosis diagnosis (years), median (IQR)	N/A	16.0 (10.00-20.50)
Functional Ambulation Category, n (%)[b]		
0-2	13 (43)	0 (0)
3-5	17 (57)	51 (100)
Berg Balance Scale score, median (IQR)[c]	41.00 (26.00-47.00)	44.00 (33.50-47.00)
Trunk Impairment Scale score, median (IQR)[d]	16.00 (13.00-18.75)	17.00 (14.50-18.00)
Dynamic Gait Index score, median (IQR)[e]	11.00 (0.00-17.00)	13.00 (8.00-17.00)
Timed Up and Go test time (seconds), median (IQR)[f]	21.00 (12.00-33.00)	16.00 (11.00-28.00)
Montreal Cognitive Assessment score, median (IQR)[g]	23.00 (20.00-24.75)	25.00 (23.00-27.00)

[a]N/A: not applicable; this measure does not apply to this group of participants.

[b]Functional ambulation scores range from 0 (a patient cannot walk or needs help from two or more persons) to 5 (a person can walk anywhere independently).

[c]The Berg Balance Scale has a maximum score of 56 points, with more points meaning better balance.

[d]Trunk Impairment Scale scores range from 0 to 23, with higher scores meaning better trunk function.

[e]Each item of the Dynamic Gait Index is scored on a scale of 0 (severe impairment) to 3 (normal performance); the maximum total score is 24.

[f]The Timed up and Go Test measures the time to stand up from a chair, walk 3 meters, turn, walk back, and sit down again; the lower the duration of this assessment, the better.

[g]The Montreal Cognitive Assessment has a maximum score of 30 points.

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Table 2. Overview of the performed steps in the Rasch analysis.

Analysis number	Description of the analysis	Observations, n	Items, n	Decisions
1	Initial analysis	785	70	• Exclude 3 items based on negative point-biserial correlations • Exclude 6 items based on item misfit
2	Final analysis	785	61	• Although misfit, leave Car Racer level 10 in the sitting position item in the analysis

Table 3. Reasons for deleting items from Rasch analysis and deleted items.

Reason for deletion	Deleted items (levels)
The exercise was performed only two to eight times; thus, not enough data were available.	• Cross the Road: free steps (2) • Veggie Guard (2) • Veggie Guard (10) • Line Roller: sidesteps unilateral (10)
The exercise resulted in negative point-biserial correlations.	• Cross the Road: free steps (4) • Veggie Guard (4) • Line Roller: sidesteps bilateral (10)
The exercise was excluded because of underfit.	• Airplane (4) • Airplane (8) • Car Racer (2)[a] • Cross the Road: forward-backward step (10) • Veggie Guard (6) • Mine Cart (2)[a]

[a]These exercises were performed in a seated position.

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Table 4. Items included in the final model in order of decreasing difficulty.

Item (level)[a]	Item parameter		Fit statistics		
	Measure (logits)	Model SE	Infit mean square	Outfit mean square	Point-biserial correlation
Line Roller: sidesteps bilateral (10)	4.62	0.53	0.42	0.53	0.72
Line Roller: sidesteps unilateral (8)	4.55	0.50	0.50	0.53	0.34
Car Racer (8)	4.10	0.15	0.61	0.71	0.77
Car Racer (10)	3.98	0.23	0.49	0.56	0.78
Car Racer (10)[b]	3.86	0.13	0.56	1.56	0.74
Line Roller: sidesteps bilateral (6)	3.10	0.31	0.45	0.50	0.85
Car Racer (8)[b]	2.81	0.09	0.63	0.87	0.74
Line Roller: sidesteps unilateral (6)	2.74	0.29	0.32	0.33	0.92
Line Roller: sidesteps unilateral (4)	2.72	0.23	0.70	0.70	0.68
Line Roller: sidesteps bilateral (4)	2.64	0.25	0.78	0.86	0.65
Berg Balance Scale item 14	2.49	0.09	1.28	1.31	0.72
Line Roller: sidesteps unilateral (2)	2.29	0.25	0.90	0.98	0.58
Berg Balance Scale item 12	1.93	0.08	1.37	1.17	0.78
Line Roller: sidesteps bilateral (2)	1.93	0.31	0.56	0.58	0.49
Cross the Road: free steps (10)	1.54	0.48	0.44	0.46	0.94
Veggie Guard (8)	1.53	0.36	0.48	0.50	0.69
Berg Balance Scale item 13	1.47	0.08	1.04	1.03	0.78
Berg Balance Scale item 11	1.32	0.08	0.90	0.87	0.83
Car Racer (4)	1.10	0.17	0.79	0.79	0.66
Car Racer (6)	0.78	0.14	1.00	1.05	0.63
Cross the Road: free steps (6)	0.69	0.54	0.97	0.90	0.72
Skiliner (5)	0.62	0.17	0.83	1.07	0.66
Mine Cart (8)	0.50	0.23	1.08	0.99	0.62
Cross the Road: free steps (8)	0.38	0.63	0.33	0.24	0.88
Skiliner (4)	0.37	0.14	0.81	0.96	0.60
Mine Cart (10)	0.20	0.38	0.79	1.21	0.44
Skiliner (3)	0.19	0.19	0.91	0.80	0.66
Berg Balance Scale item 7	0.07	0.09	1.18	0.97	0.80
Car Racer (4)[b]	0.02	0.11	1.11	1.34	0.65
Car Racer (6)[b]	–0.14	0.09	0.98	0.95	0.73
Cross the Road: forward-backward step (6)	–0.19	0.28	1.53	1.20	0.68
Berg Balance Scale item 8	–0.22	0.10	1.07	1.43	0.74
Skiliner (2)	–0.33	0.25	0.76	0.70	0.72
Mine Cart (10)[b]	–0.34	0.13	1.17	1.20	0.56
Cross the Road: forward-backward step (4)	–0.35	0.35	0.85	0.83	0.66
Berg Balance Scale item 10	–0.59	0.10	0.89	0.83	0.77
Berg Balance Scale item 9	–0.73	0.11	1.12	0.74	0.77
Airplane (2)	–0.94	0.56	1.83	1.34	0.59
Cross the Road: forward-backward step (8)	–0.95	0.39	1.16	0.76	0.47

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Item (level)[a]	Item parameter		Fit statistics		
	Measure (logits)	Model SE	Infit mean square	Outfit mean square	Point-biserial correlation
Mine Cart (2)	–1.17	0.54	0.71	0.51	0.71
Mine Cart (6)	–1.27	0.27	0.76	0.75	0.51
Berg Balance Scale item 6	–1.43	0.12	0.87	0.78	0.73
Mine Cart (8)[b]	–1.45	0.15	1.33	1.17	0.58
Berg Balance Scale item 5	–1.92	0.13	1.19	0.75	0.70
Cross the Road: forward-backward step (2)	–1.94	0.65	1.18	1.08	0.42
Car Racer (2)	–1.98	0.54	0.97	0.75	0.61
Skiliner (1)	–2.06	1.06	1.08	0.99	0.14
Airplane (10)	–2.07	0.37	1.12	1.36	0.28
Mine Cart (4)	–2.17	0.41	0.68	0.27	0.70
Berg Balance Scale item 1	–2.19	0.14	0.86	0.77	0.70
Berg Balance Scale item 4	–2.29	0.14	1.05	0.68	0.66
Mine Cart (4)[b]	–2.45	0.17	1.27	1.43	0.54
Airplane (10)[b]	–2.61	0.18	1.37	1.25	0.34
Berg Balance Scale item 2	–2.68	0.16	1.03	0.33	0.64
Airplane (4)[b]	–2.70	0.24	1.47	1.13	0.59
Mine Cart (6)[b]	–2.80	0.18	1.28	1.24	0.47
Airplane (8)[b]	–3.33	0.22	1.47	1.18	0.35
Airplane (6)	–3.38	0.62	0.80	0.51	0.39
Airplane (2)[b]	–3.87	0.45	1.09	0.49	0.63
Airplane (6)[b]	–4.03	0.25	1.31	0.80	0.46
Berg Balance Scale item 3	–8.97	1.83	mm[c]	mm	0.00

[a]Exergames are described in Figure 2.

[b]These exercises were performed in a seated position.

[c]mm: minimum measure.

Unidimensionality

As part of the partial credit model, the principal component analysis of the residuals showed that the first residual contrast had an eigenvalue of 2.36, indicating a possible secondary dimension with the strength of 2.3 items. This was close to the predefined threshold for unidimensionality of 2 eigenvalues. Given the large number of analyzed exercises (n=61), a possible secondary dimension with the size of 2.3 items is very small. In addition, the total unexplained variance in the first contrast was only 3.9% (of the total raw unexplained variance in the analysis). Visual exploration of the contrast plot of standardized residuals revealed that the device exercises had similar factor loadings and were grouped together. The Berg Balance Scale items were within the same dimension; however, eight of them covered a different facet of balance. All disattenuated correlations were close to 1, indicating that all items within the dimension measured the same trait. Therefore, it can be concluded that unidimensionality was adequate.

Point-Biserial Correlation

In the first round of the analysis, three point-biserial correlations were negative, indicating that item scores were negatively correlated with balance ability. Consideration of the items from a clinical point of view resulted in the exclusion of these items in the final model (Table 3; Cross the Road: free steps, level 4; Veggie Guard, level 4; Line Roller: sidesteps bilateral, level 8). In the final model, there were no negative point-biserial correlations, indicating that all items worked in the intended way.

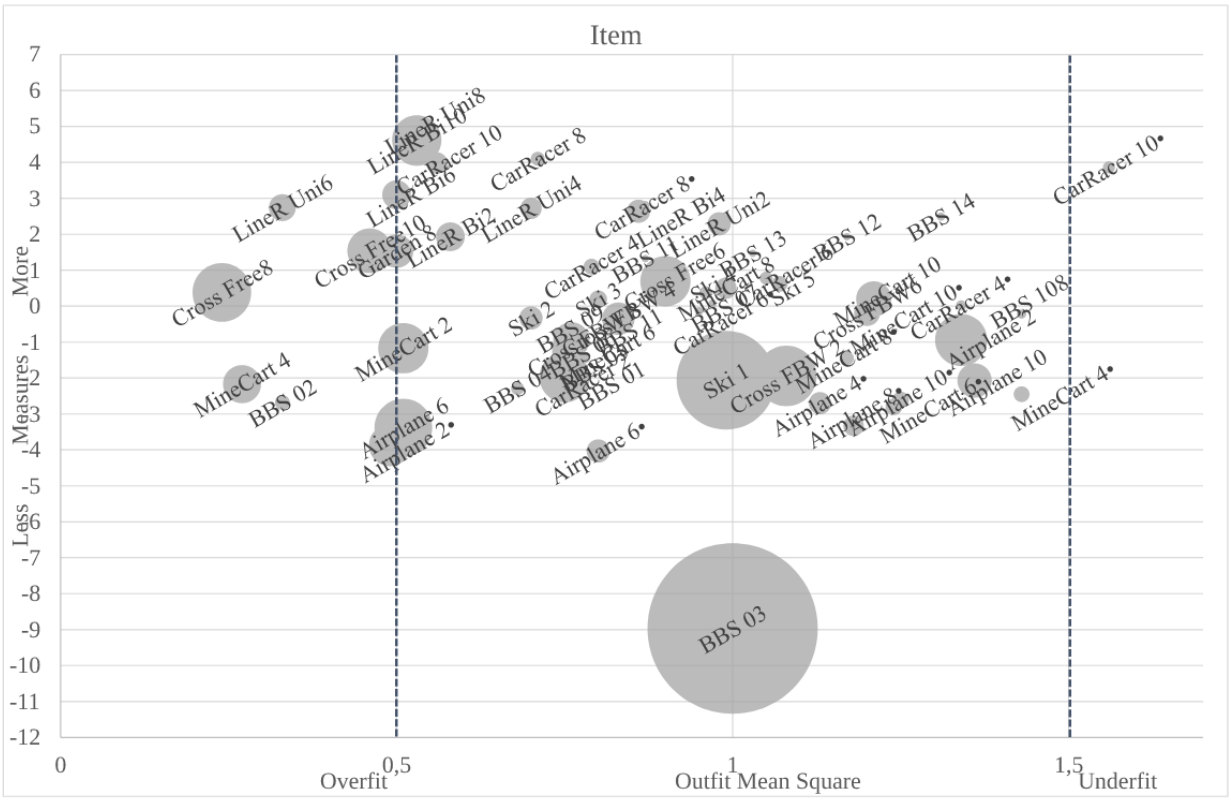
Item Fit

Based on outfit mean square statistics, values above 1.5 appointed the items that showed underfit and, thus, did not fit the model. This resulted in the deletion of following items after the first round of analysis (Table 3): Airplane, level 4, in the standing position (1.79); Airplane, level 8, in the standing position (2.12); Car Racer level 2, in the sitting position (1.77); Cross the Road, forward-backward step, level 10 (1.64); Veggie

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Guard, level 6 (3.53); and Mine Cart, level 2, in the sitting position (1.95). Various items showed values below 0.5, indicating overfit and, thus, making items redundant. However, in our study it was not the goal to delete redundant items, but to find multiple well-targeted items to deliver variation to our participants. Thus, we decided to keep these items in the model. In the final round of the analysis, only one item (ie, Car Racer, level 10, in the sitting position) showed slight underfit, with a value of 1.56 (Figure 3). We set 1.5 as our threshold in the first round of the analysis. However, Wright and Linacre [41] argue that a threshold of 1.7 is acceptable for clinical observations. Because the aforementioned item only slightly deviated from the statistical rule and had its own logit value, we did not delete this item from the analysis.

Figure 3. Bubble plot with the outfit mean square statistics. Game descriptions can be found in Figure 2. Outfit mean square values should range from 0.5 to 1.5; items below 0.5 show overfit and items above 1.5 show underfit. The size of the bubble shows the model SE. The number beside each exergame represents the exergame level, and the ● denotes the games that are performed in a seated position. The number beside BBS represents the scale item number. BBS: Berg Balance Scale; Cross FBW: Cross the Road (forward-backward step); Cross Free: Cross the Road (free steps); Garden: Veggie Guard; LineR Bi: Line Roller (bilateral); LineR Uni: Line Roller (unilateral); Ski: Skiline.



Ordering of the Item Thresholds

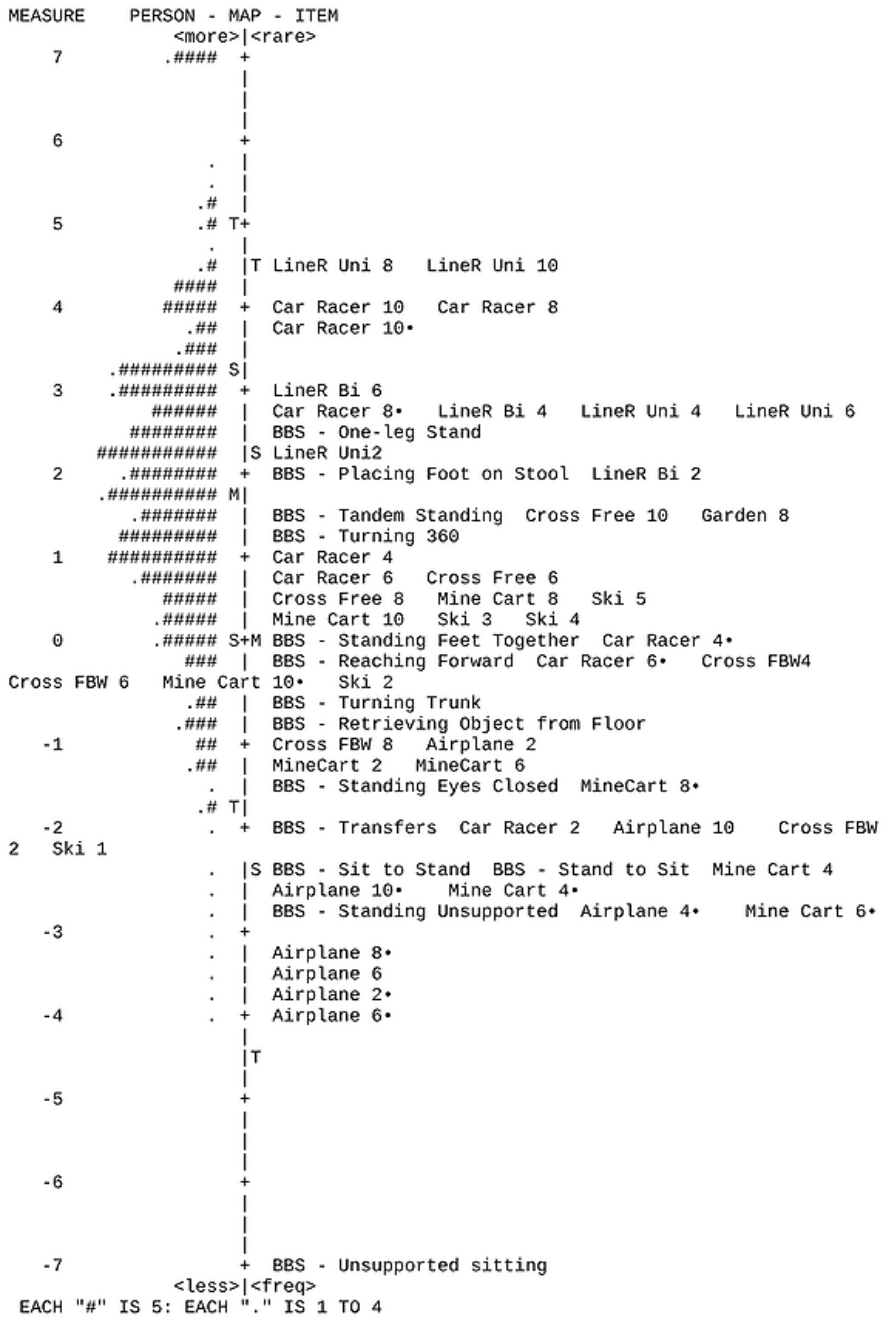
The ordering of the item thresholds was acceptable. For 38 items, the whole score range was not used and, therefore, not all thresholds were available. For nine items, the thresholds were not in the correct order, meaning the score did not increase stepwise with increasing ability.

Distribution of Responses: Person-Item Map

Figure 4 shows the final person-item map; the ability of the participant is represented on the left side and the difficulty of the items is represented on the right side of the figure. Person ability ranged from –4.0 logits to 7.0 logits, and item difficulty ranged from –4.0 logits to 4.75 logits. In general, it is seen that for participants with lower to moderate balance abilities, a great variation of exercises exists. The variation of exercises is lower for participants with higher balance abilities, especially for participants with very high balance abilities (eg, for logits of 4.5 and higher, there are no matching items available).

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Figure 4. Person-item map. This map shows the person ability and item difficulty in one scale expressed in logit values. Person ability is shown on the left side, with the lowest person ability at the bottom and highest at the top. Item difficulty is shown on the right side, whereby items are organized from least difficult at the bottom to most difficult at the top. The number beside each exergame represents the exergame level, and the ● denotes the games that are performed in a seated position. The number beside BBS represents the scale item number. BBS: Berg Balance Scale; Cross FBW: Cross the Road (forward-backward step); Cross Free: Cross the Road (free steps); Garden: Veggie Guard; LineR Bi: Line Roller (bilateral); LineR Uni: Line Roller (unilateral); M: mean; S: one SD; Ski: Skiline; T: two SD.



Pairwise DIF Contrast

The pairwise DIF contrast between persons with MS and persons with stroke showed a significant difference in difficulty in 15 out of 61 items. Of these items, only 10 showed a substantial difference of 0.5 logits, which presents a clinically noticeable difference between the groups. Of these, 7 items were exergames and 3 items were Berg Balance Scale items.

Discussion

Principal Findings

Overall, the results of our study showed adequate unidimensionality and good fit statistics of the exergame scores to the Rasch model. The resulting person-item map showed that the exergames covered the abilities of persons with neurological disorders with low to moderate balance ability and delivered

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enough variation of exercises, especially for persons with moderate abilities.

The VR exercises and many of the Berg Balance Scale items showed adequate unidimensionality. However, eight Berg Balance Scale items were at the limit of the first dimension and measured a different aspect of balance than the other items. The difference arose because the Berg Balance Scale measures static and basic balance over short time periods, whereas the exercises measure static, dynamic, and reactive balance over longer time periods of up to 2 minutes. Consequently, both of these measure balance but, as indicated by the analysis, they measure a different aspect of balance.

Fit statistics showed that 47 out of 60 exercises fitted well to the Rasch model. Three items had to be deleted from the final model because of negative point-biserial correlations. This could be due to wrongful score calculations, in combination with other game parameters that have a considerable influence on the score calculation, such as obstacles to avoid or simultaneous collection of collectables. As a consequence, the score did not reflect the participant's ability (eg, the score goes up even if the ability of the participant does not increase).

Six items were deleted after the initial analysis because of underfit; thus, these items included too much noise and did not fit sufficiently to the Rasch model. The corresponding items showed a large IQR in scores. Clinically, it was noted that certain exercises were too easy, such as Car Racer, level 2 (in the sitting position). Consequently, participants with all abilities were often distracted and reached various scores that did not seem to match with their ability. In the final analysis, Car Racer, level 10 (in the sitting position), showed slight misfit. We used 1.5 as a stricter cutoff value; however, Wright and Linacre [41] argue that a threshold of 1.7 is also acceptable for clinical observations. Since the exercise was in the top range of difficulty, had its own logit value of difficulty, and was appreciated by therapists to challenge the participant in a seated position, it was deliberated among experts to keep the exercise in the analysis. Usually, the goal of a Rasch analysis, when used for scale development, is to delete items with misfit or that are redundant, in order to make the scale leaner and less time-consuming. However, in this study, we explored the data for challenging exercises that fit the model in a proper manner. Next to that, redundancy was not an issue in our study, as variation of exercises was important for keeping the motivation of the participant as high as possible.

In the second part of the analysis, the person-item map was constructed to show the difficulty estimate of items and the ability of the participants. The device under investigation provided mainly VR exercises for the severely to moderately affected participants, with most variation for the moderately affected participants. The person-item map showed few patients with very high balance ability in the top, for whom no suitable exercises were available. However, it should be noted that not all exercises were performed, as therapists did not use four exercises because they were considered unsafe for the participant. Regarding the more difficult VR exercises, it was seen that the maximum score was not achieved. This shows us that possibilities were available for this patient group, but these were not clinically used. Therefore, the use of a harness in higher-level balance exercises is recommended, in order to adequately and safely challenge the patient on the limits of their balance capabilities.

Research into VR-based adaptive training mainly investigates how to challenge a patient within a single exercise by adapting parameters, such as accuracy, speed, and amplitude of movement [42]. By investigating only a single exercise, the importance of variation as well as progression of tasks is not addressed. The performed analysis provides an opportunity for the development of training programs in neurological rehabilitation. In sports injury rehabilitation, many protocols exist for graded rehabilitation with variation of exercises and intensity of training to optimally challenge the patient and work toward recovery. In neurological rehabilitation, such clinical protocols are scarce. A study by Wüest et al [43] is one of the few to discuss the theoretical design considerations for an exergame-based rehabilitation program that aims to improve walking in the stroke population. The model showed a clear progression in relearning how to walk, whereby exercises progressed from a stable body position with a stable environmental context to exercises with body transport and in-motion environmental context. Our clinical data–based model showed similarity with regard to the sequencing of exercises in the standing position within the model, whereby a progression was seen from weight-shifting activities to stepping activities and changing environmental contexts throughout the different exercises. Through the performed analysis, an idea was formulated toward a protocol of training balance ability using technologies in the neurological population and how to increase difficulty and, thus, challenge, while progressing through the different rehabilitation VR exercises. This model is further supported by the clinically established Berg Balance Scale that validates the VR exercises and delivers a clinically established starting point from which to choose VR exercises in daily practice [44]. Further use of the model in similar study designs and data types could show the potential of the Rasch model in creating challenging and adapted training programs with various technologies in specific patient populations.

The analysis faced some limitations. From a statistical point of view, the difficulty estimates of the various VR exercises lay in certain items very close together, meaning that exercises were almost equally difficult. The deduction of points for obstacle hits was too large and, thus, had a rather big influence on the exercise final score. Therefore, the person-item map should be interpreted with caution, and clinicians should always integrate their clinical opinion about the safety of the patient when choosing exercises. Therefore, the person-item map is a support rather than a fixed guideline. For the collection of the large amount of data, the repeated-measures model was used. This means that scores from one participant were used as independent scores to establish a minimum number of observations. In this study, an observation was created for each training week, combining one Berg Balance Scale item with VR exercises until a double-played exercise was noted. This resulted in the second observation of the week, and so on. Based on clinical experience, we presumed that participants' skills stay rather constant throughout the week and, thus, combining scores in this manner

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was feasible. The choice for this method was based on the clinical character of the study. Not every participant could play all exercises because of severely affected motor function and increased risk of falling. Next to that, there were not enough resources available to meet the high number of single observations needed for stable item calibration. A previous study by Anselmi et al [45] confirmed that repeated measurements using a health questionnaire are feasible. Therefore, we decided to use the repeated-measures model, which resulted in a good fit to the Rasch model. Data were collected from a broad neurological population with severely affected to good balance abilities. We included persons with MS and stroke, as both pathologies are often seen within the neurorehabilitation setting, and these persons suffer from similar impairments with regard to functional balance and trunk control. Therefore, results are applicable to a broad neurological population. Future research could also include healthy subjects with whom to compare results.

The person-item map can stimulate integration of various VR exercises, as it supports the clinician in the decision-making of which exercise is appropriate for which ability as well as in deciding how to continue challenging the patient by using VR and following the continuum of exercises. In this way, this would keep the player challenged and deliver variation in order to keep the player motivated over time and, thus, increase effectiveness of treatment. Future work could focus on the implementation of the person-item map in the clinical field and the feasibility of such within the device. In a second step, in line with the systematic literature review of Zahabi et al [42], the effectiveness of adaptive VR-based training should be investigated in studies with a large sample size with long-term follow-up, in order to assess the transfer of learned skills to activities of daily living.

Conclusions

The Rasch model was shown to be applicable for creating a continuum of participant ability and exergame difficulty based on VR exergame scores. Unidimensionality of the data was adequate and 47 items showed a good fit to the model. A continuum of exercises was created, whereby it was seen that persons with low and moderate balance ability could be challenged well with the exercises and most variation was available for persons with moderate balance abilities. With this continuum, therapists are supported to choose the correct exercise that delivers the optimal challenge according to the player's ability. These findings hold promise for the application of the Rasch model within the future development of challenging and tailor-made VR exercise programs for persons with MS and stroke. In future work, the implementation of such a program into clinical practice could be explored as well as the extension of use of the Rasch model for data from different rehabilitation technologies and patient populations.

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Conflicts of Interest

JK declares that part of this work was funded by MindMaze SA, Switzerland. The study was carried out independently and there was no influence from the company on the design, analysis, interpretation, and presentation of the results. EW is employed at Hocoma Medical GmbH, Switzerland, a manufacturer of rehabilitation robotics.

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Abbreviations

BASEC: Business Administration System for Ethics Committees
DIF: differential item functioning
MS: multiple sclerosis
VR: virtual reality

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Original Paper

An Exploratory Digital Board Game Approach to the Review and Reinforcement of Complex Medical Subjects Like Anatomical Education: Cross-sectional and Mixed Methods Study

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Abstract

Background: Serious games have the potential to resolve educational problems faced by medical students, such as insufficient rehearsal due to boredom and lack of motivation. However, serious games' relatively novel concepts in science and many genres of games that are common in recreation remain underresearched in the literature. Board games are one such genre that, despite their potential, affordability, and flexibility, are rarely designed for medical students, and little is known about student perceptions of them and their compatibility with rehearsal.

Objective: In this cross-sectional study, we sought to elicit, via an exploratory mixed methods approach, student perceptions of a digital serious board game specifically designed for the gamified rehearsal of complex medical subjects, with the chosen topic of anatomy.

Methods: A digital serious board game, based on self-determination theory (SDT), was first designed and developed to facilitate the rehearsal of anatomy information. Students were then voluntarily recruited to partake in the intervention and were randomly split into three teams of 2 players per game session, after which they were administered the Flow Short Scale (FSS), which is a 13-item measure where items were rated on a 7-point Likert scale ranging from 1 ("not at all") to 7 ("very much"). Students then participated in a focus group discussion to elicit their perceptions of the game. Findings from the FSS were subject to descriptive analysis, and the focus group discussion was subject to inductive thematic analysis.

Results: A total of 12 undergraduate, second-year medical students from the Lee Kong Chian School of Medicine in Singapore participated in the study. FSS results indicated a moderate level of overall flow (mean score 4.94, SD 1.07) via the subdomains of fluency (mean score 4.77, SD 1.13) and absorption (mean score 5.21, SD 1.1). Students perceived the game as fun, enjoyable, engaging, and appropriate as a rehearsal tool that alleviated the monotony of traditional methods of rehearsal.

Conclusions: Our digital board game–based rehearsal tool, when based on SDT, appeared to be suitable for gamified rehearsal in a fun and enjoyable environment due to its facilitation of intrinsic motivation in its players.

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KEYWORDS

serious games; board games; anatomy; flow

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Introduction

Background

Modern medicine demands a skilled and adaptable workforce ready to take up an ever-expanding and increasingly complex knowledge base within constrained time frames [1,2]. Didactic methodologies no longer suffice, leading to modern student-centered approaches, such as flipped classrooms, problem-based learning, and team-based learning [3-6]. However, such methods focus on taking up novel information in place of retaining what has been learned. Very few consider how the affective and cognitive states of their learners might enhance, or be enhanced by, the methodologies in question.

Once a student graduates to clinical work, knowledge that is not immediately relevant is gradually lost without rehearsal [7]. At risk are complex cornerstone topics taught early in a student's training, such as human anatomy and physiology. However, rehearsal itself may be impeded by numerous factors, such as disinterest when a student perceives lack of relevance of a complex but crucial topic with their intended field, or when the drive to rehearse is governed by contingent self-esteem (ie, the approval of others) [8].

This is a cause for concern due to the increasingly cross-disciplinary nature of medicine, where competency gaps may result in the preventable loss of life or limb. Woods et al [9] found that a mere 14% of final-year students were confident in anatomical knowledge. While students recalled two-thirds of unrehearsed knowledge at the conclusion of their preclinical years, this dropped by half after 2 years [10], further increasing the risk of preventable medical errors. The development of new methods of efficacious rehearsal are thus warranted.

Recreational video games enjoy near universal prevalence across cultures and age groups, and are receiving increasing attention from health care professionals due to their vast potential for training and therapy [11-13]. When games are purposefully designed for a nonrecreational—usually clinical or educational—application, they are termed as serious games [14,15]. Closely related is the concept of gamification, where a nongame application is enhanced with game-like elements for utilitarian purposes, such as increasing motivation and engagement [16].

When applied toward clinical training and education, serious games bear similarities to medical simulations in that they provide learners with opportunities for task training and practicing, provide active learning, aid in the solving of clinical problems, and afford experience in risk-free surroundings [17]. However, when designed well, they are also inspiring, engaging, and frequent conduits of an optimal, innately positive mental state characterized by psychological flow, motivation, and enjoyment [15,18,19]. These characteristics have seen them deployed for increasing psychomotor skills during laparoscopic surgery [20,21], teaching first-aid procedures in choking emergencies to nonexperts [22], and imparting history-taking content to medical students, among others [3,18,23].

Board Games and Tabletop Games

The near-universal household penetration of digital games may result in physical play activities, such as board games and other tabletop games, being perceived as old-fashioned [24]. The digital aspects of such games include advantageous features, such as game analytics or, in the case of education, learning analytics [25,26]; ease of upscaling or mass deployment [27]; and ease of modification without the need to physically produce new materials [27].

Nonetheless, a sizable market for modern and newly recreated recreational tabletop games remains to this day, for such games are comparatively easier to design, their production is more economical, and they are natural conduits for social inclusivity [28]; thus, they remain viable avenues of exploratory research into novel game-based interventions. To this end, in the context of education, numerous board games have since been designed and trialed, including for antismoking education [29], nutrition education [30,31], infectious and parasitic diseases education [32-35], management of chronic diseases education [31,36-38], sexual health education [32,33,39], and anatomy education [40].

The socially inclusive and usually flexible nature of board games, a natural result of the need for multiple human players [28], also allows for the exploitation of game dynamics, defined as behaviors that players exhibit when interacting with the game and each other, for serious gains [24]. Game rules or features may be designed to elicit willful and positive interaction with otherwise boring learning materials, cooperation with other players to achieve a goal, or competition with said players to reinforce engagement in the activity [28]. Behaviors normally considered negative in the real world may also be leveraged for serious purposes; such dynamics include the use of trickery, deception, conspiracy, and even betrayal, assuming considerations for ethics have been fulfilled, for a more entertaining and engaging game activity [41-43].

Board and tabletop games have varied use in medical and clinical education. However, many of these games are basic in nature, bereft of complexity found in educational material for medical students, and are not usually focused on rehearsal. Notably, many lack clear theoretical foundations to their game's design, a notable problem in the field, especially for early serious games [44,45], despite the dynamic and multifaceted nature of games qualifying them as complex interventions [46,47]. This risks unclear game mechanisms, conflicting frameworks of action, and questionable results wrought from unclear study designs [45,48,49].

Study Aims

We proposed an exploratory study to gauge the feasibility of a purpose-built digital serious board game, primarily based on self-determination theory (SDT) as defined by Deci and Ryan [50,51], to enhance the rehearsal of anatomy among medical students, with the overall aim of determining their attitudes and perceptions toward such an intervention. Under this aim, the following research questions were investigated:

1. Is SDT a useful framework for the creation of digital board games?

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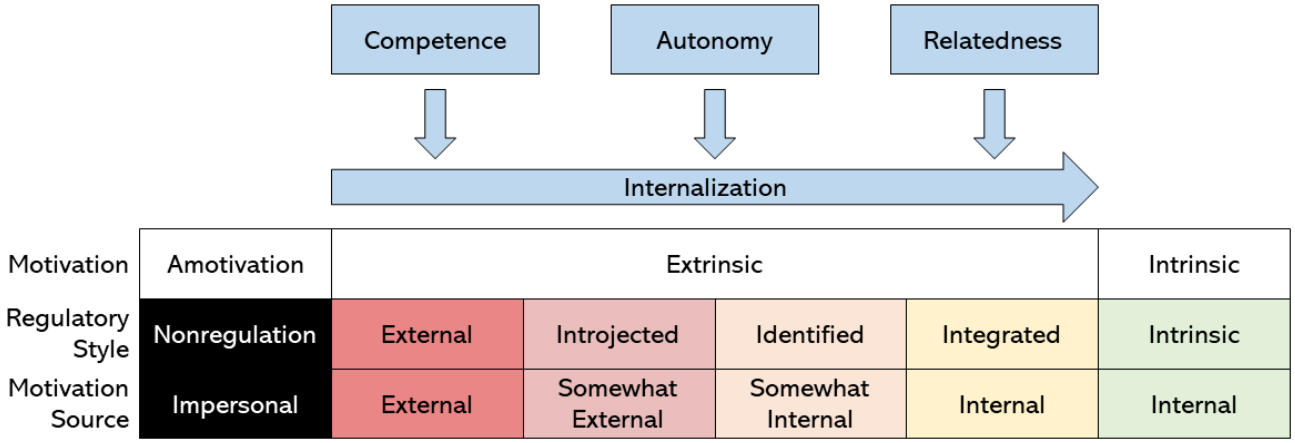
2. What are students' perceptions and attitudes toward the digital board game as a novel interventional tool for anatomy rehearsal?

Methods

Development of the Digital Board Game

SDT was chosen as the theoretical framework for the intervention due to its positing of a continuum between the wholly autonomous and wholly controlled behaviors resulting from factors that facilitate or undermine motivation [50,51]. Wholly autonomous behaviors are characterized by strong senses of choice and volition, are usually the result of intrinsic or internalized external motivators, and may be increased through fulfilling the psychological needs of competence, autonomy, and relatedness [50] (Figure 1). In contrast, the opposing end of the continuum describes wholly controlled behaviors usually regulated by compliance with greater powers, transactional rewards, or undesirable consequences should the behavior not be exhibited.

Figure 1. Self-determination theory as defined by, and adapted from, the works of Deci and Ryan [50,51]. The fulfilling of the three needs of competence, autonomy, and relatedness results in the promotion of internally regulated sources of motivation and, resultantly, an intrinsic desire to partake in the game activity.



Of the needs required of an intrinsically motivating activity, *competence* is defined as a desire to master novel skills that may be met through the creation of challenging opportunities that individuals may partake in and progress through [51]. *Autonomy* is defined as the desire for control over one's own destiny and behaviors; this desire may be met through activities that afford individuals the freedom to decide how to approach challenges, and how they wish to meet personal goals and exercise behaviors [51]. *Relatedness* is defined as the desire to develop and maintain close social relationships with others, be they as friends, partners, or groups, and this need may be met through activities that facilitate interpersonal connections, interaction, and teamwork in the context of competition [51].

SDT was thus used to guide the development of features and rule sets that would, as much as possible, allow for the internalization of the three needs and increase the amount of intrinsic motivation experienced by players, thereby keeping them engaged with the activity for as long as possible.

Game Features, Rules, and Mechanics

The design of the game's features and rule sets was primarily based on SDT to increase the amount of competence, autonomy, and relatedness felt by subjects playing the game.

To fulfill the need for competence, in-game educational materials were drawn from completed modules, and participants were permitted to look up answers from any source during play. To fulfill the need for autonomy, game rules were intentionally kept simple, minimally restrictive, and primarily enforced around the rehearsal component. To fulfill the need for relatedness, the game was played in cooperative two-person teams.

The game's final iteration was a turn-based free-for-all competition between three teams tasked to eliminate the other two (Figures 2 and 3). Each team may accomplish this through the generation of cosmetically distinct but functionally identical units, and then navigating said units into opposing bases to remove one life from an opponent. The cosmetic differences between teams, represented by team mascots, correspond to the three key topics of anatomy represented in the game. Internal organ systems are represented by humans, the musculoskeletal system is represented by zombies, and the nervous system is represented by robotic units.

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Figure 2. Overview of the game board and all elements therein. Only one copy of each team's unit is featured, due to a duplicate function that allows for easy "copying and pasting" of any item on the board.

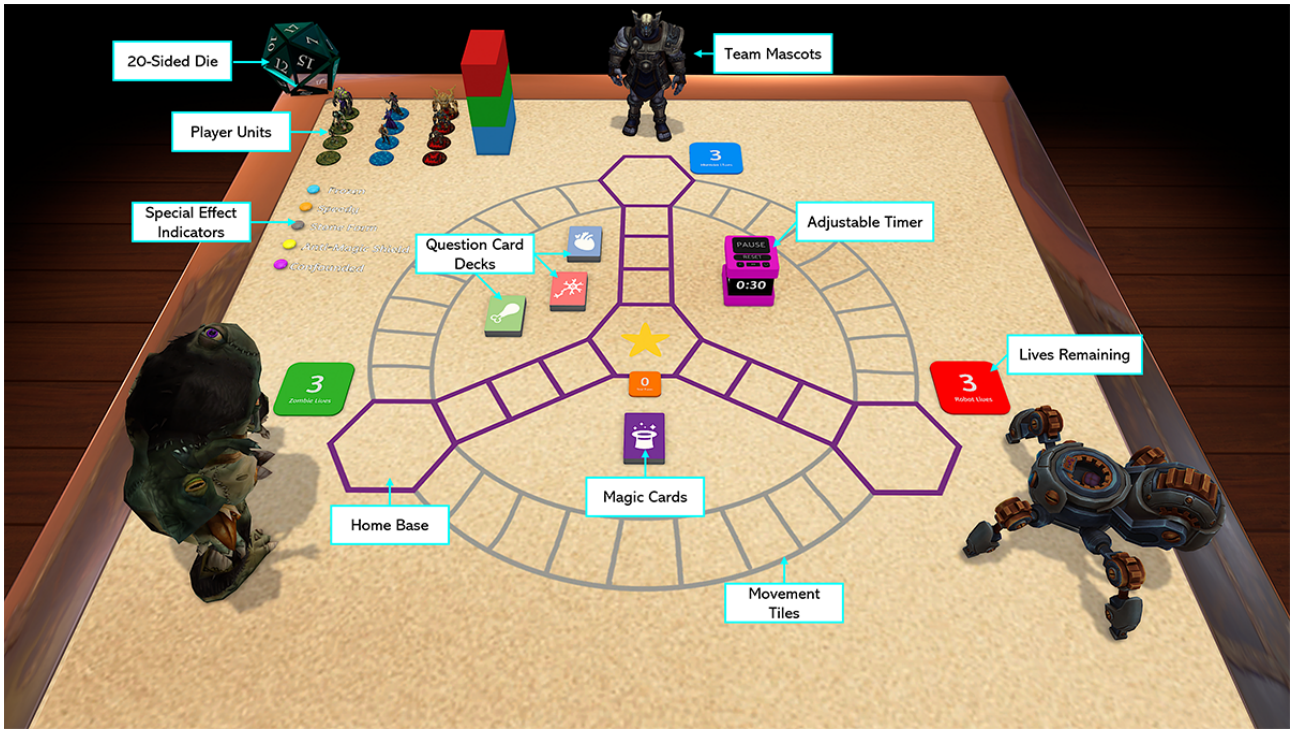


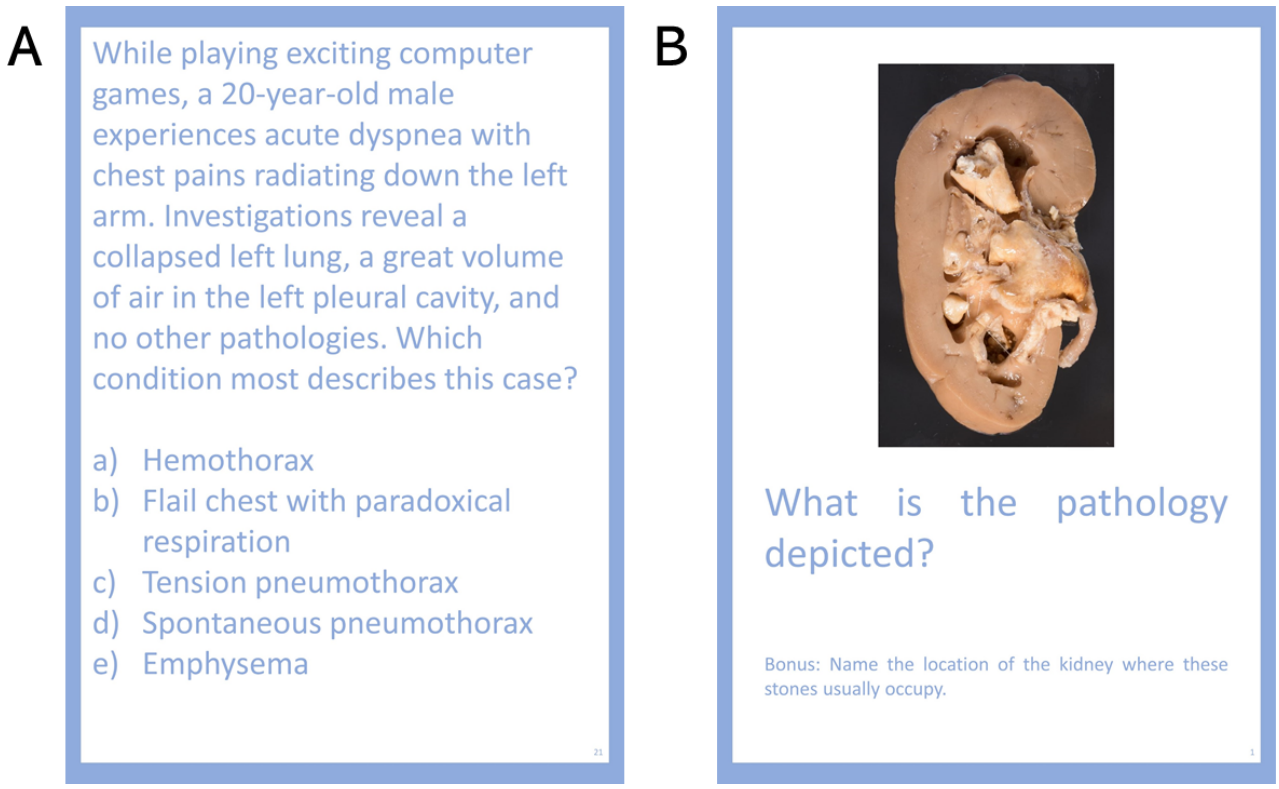
Figure 3. Close-ups of each team's functionally identical but cosmetically distinct units. All units were equipped with colored bases for ease of locating when the camera was raised high above the game board.



Unit generation may only be accomplished through interaction with the question card rehearsal activity. Decks are represented by a heart for internal organs, a nerve for the nervous system, and a chicken drumstick for the musculoskeletal system. At the start of their turns, teams may elect to draw a random question card from one of the three decks for either a multiple-choice question testing application of knowledge or an open-ended image card testing identification of anatomically relevant structures (Figure 4). Teams are permitted to look up answers to questions, but they must answer questions within a fixed time (default 30 seconds) to maintain a sense of urgency and prevent other teams from growing bored.

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Figure 4. Question cards are shown, which are comprised two types of questions: (A) multiple-choice questions and (B) open-ended questions requiring students to specify short answers.



Upon successful answering of a question, players are given a level-1 unit that they may either opt to deploy to the board immediately or retain for upgrading to a level-2 or -3 unit, subject to answering more question cards on their next turn. Units of different levels have health points, and they deal to other units a value of damage equal to their level (ie, a level-3 unit has 3 health points and deals 3 points of damage); units that receive damage are reduced in level if they do not lose all their health points in the confrontation (ie, a level-3 unit that receives 1 point of damage from a level-1 unit is downgraded to a level-2 unit). This feature serves to reduce the life expectancy of deployed units and indirectly incentivizes partaking in the rehearsal feature.

To further reduce life expectancy of deployed units, the board's tiles were designed such that players may opt to take two paths to their opponents. While grey tiles indicate a longer but safer path (nine tiles), purple tiles are shorter (seven tiles) and include an additional incentive of a "star tile" at the central intersection. Teams who successfully control the star tile for three turns in a row are allowed to draw a magic card that allows them to cast either beneficial effects on themselves or detrimental effects on their opponents.

To ensure no one team, either through luck or unusual competence, may dominate the board for too long and irreversibly damage morale in their opponents, a rule was included that awards any team that loses a life one magic card for immediate use.

Participants

Subjects were recruited from the group of second-year medical students undertaking their Bachelor of Medicine, Bachelor of Surgery (MBBS) degree at the Lee Kong Chian School of Medicine, Nanyang Technological University in Singapore. Second-year medical students were selected due to their having completed all systems-based anatomy modules required for their clinical years. Information about the study and links for registering one's interest were disseminated to prospective students via email advertisements, as well as advertisements during the break periods of student lessons. Students were repeatedly informed that participation was voluntary and had no bearing on their educational journey or course credits. Students diagnosed with, or suspected to suffer from, epilepsy, vision problems (severe myopia, photophobia, reduced visual acuity, eye strain, severe dry eyes, etc), significant psychosocial problems, or any other characteristics that may put them at risk as a result of study participation were excluded from the study.

All student participants were sent, and instructed to read, the study information sheets upon registration. All were rebriefed on the study's procedures on the actual day of the study, and a second copy of the study information sheet was presented to them prior to the collection of consent. Ethical approval was obtained from the Nanyang Technological University Institutional Review Board (IRB-2021-01-038-01).

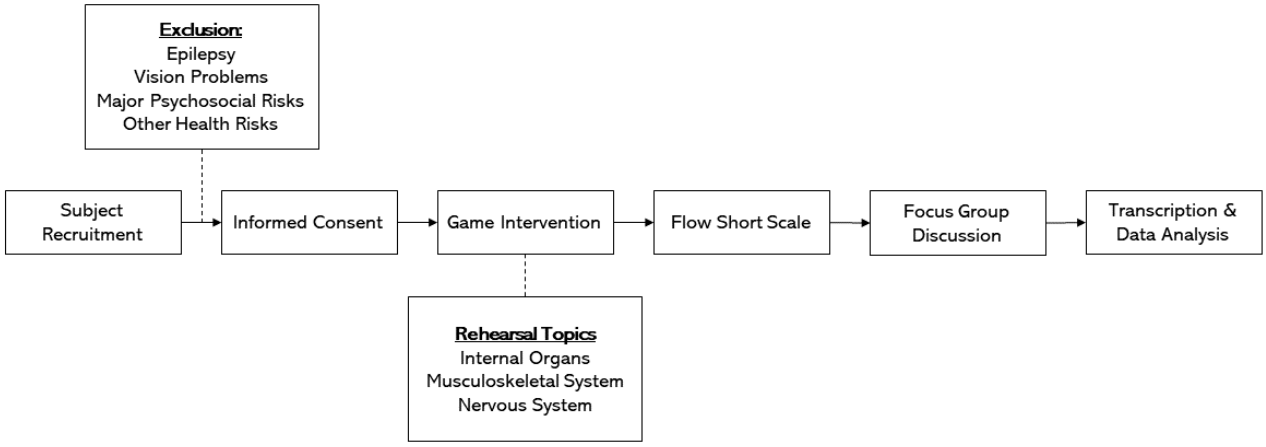
Evaluation of the Intervention

This cross-sectional study employed a mixed methods exploratory approach (see Figure 5 for an overview) conducted in two sessions to evaluate the digital game for anatomy rehearsal. For each session, 6 voluntary subjects—the maximum allowed by the board game—were randomly sorted into three teams of 2 required to play the game. The game activity lasted approximately one hour and was comprised of a blend of play and rehearsal; the latter featured material drawn from the entirety

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of the students' anatomy education split into internal organs, the musculoskeletal system, and the nervous system. Students remained blinded to the topics until commencement of the activity. Rehearsal materials were presented as question cards containing either multiple-choice or open-ended image questions, and students were, by default, given 30 seconds to answer each question. The game was conducted as per the rules described in the above sections. During all rounds of play, a member of the study team (JWT) facilitated the group to ensure compliance to the basic rules and checked all proposed answers against an answer sheet. Participants from the first session were instructed not to reveal the study details, methods, and procedures to other students, in order to maintain the integrity of the experiment.

Figure 5. Overview of the mixed methods study design, wherein collection of quantitative data comprised the Flow Short Scale and qualitative data was comprised of transcriptions from the focus group discussions.



Flow Short Scale

After the intervention, the Flow Short Scale (FSS) was administered; this scale is a 13-item measure, with items rated on a 7-point Likert scale ranging from 1 ("not at all") to 7 ("very much"). The FSS has demonstrated construct validity [52] and good psychometric properties (α=.90), and it measures a stable three-factor structure comprising fluency of performance, absorption by activity, and perceived importance or outcome importance of the activity [53]. The scale is most frequently used as a retrospective measure of flow experienced during an immediately preceding activity. To eliminate the risk of fomites, the FSS was digitized and transmitted to subjects via a QR code to university-secured Google Forms.

Focus Group Discussion

Following the FSS and before participating in focus groups, participants were reminded that the focus group discussions would be recorded for transcription by a third-party transcription company. All focus group discussions were assigned facilitators who had previously been familiarized with the game intervention, who were not present during gameplay, and who themselves had no expertise with anatomy. Guiding questions comprised the following:

1. Was there anything you found memorable when playing this game?
2. How would you change this game to make it more helpful?
3. How could we have made the game more fun for you?
4. When did you feel yourself entering a state of flow and what were you doing just before?

Data Analysis

Quantitative data were comprised solely of the FSS results, with the first 10 items, measuring the dimension of flow, tallied and the mean derived as an indicator of how much flow was experienced. The last three items, measuring perceived importance, were similarly averaged.

The transcribed focus group discussions were subject to inductive thematic analysis in accordance with guidelines established by Braun and Clarke [54], due to the exploratory nature of the study and the lack of existing theoretical models describing user engagement in educational board games. Transcriptions were analyzed by two authors (JWT and SRM) who have extensive experience with qualitative research. While both have had prior experience playing board games, none actively or regularly play in the present day. Prior to coding, both authors familiarized themselves with the data by reading through the transcripts. A selective coding process was administered given the study's exploratory nature and the need to elicit the perceived relevance and value of the game for student rehearsal, that is, factors that facilitated the recall of information, personal enjoyment, and elements, if any, that were perceived to assist in increasing the efficacy of the intervention [54]. Both authors coded independently with no input from the other until completion. Codes were then compared, and differences were discussed until a resolution was reached.

Results

Overview

A total of 12 subjects participated in the study; this included 7 males (58%) and 5 females (42%), and subjects were aged between 20 and 23 years (mean 20.91, SD 0.99). Sessions comprised 4 males and 2 females in the first group, and 3 males and 3 females in the second group.

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Flow Short Scale

The results of the FSS, whose items were rated on a 7-point Likert scale ranging from 1 (“not at all”) to 7 (“very much”), indicated a moderate degree of overall flow resulting from moderate levels of fluency of performance and absorption by activity subdomains. The perceived importance of the activity, independent from flow, was low (Table 1).

Table 1. Results of the Flow Short Scale (FSS) indicating moderate levels of flow via the subdomains of fluency and absorption, and a low degree of perceived importance.

Subdomain	Female participants (n=5), FSS score[a]		Male participants (n=7), FSS score		Total participants (N=12), FSS score	
	Range	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)
Overall flow	3.94-5.96	5.00 (0.81)	2.46-6.22	4.90 (1.29)	2.46-6.22	4.94 (1.07)
Fluency	3.40-5.80	4.80 (0.97)	2.60-6.20	4.74 (1.31)	2.60-6.20	4.77 (1.13)
Absorption	4.75-6.50	5.30 (0.72)	2.25-6.25	5.14 (1.37)	2.25-6.50	5.21 (1.10)
Perceived importance	2.00-5.33	3.67 (1.20)	1.33-5.33	3.52 (1.65)	1.33-5.33	3.58 (1.42)

[a]FSS items were rated on a 7-point Likert scale ranging from 1 (“not at all”) to 7 (“very much”).

Thematic Analysis

The focus group discussions elicited a wealth of insights centered around students’ views of the game’s fun and enjoyability, the degree to which they found it engaging, and its effectiveness as a rehearsal tool. Students were mostly in agreement in their perceptions of the game and persistent in their attempts to offer suggestions on how to improve the intervention. For reasons of confidentiality, all participant quotations mentioning names and the speakers themselves were deidentified. Students were then issued a unique code (eg, G2B) for identification among the study team. All participants were Singaporeans and communicated primarily in the local vernacular, Singlish, an English-based creole language; while comprised almost completely of English words, Singlish uses a grammatical structure that may be perceived to be incorrect by a nonlocal English speaker. To avoid accidental changes in meaning, quotations retained conversational Singlish quotations verbatim, such as the term “ya,” an analog of “yes,” usually used as an affirmation, and the ubiquitous particle “lah,” which is typically used at the end of a sentence that, when combined with an appropriate tone, may modify or emphasize the meaning of an entire utterance akin to the use of adverbs on a target word.

Perceptions of Fun and Enjoyment

Participants could differentiate between the educative rehearsal components and the actual game activity, with many expressing surprise that the board game could contain elements they perceived to be fun and enjoyable. These elements were attributable to the game’s flexible and unrestrictive rule set, with notable moments of cooperation during the mid- and late stages of gameplay, where teams formed temporary alliances against particularly competent players.

> *Then I was surprised with the fact that, I mean, if you put all the academics aside, it really functions as like a real game and real strategies.* [Student G2B]
>
> *I don’t know whether the original game was supposed to be about forming alliances, but I think it’s very fun to be able to form alliances.* [Student G1E]

Of note, and although not surfaced during focus group discussions, the formation of alliances was often accompanied by friendly banter between parties, including those left out of said alliance.

Perceptions of Engagement

Although students required time to familiarize themselves with the intervention, most eventually found the activity capable of engagement and sustained attention. This was attributed to the game’s interactive component, such as the manipulation of objects in the digital space. Interaction with other players, such as forming alliances against a common foe, appeared to facilitate engagement alongside the previously noted fun and enjoyability.

> *I think it was very cool...like, you can move the cards around, like, actual board game but it’s online.* [Student G1A]
>
> *...so that’s why we formed alliance against them. [Laughing]. To stop their progress across the board.* [Student G1B]

The use of strategy appeared to be directly facilitated by the competitive element. However, the risk of losing one’s units occasionally resulted in feelings of frustration, especially when facing two allied teams, to the point that students needed reminders on the game’s comeback mechanics.

> *Cause, I mean, you can’t...it’s like you have to choose someone to target, and then it’s easier to target one person than all.* [Student G2C]

Beyond this, students also noted that the mere notion of a play activity immediately after the rehearsal task acted as an incentive to continue partaking in the rehearsal activity. Once engaged, students appreciated a balance between the difficulty of question cards and their own skill.

> *...I think it also gives us an incentive to actually...remember the, like, the questions...so it makes it more fun to learn.* [Student G1C]
>
> *And the questions...they weren’t, like, very easy. Like, it’s not, like everyone just get correct.* [Student G1A]

Finally, students were willing to re-engage with the game intervention immediately after the conclusion of the focus group discussions and, thus, the study. These views were not captured as a result, but they were taken as observational findings by the

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study team that the intervention was acceptably engaging for use in rehearsal.

Perceptions of the Rehearsal Tool

Most students were appreciative that the rehearsal tool provided them with immediate feedback, although some requested more detailed explanations for correct answers. Overall, students reported positive impressions of the rehearsal activity, in particular, the time limit, chance for immediate rewards, and that all students could view the questions at the same time.

> *Ya, but if there's like explanations...like, a sort of like answer booklet that is quite detailed.* [Student G2F]
>
> *And the questions are quite relevant to what we've already studied. So, it's...a better grasp of what, like, we see in the labs.* [Student G1E]
>
> *Now this they're introduced more of like VR, but like, I think having, like, a board game really takes it to a different level.* [Student G1D]

Student Perceptions of Flow

When discussing their inputs into the FSS, which was conducted prior to the focus group discussion, most students were able to pinpoint the time that they first noticed themselves entering a state of flow.

> *I think at the point where you managed to destroy your first unit...that's the point where you really get into the game.* [Student G1B]
>
> *Like, the first round of questions when you got to see, like, a taste of what the questions are like. Then it, it made me quite involved really...like, that was when I was like, like, when I was in the zone.* [Student G1E]

Other students did not observe themselves entering a flow state and cited reasons of fatigue and the continuous rotation between rehearsal and play hindering the commencement of a flow state.

> *I don't think I reached any state of flow. [Laughing]. There [was] no coffee.* [Student G1F]
>
> *I mean if you're playing a game, of course you enter the flow, just like don't see time going, but this is still like sort of studying and playing.* [Student G2B]

However, students who did not perceive themselves as having entered flow states also noted an altered perception of time and the suspension of fatigue until after the conclusion of the intervention, both possible indicators of flow.

> *Ya, I didn't feel the one hour.* [Student G2B]
>
> *Just that you couldn't...You feel fatigued but you don't feel that it is one hour long. Ya.* [Student G2D]

Student Recommendations for Improvement

Students offered a surprising number of suggestions on how the game could be improved. Suggestions included the need for automation, more complexity and opportunities to strategize during the play phase of each team's turn, even more powerful magic cards with opportunities to use them, a faster overall game pace, and gamification of the rehearsal element through a "snatching" feature, wherein a team who is unable to answer, or incorrectly answers, a question will open that question to the other two teams for answering.

> *Like there's no, there's no like superpower card or something whereby you can be like, oh, you suddenly can ward off all the damages.* [Student G2D]
>
> *I think it's a bit slow...So I think, like, you can just reduce the, the number of steps in, like, every direction. So just shorter overall.* [Student G1A]
>
> *Maybe if your team cannot answer the question you can ask other teams to answer.* [Student G2F]
>
> *I think they should automate all the, like, the placing of the units and stuff. And then sometimes you also forget to move the thing.* [Student G1D]

Discussion

Principal Findings

The creation of active student-centered learning environments that promote learning, participation, and engagement has long been a need in education [55]. To this end, the exploratory intervention in this study appears to have been successful, due to students mostly perceiving it as a fun, enjoyable activity that suitably facilitated gamified rehearsal and engagement, the latter of which appeared to occur based on the moderate degrees of flow indicated by results of the FSS. Although it had not been the original intention, the intervention, once subject to a few minor revisions based on feedback, appears suitable for a student-centered model of rehearsal due to its dynamic nature, unpredictability due to elements of luck and strategy, and means for students to exert control over the learning process [3,56,57].

While the use of strategy appeared most linked to perceptions of fun, enjoyability, and engagement, to the best of our knowledge this study appears to be the only medical student–focused digital board game intervention, if not the only such intervention, to have encountered such a finding. While numerous publications have described games requiring the use of strategy, study designs and subject population types largely varied enough that none were able to draw similar conclusions [29-40]. Notably, research in serious games commonly features validation and efficacy studies, thus minimizing the chance for such conclusions to be drawn [11,12,20-23,29-40].

However, findings from this study bear similarities to gamified rehearsal-based interventions designed to complement existing teaching. While not an explicit game like the one in this study, the TERMInator tool, developed by Seidlein and colleagues [58] to facilitate the rehearsal of medical terminologies, was noted to be an approachable tool that students were inclined to engage with, most likely due to the introduction of gamified rehearsal.

Such findings also bore similarities to results from motivational reinforcers used to enhance retention in cognitive therapies, such as task-switching in young children with cognitive control problems, such as attention deficit hyperactivity disorder [59]. While not explicitly stated, when such reinforcers comprised the introduction of game or game-like elements that required the use of strategy in overcoming tasks, motivation to continue

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with an otherwise unattractive task was noted to increase across both laboratory and commercialized cognitive training tools [59-61]. Although the intent of such interventions is to train, as opposed to rehearse, the similarities of the findings despite differing approaches remain notable.

Nonetheless, medical student subjects from a study examining the only other anatomy-based board game, published in 2014 by Anyanwu [40], reported similar perceptions, such as interest and enjoyment, despite the two studies' differing theoretical foundations, approaches, and intents. The findings of Moro and colleagues [62], who created a physiology and anatomy revision game, also bore similarities to this study in that the interweaving of rehearsal and game elements likely contributed to increased motivation and engagement as well as a more positive view of the rehearsal activity.

Aside from the use of strategy, most perceptions of fun and enjoyability were linked to interactions with one's teammate, opponents, and the play activity itself. Due to the aforementioned focus on validation studies [28-39], the authors were unable to identify any studies whose designs allowed for the direct attribution of enjoyment to any of the interpersonal relations, although overarching perceptions of fun, most likely with the actions of play, were still observed [40]. However, existing research into the conduciveness of learning environments has suggested that decreasing or disallowing both teacher-student and student-student interactions, thereby decreasing the quality of social interactions, interferes with beliefs of self-efficacy and self-concept of ability [63-65]. The apparent underreporting on whether an intervention is fun, enjoyable, or engaging is possibly linked to the presumption that it must be these things if it was to be successful. However, this paper posits that not knowing if a game-based activity is enjoyable risks misattributing efficacious results to other factors, such as the benefits of increased exposure even if an intervention is not engaging [66,67].

Instead, findings of a similar nature have been noted in gamified, as opposed to explicit game-based, interventions. Felszeghy and colleagues [68] noted that a gamified and collaborative team-based approach to histology education among dental and medical students resulted in increased motivation to learn and interest in histology, and it scored high in participant satisfaction. While they also noted that their students appeared to prefer histology learning materials in traditional mediums as opposed to reading them off of screens [68], this was not surfaced in the focus group discussions of this study, likely due to the conciseness of the question cards.

Although the intention was for the rehearsal activity to remain minimally gamified to preserve the efficacy of known rehearsal methods, students held opposing views and suggested a means for teams to "snatch" a question card and its benefits, should the drawing team be unable to answer it. While similar features, though uncommon, have previously been noted in the literature to no obvious detriment [40], such a feature is not likely to negatively impact the rehearsal activity. Presently, any one team may wait up to 2 minutes between their turns, and unexpected delays (ie, a team taking too long to make their moves) may risk onset of boredom and distract from engaging with the activity. While this was not observed in this exploratory study, it remained one of the justifications for setting a 30-second time limit to answer question cards, and such a rule should serve only to maintain psychological arousal until a team's next turn.

Of note, engagement appeared most strongly linked with fun and enjoyability, as supported by the findings from the FSS, which indicated a moderate degree of absorption and overall flow. A possible explanation is the free-spirited and unrestrained nature of the play component, which appeared to allow students to exercise creativity when strategizing against their opponents, resulting in an intrinsically motivating desire to continue partaking in the game. An unexpected development was the formation of informal alliances between two teams against a more competent third team who, by virtue of correctly answering many question cards, was able to control significant portions of the game board with more and stronger units. Interestingly, the formation of such alliances was not always deemed negative by the third team, despite such behaviors usually being considered negative in real-world settings [69,70]. This was especially true if the third team was still able to maintain an advantage, despite two teams uniting against them.

Feelings of frustration were noted when two allied teams were able to push back a third team, but these were, to a degree, alleviated by the game's comeback mechanics, in particular, a rule where any team who loses a life is automatically allowed to draw a magic card. Such feelings are often unavoidable in games requiring some manner of human collaboration [70], and the inclusion of such comeback mechanics based on SDT was helpful in easing frustration. Although students had refrained from mentioning this during the focus group discussions, alliances, due to their informal nature [70], were sometimes broken by teams wishing to exploit opportunities (ie, securing the star tile at the central intersection) and press advantages. Such betrayals occurred infrequently and did not appear to be negatively received by their peers, and it was decided that rules against such behaviors were unnecessary at this time.

Although the method (ie, question cards) of rehearsal was positively received by students, many students disagreed with the choice to present question cards from the entirety of their anatomy education, deviating from an identical design choice of similar games [40]. While this was deemed suitable due to all subjects having completed their anatomy modules by the time of the study, students instead preferred having the option to pick questions from card decks sorted by both topic and difficulty, such that they may opt for an easier question in exchange for a lesser reward should they not feel confident in their mastery of any such topic. This preference is likely attributable to the digital flashcard smartphone apps commonly used by students for rehearsal, such as Anki [71,72], due to their similarities, but note that there is little in the literature that indicates the superiority of one method over the other.

A contrast was noted between the perceived importance of the activity as indicated by the FSS and what was verbally spoken during the focus group discussion. Although students appeared immensely invested at the prospect of gamified rehearsal, as evidenced by the enormous amount of feedback and suggestions they provided, the mean perceived importance of the activity

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was rated a low value of 3.59. While the rationale for such a discrepancy could not be discerned from the available data, it is possible that the playing of games, even for rehearsal purposes, is ultimately given a lower priority for students in their second year, due to the many undertakings expected of them during their education. It is also likely, as mentioned by one student, that students were able to discern that the proper use of gamification results in the exchange of some efficiency for motivation and is often used when traditionally efficient methods no longer suffice; thus, they rated the activity accordingly.

Finally, although the intervention may readily serve as an additional means of rehearsal, the game may also serve as a capstone event, such as a course-wide gaming challenge, to further reinforce what students have learned during their education. Competitive learning tools, when well used, have been known to improve motivation and satisfaction in blended learning environments [73,74]. Coupled with the higher-than-average levels of competitiveness observed in medical students [75], this appears to be a prospective avenue warranting further investigation.

Limitations

Due to the exploratory nature of this study, the authors were neither able to predict findings, such as the formation of informal alliances and the unusually low levels of importance given to the activity, nor generate hypotheses, a priori or otherwise, regarding their nature. Although the gamification of rehearsal appears well received and helpful, the exploratory nature of this study serves instead as a starting point from which further research, both qualitative and quantitative, may commence to identify further means of increasing efficiency when compared to traditional methods. The small sample size and broad distribution of data have also limited the interpretation of findings from the FSS. Due to the focus on confirming the feasibility of the intervention, the game's educational impact may only be determined in a follow-up study once necessary improvements have been made. An element of self-selection bias, in favor of students with existing interests toward playing board games, may have been present due to the nature of the study and voluntary nature of recruitment.

Conclusions

This study demonstrated the evidence to support the use of SDT as an appropriate theoretical base to develop game rules and features that facilitate a high degree of intrinsic motivation in a digital educational intervention. The new digital board game of anatomy examined in this study appears to hold its promise as an intervention for rehearsal and practice of learned material in a fun and enjoyable environment.

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Conflicts of Interest

None declared.

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Abbreviations

FSS: Flow Short Scale
MBBS: Bachelor of Medicine, Bachelor of Surgery
SDT: self-determination theory

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Original Paper

Mixed Reality and Haptic–Based Dental Simulator for Tooth Preparation: Research, Development, and Preliminary Evaluation

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Abstract

Background: Virtual reality (VR) dental simulators are currently used in preclinical skills training. However, with the development of extended reality technologies, the use of mixed reality (MR) has shown significant advantages over VR.

Objective: This study aimed to describe the research and development of a newly developed MR and haptic–based dental simulator for tooth preparation and to conduct a preliminary evaluation of its face validity.

Methods: A prototype of the MR dental simulator for tooth preparation was developed by integrating a head-mounted display (HMD), special force feedback handles, a foot pedal, computer hardware, and software program. We recruited 34 participants and divided them into the Novice group (n=17) and Skilled group (n=17) based on their clinical experience. All participants prepared a maxillary right central incisor for an all-ceramic crown in the dental simulator, completed a questionnaire afterward about their simulation experience, and evaluated hardware and software aspects of the dental simulator.

Results: Of the participants, 74% (25/34) were satisfied with the overall experience of using the Unidental MR Simulator. Approximately 90% (31/34, 91%) agreed that it could stimulate their interest in learning, and 82% (28/34) were willing to use it for skills training in the future. Differences between the 2 study groups in their experience with the HMD (resolution: P=.95; wearing comfort: P=.10), dental instruments (P=.95), force feedback of the tooth (P=.08), simulation of the tooth preparation process (P=.79), overall experience with the simulation (P=.47), and attitude toward the simulator (improves skills: P=.47; suitable for learning: P=.36; willing to use: P=.89; inspiring for learning: P=.63) were not significant. The Novice group was more satisfied with the simulator's ease of use (P=.04). There were significant positive correlations between the overall experience with the simulation and the HMD's resolution (P=.03) and simulation of the preparation process (P=.001).

Conclusions: The newly developed Unidental MR Simulator for tooth preparation has good face validity. It can achieve a higher degree of resemblance to the real clinical treatment environment by improving the positional adjustment of the simulated patients, for a better training experience in dental skills.

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KEYWORDS

dental education; simulator; mixed reality; tooth preparation

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Introduction

Skills training for tooth preparation is an important part of the preclinical training in dental education [1]. Dental phantoms, resin teeth, and extracted teeth have been used in traditional preclinical training [2,3]. With the development of virtual reality (VR) technology, the dental simulator was invented in the 1990s [4,5] and applied gradually in preclinical dental education. Construction of the dental simulator is based on VR to simulate oral hard and soft tissues and dental instruments and force feedback technology to simulate the feeling of force between the oral tissues and dental instruments [6,7].

Dental simulators realize the digitalization of dental skills training, record the entire training process [8], provide timely feedback to students' operations, and offer objective evaluations of the operation's results [9,10]. As resin teeth are different from real teeth in terms of material and structure and extracted teeth are difficult to acquire [3,11], the instructor can only evaluate the results subjectively through visual observation after the dental preparation is completed. Therefore, a dental simulator has obvious advantages over the traditional methods used in dental skills training.

The main display method of dental simulators is VR; similar technologies include augmented reality (AR) and mixed reality (MR) [12]. Although AR and MR superimpose virtual information on the real world, VR creates a complete virtual environment [13]. The major advantage of MR over AR is that MR allows switching freely between the real world and a virtual environment, thereby enhancing the vivid portrayal of interactions. Thus, these features indicate that MR may be a better choice for a dental simulation display method.

When combining MR with a dental simulator, the virtual part of the MR can be used to construct a virtual oral environment, simulating oral hard tissues, soft tissues, and dental instruments, which can solve the problem of material consumption during skills training. A phantom head in the real world can simulate the patient's head, which can align with the virtual oral environment, thereby solving the problem of adjusting the patient positioning in the clinical treatment scene. Together with the cooperation of haptic devices, a dental tooth preparation simulator with a higher degree of similarity to the real clinical treatment environment can be constructed, allowing users to participate in a more realistic training experience.

The purpose of this study was to describe the research and development of a new MR and haptic–based dental simulator for tooth preparation and to conduct a preliminary evaluation of its face validity.

Methods

Ethics Approval

This study was approved by the ethics committee of Peking University School and Hospital of Stomatology (PKUSSIRB-202273003-免).

Participants

This study was conducted at Peking University School and Hospital of Stomatology with 34 volunteers: 14 (41%) men and 20 (59%) women, aged 23 years to 30 years. Fifth-year undergraduate dental students, postgraduate students, and residents in the Department of Prosthodontics participated in the study. They were divided into 2 groups based on their clinical experience: the Novice group and the Skilled group. Participants in the Novice group (n=17) had 0 to 1 year of clinical experience, and those in the Skilled group (n=17) had more than 3 years of clinical experience in prosthodontics.

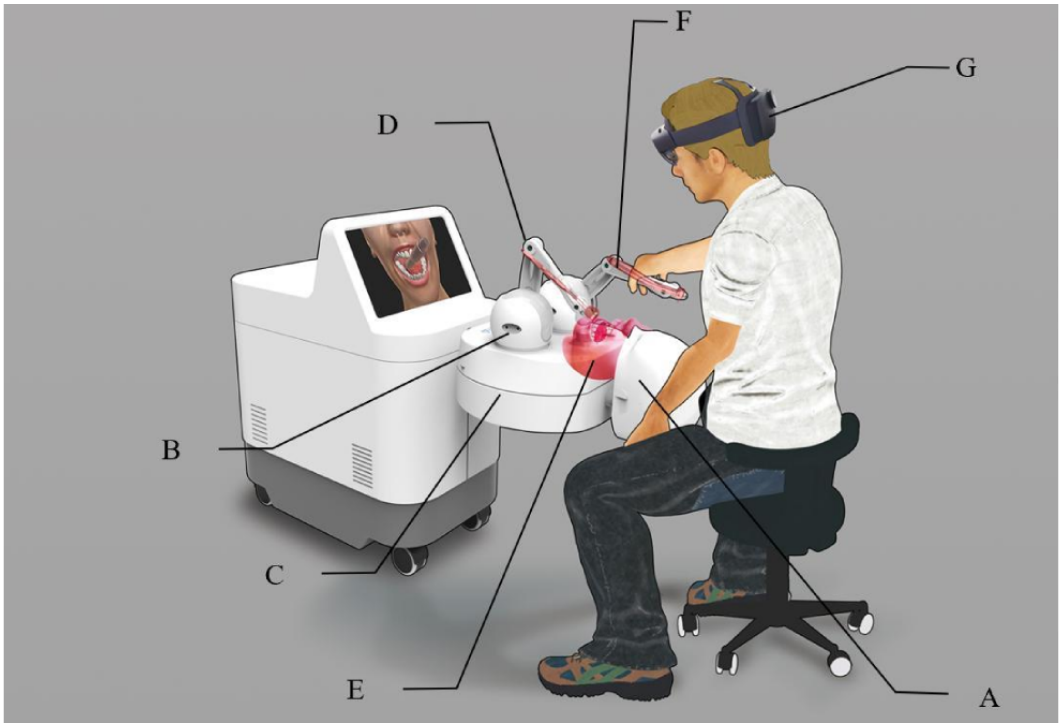
Introduction of the Unidental MR Simulator

The Unidental MR Simulator was researched and developed by Peking University School and Hospital of Stomatology and the State Key Laboratory of Virtual Reality and Systems of Beihang University. It is an MR and haptic–based dental simulator, mainly used for preclinical dental skills training for the preparation of crowns, inlays, and veneers.

A schematic diagram of the Unidental MR Simulator is shown in Figure 1. The computer for synthetic processing lies inside the hardware platform and contains a CPU (IntelCore i5-9400F, Intel Corp, Santa Clara, CA), a graphics card (GeForce GTX 1060, 3GB RAM, NVIDIA Corp, Santa Clara, CA), a hard disk (Green SSD, 240G, Western Digital Corp, Lake Forest, CA), a 14.600 full high-definition (HD) liquid crystal display (LCD), and an operating system (Windows 10, Microsoft Corp, Redmond, WA). A head-mounted display (HMD)-MR with glasses (HoloLens 2, Microsoft Corp, Redmond, WA) has a wireless connection to the computer for observing a simulated world mixed with the real environment.

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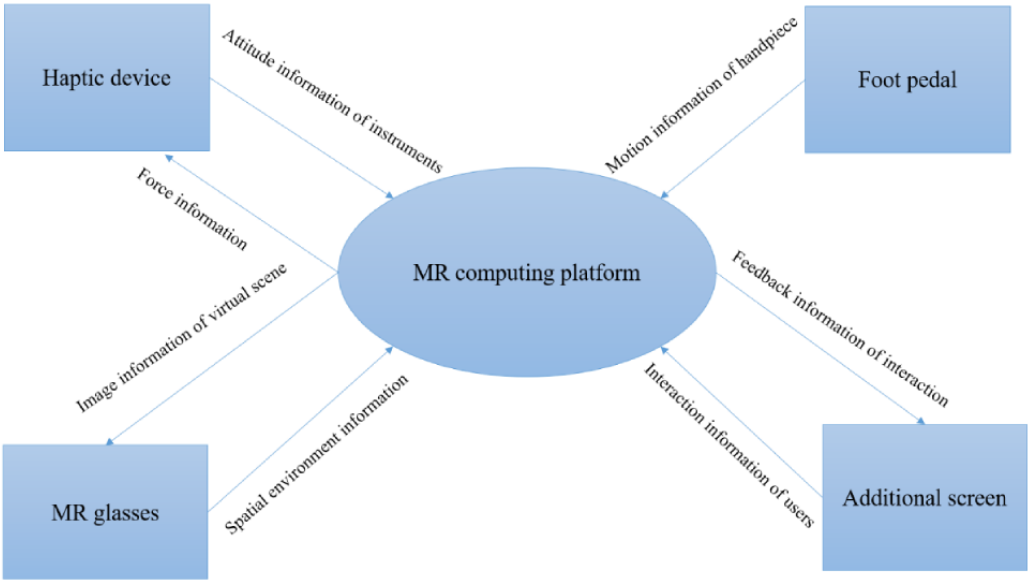
Figure 1. Schematic diagram of the Unidental Mixed Reality (MR) Simulator with (A) a phantom head, (B) haptic device base, (C) haptic device motion platform, (D) haptic device handles, (E) virtual oral environment, (F) virtual dental instruments (red), and (G) mixed reality eyeglasses.



As illustrated in Figure 1, the Unidental MR Simulator includes a simulation training platform that was constructed based on a phantom head model, which serves as a finger rest and spatial reference during the user's operation (Figure 1A). It also includes a dental skills training system based on a haptic device, which provides a range of force feedback during dental treatment simulations through the output force of the force feedback device (Figures 1B, 1C, and 1D); a virtual training environment that was constructed based on cone beam computed tomography (CBCT) data and an intraoral scan image (Figure 1E); virtual dental instruments for training that were constructed based on their actual size (Figure 1F); and a display system based on the MR glasses (HoloLens 2, Microsoft Corp, Redmond, WA; Figure 1G). The virtual dental training environment was registered spatially to ensure it matched spatially with the phantom head (Figure 1E). The display system can realize the coordinated display of the virtual training environment, phantom head, user's operating hand, and other virtual and real environments to enhance the trainee's immersion in the situation. Data, such as the spatial attitude of the haptic device, the orientation of the MR glasses, the matched virtual training environment, and the instruments, are passed to the algorithm platform, which calculates the output force information and visual grid, and then are transmitted to the haptic device and MR glasses for output, respectively, thereby achieving a closed loop. The visual information transmitted from the algorithm platform is simplified, based on the grid simplification algorithm to achieve a visual thread refresh frequency greater than 60 Hz. The output force is calibrated based on the force perception-visual space calibration algorithm to ensure the user feels the output force direction and the observation's direction is consistent, and then, it is transmitted to the haptic device for output. Based on the structure of the dental simulator as already described, the working principles of the Unidental MR Simulator are outlined in Figure 2.

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Figure 2. Working principles of the Unidental Mixed Reality (MR) Simulator.



The work of the Unidental MR Simulator consists mainly of inputs, computations, and outputs. The haptic device captures information about the user's instrument position within the virtual environment, the foot pedal collects attitude information about the instruments, the additional screen collects information about the user's interaction, and the MR glasses capture information about the spatial environment. The information is inputted into the MR computing platform, which calculates the input information and then outputs the feedback information through the output devices. The haptic device outputs the force information of the corresponding instrument's posture, the MR glasses output the corresponding virtual scene's image information, and the additional screen outputs the feedback information of the interaction. Various parts of the MR Simulator coordinate with each other to ensure the tooth preparation training process proceeds smoothly.

Evaluation of Face Validity

The face validity of the simulator is the degree to which the training situation resembles the real clinical situation [14]. The criterion for achievement is uniform positive evaluations of the simulator from users of different educational backgrounds [15]. To evaluate the simulations' face validity, we designed a questionnaire to collect data on aspects of the users' reported experiences, the simulation of the tooth preparation process, and the attitudes of the Novice and Skilled groups toward the simulator.

The study was divided into 2 phases: the experience phase and the study phase. In the experience phase, the study's designer provided a demonstration of the use of the simulator to the participants and helped them with the alignment and calibration of the HMD. Each participant could adjust the position of the phantom head of the simulator to the position that best suited their operation and was given 30 minutes to familiarize themselves with the use of the equipment. During the experience phase, the instructor provided guidance and assistance when the participant asked for help. In the study phase, each participant prepared a maxillary right central incisor for the all-ceramic crown in the dental simulator and completed a predesigned questionnaire after the preparation.

There were 12 items on the questionnaire. The response options were 1=strongly dissatisfied or strongly disagree, 2=dissatisfied or disagree, 3=neutral, 4=satisfied or agree, and 5=very satisfied or strongly agree. An open-ended question was also included to collect data on the deficiencies of the simulator.

Differences in the assessments of the various aspects of the simulator and the attitudes toward the simulator between the Novice and Skilled groups were analyzed with the Mann-Whitney *U* test. A correlation analysis of the various items related to the simulator and the overall experiences of the users was conducted to determine which aspects affected the overall user experience. SPSS v26.0 (IBM Corp, Armonk, NY) was used to analyze the data.

Results

A prototype of the MR dental simulator for tooth preparation (the Unidental MR Simulator) was successfully developed (Figure 3 and Figure 4).

Figure 5 shows the results of the participants' evaluation of the Unidental MR simulator and their attitudes toward it. Of the participants, 74% (25/34) were satisfied with their overall experience with the simulator, more than 90% (31/34, 91%) agreed that it could stimulate their interest in learning, and more than 80% (28/34, 82%) were willing to use dental simulations for skills training in the future. Table 1 shows the contents of the questionnaire and responses of the 2 study groups to the questionnaire items.

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Figure 3. Exterior training scene of the Unidental Mixed Reality (MR) Simulator.



Figure 4. View from the head-mounted display (HMD) of the virtual training environment.

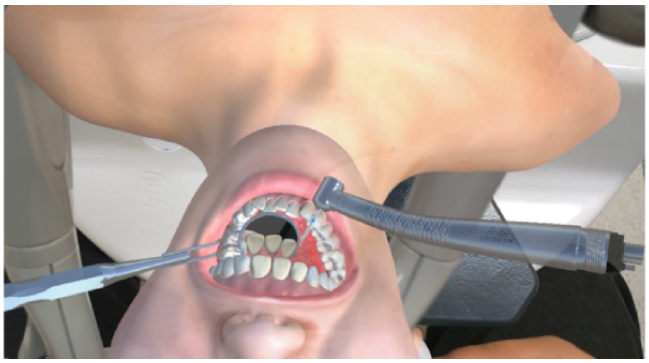
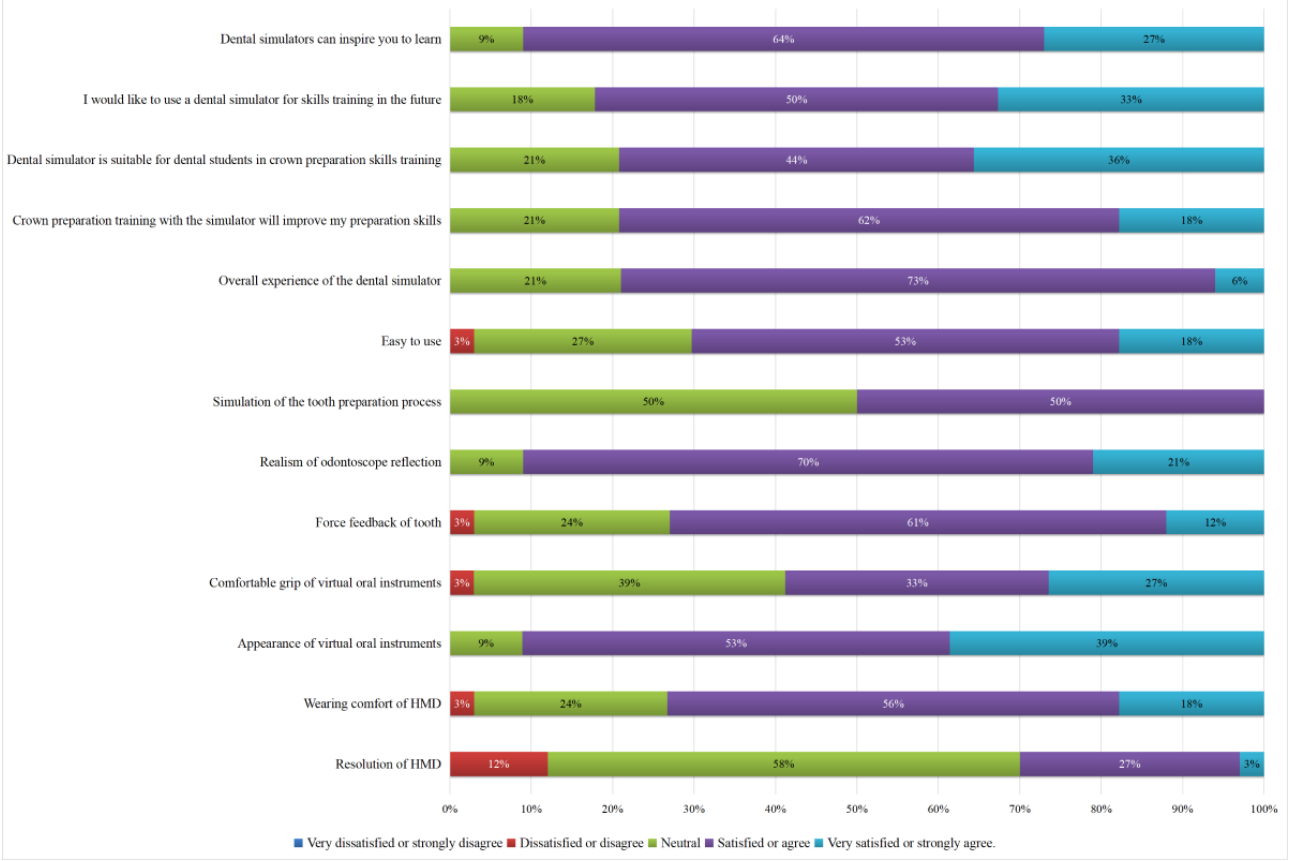


Figure 5. Participants' evaluations of the Unidental Mixed Reality (MR) Simulator and their attitudes toward using it. HMD: head-mounted display.



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Table 1. Responses of the Novice (n=17) and Skilled (n=17) groups to the items on the questionnaire (total n=34).

Questionnaire item	Very dissatisfied or strongly disagree, n (%)		Dissatisfied or disagree, n (%)		Neutral, n (%)		Satisfied or agree, n (%)		Very satisfied or strongly agree, n (%)		*P* value
	Skilled group	Novice group	Skilled group	Novice group	Skilled group	Novice group	Skilled group	Novice group	Skilled group	Novice group	
Resolution of the HMD[a]	0 (0)	0 (0)	2 (6)	2 (6)	10 (29)	10 (29)	4 (12)	5 (15)	1 (3)	0 (0)	.95
Wearing comfort of the HMD	0 (0)	0 (0)	1 (3)	0 (0)	6 (18)	2 (6)	8 (24)	11 (32)	2 (6)	4 (12)	.10
Appearance of virtual oral instruments	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)	1 (3)	8 (24)	10 (29)	7 (21)	6 (18)	.95
Comfortable grip of virtual oral instruments	0 (0)	0 (0)	0 (0)	1 (3)	7 (21)	6 (18)	6 (18)	5 (15)	4 (12)	5 (15)	.97
Realism of the odontoscope's reflection	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	2 (6)	11 (32)	13 (38)	5 (15)	2 (6)	.31
Force feedback of the tooth	0 (0)	0 (0)	0 (0)	1 (3)	2 (6)	6 (18)	12 (35)	9 (26)	3 (9)	1 (3)	.08
Simulation of the tooth preparation process	0 (0)	0 (0)	0 (0)	0 (0)	9 (27)	8 (24)	8 (24)	9 (26)	0 (0)	0 (0)	.79
Easy to use	0 (0)	0 (0)	0 (0)	1 (3)	7 (21)	2 (6)	10 (29)	8 (24)	0 (0)	6 (18)	.04
Overall experience of the dental simulator	0 (0)	0 (0)	0 (0)	0 (0)	3 (9)	4 (12)	12 (35)	13 (38)	2 (6)	0 (0)	.47
All crown preparation training with the simulator will improve my preparation skills	0 (0)	0 (0)	0 (0)	0 (0)	5 (15)	2 (6)	9 (27)	12 (35)	3 (9)	3 (9)	.47
Dental simulator is suitable for dental students in crown preparation skills training	0 (0)	0 (0)	0 (0)	0 (0)	6 (18)	1 (3)	5 (15)	10 (29)	6 (18)	6 (18)	.36
I would like to use a dental simulator for skills training in the future	0 (0)	0 (0)	0 (0)	0 (0)	4 (12)	2 (6)	7 (21)	10 (29)	6 (18)	5 (15)	.89
Dental simulators can inspire you to learn	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	2 (6)	11 (32)	11 (32)	5 (15)	4 (12)	.63

[a]HMD: head-mounted display.

No significant differences were found between the 2 groups in the experience of wearing the HMD (resolution: *P*=.95*;* wearing comfort: *P*=.10), simulation of the dental instruments (*P*=.95), realism of the force feedback of teeth (*P*=.08), simulation of the tooth preparation process (*P*=.79), overall experience with the simulator (*P*=.47), or attitudes towards the simulator (improves skills: *P*=.47; suitable for learning: *P*=.36; willing to use: *P*=.89; inspiring for learning: *P*=.63). However, satisfaction with the simulator's ease of use was significantly higher (*P*=.04) among the students in the Novice group.

The resolution of the HMD (rho=0.375, *P*=.03) and the simulation of the tooth preparation process (rho=0.541, *P*=.001) had significant positive correlations with the students' overall experience of using the simulator, whereas comfort while wearing the HMD, simulation of the oral instruments, realism of the force feedback, and the simulator's ease of use showed no significant correlations with participants' overall experience of using the simulator (Table 2).

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Table 2. Results of the correlation analysis between the responses to the items on the Unidental Mixed-Reality (MR) Simulator and the users' overall experience.

Parameter	Spearman rho	*P* value
Resolution of the HMD[a]	0.375	.03
Comfort of wearing the HMD	0.261	.14
Appearance of the virtual oral instruments	0.321	.06
Comfortable grip of the virtual oral instruments	0.123	.46
Realism of the odontoscope's reflection	0.068	.70
Force feedback of the tooth	0.299	.09
Simulation of the tooth preparation process	0.541	.001
Easy to use	0.055	.71

[a]HMD: head-mounted display.

Discussion

Principal Findings

The world is in an anxious phase as COVID-19 spreads; therefore, it is important to adjust the way medical skills training is conducted during this period [16,17]. Traditional methods of dental skills training use extracted teeth, but if an extracted tooth is not sterilized completely [3], it will produce numerous bio-aerosols in the air when handpieces are used, causing the spread of the virus [16]. Dental simulators change the entire skills training process to a digital process, thereby avoiding this type of viral transmission and improving the safety of the skills training process.

Simulators that have been developed and utilized for tooth preparation training include DentSim (DenX Corp, Jerusalem, Israel) [18], PREPassistant (KaVo, Biberach, Germany) [19], Virtual Education System for Dentistry (Suzhou Digital-health Care Co Ltd, Jiangsu, China) [20], and Simodent (MOOG, Amsterdam, Netherlands) [10]. The first 3 systems use resin teeth, which provide an irreversible training process. The Simodent simulator is similar to the Unidental Simulator, as it uses VR and force feedback technology to simulate real teeth and oral instruments, without material consumption during the training process. The Unidental MR Simulator achieves a 3D display by using the HMD, which has a better image presentation than the 3D glasses combined with the 2D display of the Simodent. Combined with the phantom head, the Unidental MR Simulator can recreate training scenes that are closer to the clinical environment, and it is possible to achieve postural training. The operational postures of the Simodent are fixed during the training process, and users must rotate a 3D mouse in order to change the visual angle, which can be very inconvenient.

The Unidental MR Simulator is specifically designed for developing tooth preparation skills, and it can simulate the clinical environment for different types of tooth preparation. It can be used in skills training for tooth preparation without training material consumption and can solve the problem of adjusting the patient position in clinical treatment scenes. As information from the real world is preserved, a transition from the virtual training environment to clinical operations can be guaranteed, ensuring a training experience that is closer to the clinical environment.

The evaluations of the simulator by the Novice and Skilled groups were not significantly different, except for ease of use, which indicated that the Unidental MR Simulator has good face validity. The Novice group gave a more favorable evaluation of the simulator's ease of use than did the Skilled group. The most likely reason is that the students in the Skilled group were accustomed to performing tooth preparation in real clinical environments and considered the simulator as difficult to use because they were unaccustomed to it.

The results of the correlation analysis demonstrated that the resolution of the HMD and the simulation of the tooth preparation process were of great importance to the overall experience with using a simulator. The results of the questionnaire showed that 59% (20/34) of the volunteers assigned a neutral rating to the resolution of the HMD, 12% (4/34) were dissatisfied, and only 29% (10/34) were satisfied with the HMD's resolution. In the response to the open-ended question ("What are the shortcomings of the dental simulator?"), most participants felt that the resolution of the HoloLens 2 was not adequate. The Unidental MR Simulator uses the HoloLens 2 as the HMD and the MR glasses developed by Microsoft. The resolution of the HoloLens 2 was 2K (2048 x 1080 for both eyes), and its imaging principle is binocular stereo vision; thus, the true resolution was actually 1024 x 1080. The pixel resolution is not ideal during the display of a single tooth. During the test phase, the edges of the target graphics were found to be blurred when the HoloLens 2 was closer to the projection position, and the image presentation was best when the distance between the HMD and the projection position was approximately 50 cm. Consequently, it was necessary to find a suitable position to prepare the tooth in the MR simulator when wearing the HoloLens 2.

Of the participants, 50% (17/34) felt the simulation of the tooth preparation process was mediocre. Among the deficiencies noted in the questionnaires, many participants indicated that the Unidental MR Simulator did not provide a finger rest or a water spraying effect. Many participants also reported that the simulator did not allow for occlusal simulation, so they could not estimate incisal and lingual reductions. The simulation of

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the tooth preparation process showed a significant positive correlation with the overall user experience with the simulator; therefore, the simulator still needs to be improved.

Many participants suggested that the simulator did not have force feedback technology for soft tissues. During the program's testing, when the force feedback of a tooth was used individually, the image frame rate could reach 25 fps with a delay of 35.7 milliseconds, which was within the acceptable range. However, when force feedback for soft tissues was added, the computation and data transmission abilities of the HoloLens 2 were insufficient due to the large amount of data, causing a delay of 2-second to 3-second delay. Therefore, the soft tissue force feedback in the present situation had to be removed. Data on the oral soft tissues were obtained using an intraoral scanner and processed using a mesh format; it will be possible to compress the data size of the soft tissue by reducing the number of meshes in the future. In addition, 5G wireless network technology will greatly increase the transmission rate of high-resolution video data from the server host to the display device, thus reducing response latency [21,22]. Image delays will be solved in the future using a combination of 5G technology and the Unidental MR Simulator.

Dental simulators will be the main method for preclinical skills training in the future. Currently, in many fields, such as flight [23] and laparoscopic surgery [15], simulation is a mandatory training stage before the learner is allowed to perform the relevant skills in a real situation [14]. As the development of technology does not happen overnight, dental simulators are in a phase of continuous development and breakthroughs. Although it is impossible to replace traditional training methods at the present time [24], simulators will play a significant role in the future as technology continues to advance.

Strengths and Limitations

The strength of this study is the combination of MR and force feedback technology in the newly designed and developed Unidental MR Simulator. It could simulate adjusting the position of patients, thereby creating a training environment with a close resemblance to the clinical environment. However, there are some limitations in this study. Participants were divided into only 2 study groups. Yet, in the assessment of the validity of a laparoscopic surgery simulator, van Ginkel et al [14] divided participants into Novice, Intermediate, and Expert groups, which provided a more precise measurement. Barsom et al [15] proposed the assessment criteria necessary for establishing the validity of simulators, which consisted of face, content, construct, concurrent, and predictive validity. In this study, only the simulator's face validity was assessed because of time constraints and technical bottlenecks. Therefore, further experiments are needed to investigate the training effectiveness of the Unidental MR Simulator.

Conclusions

The newly researched and developed Unidental MR Simulator for tooth preparation has good face validity. It can provide users with a better skills training experience by achieving the ability to adjust the position of patients, resulting in a higher degree of similarity to the real clinical treatment environment. The display's visual presentation of the tooth preparation simulation and the force feedback of the teeth require improvements to achieve a better simulation experience.

Acknowledgments

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Authors' Contributions

YL designed the organization of this manuscript and wrote the paper. SW, XZ, YL, LL, PZ, and XZ collected the data and revised the manuscript. HY and YZ conceived the study and revised the manuscript. All of the authors approved the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AR: augmented reality
CBCT: cone beam computed tomography
CPU: central processing unit
HD: high definition
HMD: head-mounted display
LCD: liquid crystal display
MR: mixed reality
VR: virtual reality

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Original Paper

Visual Attention of Anesthesia Providers in Simulated Anesthesia Emergencies Using Conventional Number-Based and Avatar-Based Patient Monitoring: Prospective Eye-Tracking Study

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Abstract

Background: Inadequate situational awareness accounts for two-thirds of preventable complications in anesthesia. An essential tool for situational awareness in the perioperative setting is the patient monitor. However, the conventional monitor has several weaknesses. Avatar-based patient monitoring may address these shortcomings and promote situation awareness, a prerequisite for good decision making.

Objective: The spatial distribution of visual attention is a fundamental process for achieving adequate situation awareness and thus a potential quantifiable surrogate for situation awareness. Moreover, measuring visual attention with a head-mounted eye-tracker may provide insights into usage and acceptance of the new avatar-based patient monitoring modality.

Methods: This prospective eye-tracking study compared anesthesia providers' visual attention on conventional and avatar-based patient monitors during simulated critical anesthesia events. We defined visual attention, measured as fixation count and dwell time, as our primary outcome. We correlated visual attention with the potential confounders: performance in managing simulated critical anesthesia events (task performance), work experience, and profession. We used mixed linear models to analyze the results.

Results: Fifty-two teams performed 156 simulations. After a manual quality check of the eye-tracking footage, we excluded 57 simulations due to technical problems and quality issues. Participants had a median of 198 (IQR 92.5-317.5) fixations on the patient monitor with a median dwell time of 30.2 (IQR 14.9-51.3) seconds. We found no significant difference in participants' visual attention when using avatar-based patient monitoring or conventional patient monitoring. However, we found that with each percentage point of better task performance, the number of fixations decreased by about 1.39 (coefficient –1.39; 95% CI –2.44 to –0.34; *P*=.02), and the dwell time diminished by 0.23 seconds (coefficient –0.23; 95% CI: –0.4 to –0.06; *P*=.01).

Conclusions: Using eye tracking, we found no significant difference in visual attention when anesthesia providers used avatar-based monitoring or conventional patient monitoring in simulated critical anesthesia events. However, we identified visual attention in conjunction with task performance as a surrogate for situational awareness.

(JMIR Serious Games 2022;10(1):e35642) doi:10.2196/35642

KEYWORDS

Anesthesia; eye-tracking technology; patient monitoring; patient simulation; situation awareness; task performance; visual attention; avatar based model; simulated anesthesia; perioperative

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Introduction

Continuous patient monitoring in anesthesia is well established in today's operating theaters and described by the World Health Organization as essential to achieving safe surgical conditions [1]. However, although patient monitoring is a crucial tool for situation awareness in the perioperative setting [2-4], it has several shortcomings, mainly related to the number- and waveform-based monitoring, which may not fully exploit the capabilities of human sensory perception [5-7]. Information overload and alarm fatigue adversely affect care providers' situation awareness [6-9], potentially leading to critical errors during anesthesia [10].

To enhance situation awareness, new approaches are explored [8,11-15], one being avatar-based patient monitoring [16]. Based on the conventional numerical monitoring data, we created the visual-patient-avatar, representing an animated virtual model of the monitored patient. The avatar abstracts the information and enables health care professionals to assess the patient's condition globally and detect subtle but consequential changes [17]. Computer-based studies found that health care professionals retrieved more vital signs with increased diagnostic confidence and reduced perceived workload when using avatar-based instead of conventional monitoring [17-19]. In addition, a high-fidelity simulation study found that the technology helped anesthesia teams to diagnose what was wrong with the patient more quickly [20]. Moreover, the technology received positive feedback from health care professionals and was rated as easy to learn and use [21,22].

Exploring how health care providers visually interact with new medical devices may provide insights into their usage and acceptance and identify areas for improvement. Furthermore, the spatial distribution of visual attention is a fundamental process for achieving adequate situation awareness [23] and thus a potential quantifiable surrogate for situation awareness [24]. A powerful tool for objectifying the visual attention between users and their environment is eye tracking [25].

Using realistically simulated critical anesthesia events, this study used eye tracking to investigate whether avatar-based patient monitoring influences anesthesia providers' visual attention on the patient monitor. Based on the accelerated and simplified information transfer found in the previous studies [17-19,26,27], we hypothesized that the anesthesia provider's visual attention on the patient monitor would decrease when using avatar-based patient monitoring. Furthermore, we tested how several potential confounders such as work experience, profession (ie, physician or nurse anesthetist), or task performance in managing the simulated critical events influenced visual attention on the patient monitor.

Methods

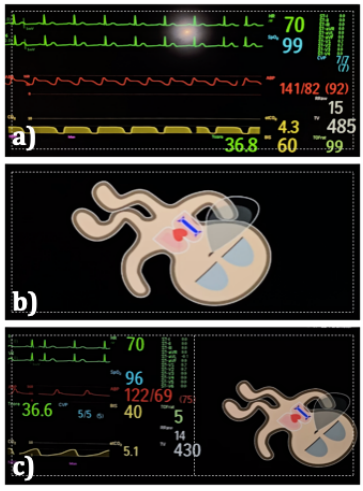
Ethics Approval

The Cantonal Ethics Committee of Zurich, Switzerland, reviewed the study protocol and issued a declaration of no objection (Business Management System for Ethics Committees Number Req-2020-00059). We collected all data under written informed consent by all participants.

Study Design

This investigator-initiated, prospective, randomized, eye-tracking study investigated anesthesia providers' visual attention on the patient monitor during simulated critical anesthesia events. We used three different patient monitor screen modalities (Figure 1). We collected all eye-tracking data during a simulation study conducted in May 2020 at the University Hospital Zurich in Switzerland [20].

Figure 1. Different screen modalities used in the simulation study. a) Conventional number- and waveform-based monitoring. b) only avatar-based monitoring. c) split-screen monitoring, displaying both modalities side-by-side. White boxes indicate our area of interest on the patient monitor used for post hoc semi-automated video analysis.



Study Procedure

We included 52 anesthesia teams consisting of a nurse anesthetist and an anesthesiologist. In randomized order, each team simulated the scenario of severe bronchospasm, myocardial infarction, and malignant hyperthermia once. Each simulated scenario lasted 10 minutes. For each scenario, the teams used a different screen modality: only conventional patient monitoring (ie, number- and waveform-based monitoring), only the avatar-based patient monitoring (visual-patient-avatar), or

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split-screen monitoring consisting of both modalities shown side-by-side simultaneously (Figure 1). In a randomized order, we chose one of the team members to be the team leader. During the scenarios, mentioned leader (ie, either the nurse anesthetist or the physician) wore a mobile eye-tracking device (Pupil Invisible; Pupil Labs, GmbH) while the team managed the critical incident together. We used Research Randomizer Version 4.0 [28] to randomize the order of the scenarios, respective team leaders, and screen modality.

Simulation Environment

We conducted the study in a backup operating room with an analogous setup as the study center's active operating rooms. To enhance the simulation fidelity, we used real medications and airway management tools in addition to a state-of-the-art, full human patient simulator (HAL S301; Gaumard Scientific Company, Inc). We used a Philips InteliVue MX500 (Koninklijke Philips NV) patient monitor to closely resemble the study center's MX550 and MX800 monitors. In the simulation environment, we tagged the patient monitor as our area of interest using pre-generated QR codes. These QR codes enable the Pupil Player software to automatically detect mentioned areas of interest, a prerequisite for automated processing. In Multimedia Appendix 1, we present a video sequence showing an anesthesia team managing a critical anesthesia event, providing a good overview of the simulation environment, the patient monitor used, and the eye-tracking footage.

Data Collection, Video Analysis, and Data Exclusion

Before starting each scenario, we calibrated the eye-tracking device to the participant. We recorded the subject's field of view as a video feed with Pupil Invisible, a mobile eye-tracking device similar in shape and size to regular glasses. The device was connected to a mobile phone that participants carried in their pockets, which served as a power source and storage unit. After each recording, we uploaded the eye-tracking data to a research server and made backup copies on physical hard drives.

For the analysis, we first manually checked the eye-tracking data's quality. Then, for the post hoc semi-automated video analysis, we used Pupil Labs proprietary software Pupil Player on an Acer Aspire V15 Nitro laptop (Acer Inc). Within Pupil Player, we delimited the patient monitor as our area of interest, using the surface tracker plugin. Using the fixations detector plugin and cropping the videos to the start and end of the 10-minute simulation (designated by a bell signal), we were then able to automatically export all fixations and their durations as Microsoft Excel spreadsheets (version 16.58; Microsoft Corporation). During post hoc editing, all recordings were manually stopped five times per recording to ensure the accuracy of the boundaries of the areas of interest. Multimedia Appendix 2 shows an example sequence of the analyzed eye-tracking data in Pupil Player.

Outcome Measures

As our primary outcome, we defined visual attention as fixation count and dwell time. As a fixation, we counted every instance where the subject's gaze rested in one single location within the area of interest for more than 100ms. The dwell-time corresponds to the cumulative time in seconds that the participant's gaze was focused on the predefined area of interest. In addition to visual attention, we collected potentially influencing variables such as screen type (only conventional, only avatar or split-screen monitoring), scenario (bronchospasm, myocardial infarction, or malignant hyperthermia), sequence of the scenarios, profession (nurse anesthetist or anesthesiologist), and work experience (in years). Furthermore, we looked at the relation of our primary outcome and the participant's task performance. The task performance was based on the time required for participants to perform critical diagnostic and therapeutic tasks during the scenarios [20]. An example of such a therapeutic task in the malignant hyperthermia scenario is stopping the trigger or administrating dantrolene.

Statistical Analysis

In this exploratory study design, a power calculation was not performed. For descriptive statistics, we report means with standard deviation and medians with IQRs for continuous data and numbers and percentages for categorical data. We used mixed linear models to analyze fixations count and dwell time. In the models, we included the potentially influential variables task performance, screen type, scenario, sequence of the scenarios, profession, and work experience as covariates. We used R version 4.0.5 (R Foundation for Statistical Computing,) to analyze all data and used Prism 9 (GraphPad Software Inc) to create all figures. We considered a *P*-value of less than .05 to determine statistical significance.

Results

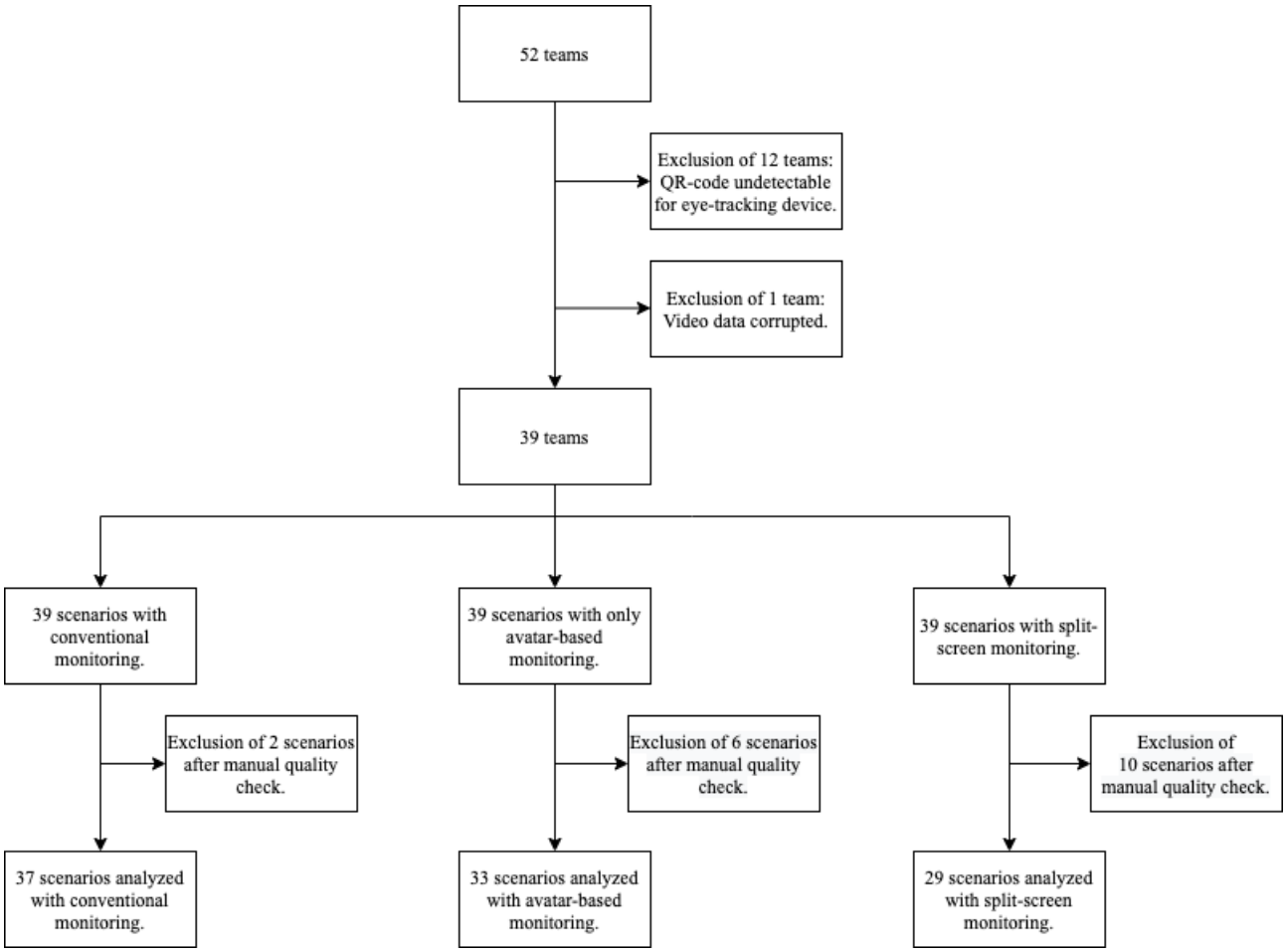
In May 2020, we recruited 52 teams performing 156 simulations. We excluded 12 teams as the eye-tracking setup was revised because the laminated QR codes used reflected and were not detected by the eye-tracking software. In addition, we had to exclude another team because the video footage was incompletely recorded. Finally, after a manual quality check of the data, we excluded 18 scenarios due to inaccuracies in eye-tracking calibration (eg, alternate blinking or wearing of prescription glasses). This left us with 99 ten-minute video sequences for the eye-tracking video analysis. Table 1 provides additional study and participant characteristics. Figure 2 shows the study setup and the exclusion criteria of the video footage in more detail, and Figure 3 summarizes our results.

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Table 1. Study and participant characteristics.

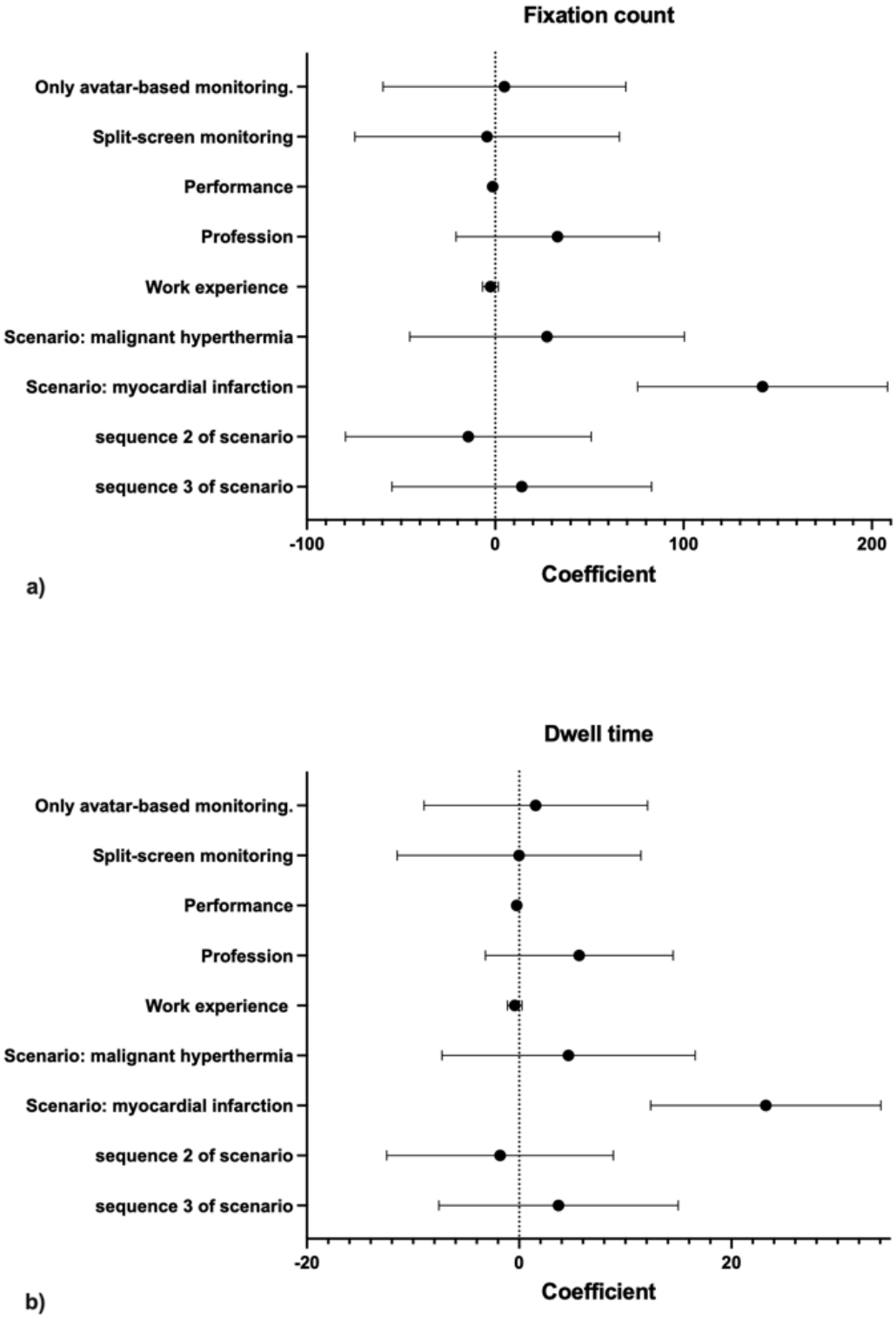
Study characteristics	Values
Number of simulations conducted, N	156
Number of eye tracking analyzed, N	99
Screen modalities, n (%)	
Only conventional monitoring	37 (37%)
Only visual-patient-avatar	33 (33%)
Split-screen monitoring	29 (30%)
Scenarios, n (%)	
Severe Bronchospasm	30 (30%)
Myocardial infarction	36 (36%)
Malignant hyperthermia	33 (33%)
Participant characteristics, N	39
Team leader	
Nurse anesthetist	16 (41%)
Anesthesiologist	23 (59%)
Experience team leader (years), median (IQR)	4 (1.5-8)

Figure 2. Study setup and exclusion criteria. We analyzed 99 ten-minute scenarios performed by 39 anesthesia teams. Exclusion of 12 teams because the laminated QR codes used reflected and were not detected by the eye-tracking software; exclusion of 1 team because the video footage was incomplete; exclusion after the manual quality check of 18 scenarios due to inaccuracies in eye-tracking calibration (e.g., alternate blinking or wearing of prescription glasses).



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Figure 3. Results for adjusted, mixed linear models a) for fixation counts and b) for dwell time. Both models take the potential influential variables screen type (conventional, only avatar or split-screen monitoring), performance in managing the simulated critical anesthesia events (task performance, in percent), profession (nurse anesthetist or anesthesiologist), work experience (in years), the simulated scenario (bronchospasm, myocardial infarction, or malignant hyperthermia) and the sequence of simulation into account.



Visual Attention on the Patient Monitor

Overall, participants had a median (IQR) of 198 (93-318) fixations on the monitor with a median (IQR) dwell time of 30.2 (14.9-51.3) seconds. This means that participants spent around 5% of their visual attention on the patient monitor screen during the 10-minute simulation.

Visual Attention and Screen Modality

Comparing the fixations on the two avatar-based screen modalities with the fixations to conventional monitoring, the mixed linear model yielded a coefficient of 4.89 fixations (95% CI –59.57 to 69.35; *P*=.89) for only avatar-based monitoring and a coefficient of -4.33 fixations (95%CI: –74.55 to 65.90;

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P=.91) for the split-screen modality. This means that participants using only avatar-based monitoring in the simulated scenarios had about five fixations more, and participants using the split-screen modality had about four fixations less than when they used conventional monitoring. However, those results were not statistically significant.

Comparing the dwell time on the avatar-based screen modalities with the dwell time on the conventional monitor using an adjusted, mixed linear model, we found a coefficient of 1.56 seconds (95% CI –8.98 to 12.09; *P*=.78) for only avatar-based monitoring and a coefficient of –0.02 seconds (95% CI –11.50 to 11.46; *P*=1.00) for the split-screen modality. This means that participants using only avatar-based monitoring in the simulated scenarios looked around 1.6 seconds longer on the monitor screen. Participants using the split-screen spent as much time on the patient monitor as those using conventional monitoring. However, those results were also not statistically significant.

Visual Attention and Task Performance

Regarding task performance, the mixed linear models showed that the fixation count and the dwell time decreased with better task performance regardless of the screen modality used (fixation: coefficient –1.39; 95% CI –2.44 to –0.34; *P*=.02 and dwell time: coefficient –0.23; 95%CI –0.4 to –0.06; *P*=.01). Thus, with each percentage point of better task performance, the number of fixations decreased by about 1.39, and the dwell time diminished by 0.23 seconds.

Visual Attention and Other Potentially Influencing Factors

Regarding the potentially influential variables, profession, work experience, and sequence of the scenarios, the mixed linear models yielded no evidence for differences in fixations and dwell time (Figure 3). However, the scenarios themselves differed with respect to fixation and dwell time (Figure 3). Participants had significantly more fixations (coefficient 141.97; 95% CI 75.62 to 208.32; *P*<.001) and a higher dwell time (coefficient 23.23; 95%CI 12.48 to 34.08; *P*<.001) on the patient monitor in the myocardial infarction scenario.

Per-Screen Analysis For Split-Screen Modality

Further, we found that for the conventional half of the split-screen modality, participants had 158 (IQR 63-226) fixations and a dwell time of 24.3 (IQR 10.0-36.8) seconds. For the avatar-based half of the split-screen modality, participants had 44 (IQR 28-84) fixations and a dwell time of 6.8 (IQR 4.3-13.3) seconds. Using a Mann-Whitney test to compare both halves of the split-screen, we found that subjects had significantly fewer fixations (*P*<.001) and significantly less dwell time (*P*=.001) on the avatar part of the patient monitor.

Discussion

Overview

This study investigated whether avatar-based patient monitoring influences the visual attention of anesthesia providers on the patient monitor. We assessed 99 eye-tracking videos of anesthesia personnel managing simulated critical anesthesia events. We found no significant difference in visual attention when anesthesia providers used avatar-based or conventional patient monitoring in simulated critical anesthesia events using adjusted, mixed linear models.

Visual Attention on the Patient Monitor

Anesthesia personnel devoted about 5% of their time to the patient monitor. These results are consistent with findings under real-life conditions [29]. However, other simulation studies reported higher percentages of dwell time on the patient monitor [29,30]. The high fidelity of our simulations may explain these differences. We used an in-situ simulation design and enhanced the simulation's fidelity further by using real medications and airway management tools in addition to a state-of-the-art, full human patient simulator. Thus, it is conceivable that a very realistic simulation is more likely to align participant behavior with outcomes under real-life conditions than a simulation with lower fidelity.

Visual Attention and Screen Modality

We hypothesized that the anesthesia provider's visual attention on the patient monitor would decrease with avatar-based patient monitoring due to accelerated and simplified information transfer found in the previous studies [17-19,26,27]. The basic idea behind this hypothesis is that the qualitative visualization of the patient avatar may lead to a quicker overview of the patient's situation [27,31]. In addition, avatar-based patient monitoring highlights pathophysiological changes, eliminating the time-consuming task of creating a mental model from the various numerical values of the conventional patient monitor [5,6,32]. This may speed up the perception of the situation, lead to fewer fixations and less dwell time on irrelevant vital signs and consequently lead to less visual attention on the patient monitor. In other words, the anesthesia provider knows where to look and can therefore perceive the necessary information with less visual attention. However, this eye-tracking study did not confirm our hypothesis. We found no significant difference in participants' visual attention when using avatar-based monitoring compared to conventional patient monitoring. Unfamiliarity with the novel, avatar-based technology may have masked its potential benefits and may serve as a possible explanation for the finding as all participants used the visual-patient-avatar for the first time. Benefits and acceptance of a new technology depend heavily on users' exposure [33].

However, we found significant differences between the two halves of the split-screen modality. Participants had significantly more visual attention on the conventional part than on the avatar part of the split-screen monitor. This may indicate an interaction effect after all. Perhaps the avatar drew their attention to something (eg, a vital sign outside the norm) that they checked on the conventional screen. Because the qualitative visualization provided by the avatar is intuitive and quickly understood [27,31], participants paid relatively little visual attention to the avatar. To verify the qualitative input, participants had to extract information from the various numbers and waveforms on the conventional screen, a time-consuming task [5,6,32].

Qualitative data collection on how participants used the patient monitors might have helped clarify the result concerning the split-screen modality. Mixed methods are often more powerful

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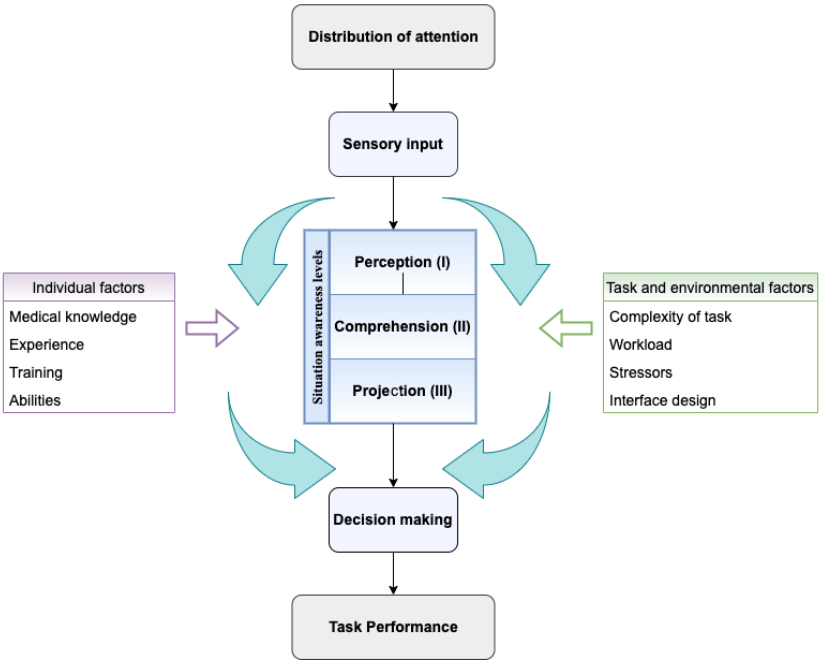
than purely quantitative data analysis for such complex human factors work [34].

Visual Attention, Task Performance, and Situation Awareness

We found that an increase in the anesthesia team's task performance was associated with decreased visual attention. The correlation between the two parameters supports the notion that visual attention and task performance act as indirect indicators of situation awareness [4,30,35-38]. The distribution of visual attention determines what is in the perceptual field and, therefore, contributes to the sensory input, an essential aspect of perception (ie, situation awareness level I) [32]. Good clinical performance in managing the simulated critical anesthesia events comes at the end of good decision-making [38,39], which requires a sufficient understanding (ie, situation awareness level II) and a projection of the situation's near future (ie, situation awareness level III) [32]. A combination of eye tracking and performance measures simultaneously determined what information had been seen and to what degree this information had been perceived and comprehended by the anesthesia provider, giving us a good idea about all three levels of situation awareness achieved (Figure 4).

This study may contribute exciting aspects to the current debate on how to best measure situation awareness [4,30,40-42]. Questionnaires to be used during simulations were proposed and validated as direct measurement tools for situation awareness [4,40]. These direct measurement methods require pausing the simulation to answer the questionnaire before resuming the task again [40]. Evidently, this instrument for assessing situation awareness has limited application in clinical reality, as there is no time to stop the treatment of a critical patient to interview the treating physician. For this reason, we propose the combination of the indirect measurement parameters visual attention and task performance as a surrogate when measurements of situation awareness in clinical praxis are wanted.

Figure 4. Illustration of situation awareness in the context of health care. (Adapted from Schulz, C.M. et al., Situation Awareness in Anesthesia: Concept and Research. Anesthesiology 2013; 118:729–742 and Endsley, M.R., Towards a theory of situation awareness in dynamic systems. Hum Factors 1995; 37:32–64) The framework illustrates that adequate situation awareness is a prerequisite for informed decision-making. The acquisition of situational awareness starts with the perception of sensory inputs (mainly visual and auditive). The inputs must be understood, and based on that understanding, a projection must be made on the present and future of the situation. Now good decision-making can occur, leading to good task performance in the clinical context. Individual, task, and environmental factors may influence all levels of situation awareness. As a situation changes over time, a continuous reevaluation is obligatory to maintain adequate situation awareness.



Visual Attention and Other Potentially Influencing Factors

The three simulated emergencies received different amounts of visual attention. In the myocardial infarction scenario, participants looked at the patient monitor more frequently and had a higher dwell time (Figure 3). In this simulation, there was the additional option of displaying a 12-lead electrocardiogram on the patient monitor, necessary to diagnose myocardial infarction. Although we manually cropped the 12-lead electrocardiogram sequence because we did not analyze it in the context of conventional patient monitoring or avatar-based patient monitoring, participants may have searched for a relatively long time on the monitor to activate the 12-lead electrocardiogram function. This circumstance may explain the significantly increased visual attention on the patient monitor in this scenario.

Furthermore, we found a tendency (not significant) that anesthesia nurses had more fixations and a higher dwell time on the patient monitor (Figure 3). Anesthesia nurses perform important preparatory tasks but generally spend less time with direct anesthesia management. This circumstance may result in anesthesia nurses paying slightly more visual attention to the patient monitor to gain the same level of situational awareness

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as an anesthesiologist whose main task is anesthesia management.

Strengths and Limitations

Our study had several limitations. First, we had to exclude more than one-third of all simulations from our analysis due to technical issues or poor data quality of the eye-tracking footage. Although we used one of the latest mobile eye-tracking devices on the market, we faced several challenges while recording the data: calibrating the glasses for ocular pathologies (eg, alternating squinting or wearing prescription glasses), battery-life issues, or the device slipping of the participants face during physical tasks (eg, manual resuscitation). This shows that despite the massive development of eye-tracking hardware and software in recent years, the technology is still error-prone. Second, all study participants were unfamiliar with avatar-based patient monitoring. Therefore, the results may vary as anesthesia personnel becomes accustomed to this new technology. Third, the median work experience of our participants is relatively low at four years. Finally, we conducted this study in a university hospital in Europe. Therefore, results may differ under other conditions and in other parts of the world.

The study had several strengths. First, we reduced selection bias by balanced participant selection and consistent randomization of the scenario sequence, team leader, and screen-modality. Second, a rigorous manual quality check of the eye-tracking recordings ensured excellent data quality, allowing us to replace error-prone manual eye-tracking analysis with automated analysis. Third, we attempted to circumvent the bias of authenticity inherent in all simulation-based studies [43] through our in-situ study design and our efforts to represent clinical reality as accurately as possible in this high-fidelity simulation study. Finally, we used eye-tracking hardware that was no more distracting than wearing regular glasses to produce high-quality video footage.

Conclusions

We found no significant difference in visual attention when anesthesiologists used the novel avatar-based or the conventional patient monitoring in simulated critical anesthesia events. However, when using the split-screen displaying the conventional monitoring alongside the avatar-based monitoring, significantly less visual attention was paid to the avatar side of the screen. This may indicate an interaction effect. Perhaps the avatar drew the participant's attention to a vital sign outside the norm that they checked on the conventional screen. Because the qualitative visualization provided by the avatar is intuitive and quickly understood, participants paid relatively little visual attention to the avatar. To verify the qualitative input on the conventional monitor screen seems to have taken more time. In addition, we identified visual attention in conjunction with task performance as a valuable surrogate for situational awareness as it covers all three levels of situational awareness.

Acknowledgments

The authors are very thankful to all study participants for their time and effort.

Conflicts of Interest

DWT and CBN are designated inventors of visual-patient-avatar, for which the University of Zurich holds various patents and trademarks. There are cooperation and licensing agreements with Philips Medizin Systeme Böblingen GmbH, Böblingen, Germany; Koninklijke Philips NV, Amsterdam, The Netherlands; Philips Research/Philips Electronics Nederland BV, Eindhoven, The Netherlands; Philips USA, Cambridge, MA, USA. Under these agreements, DWT receives research funding, and DWT and CBN may receive royalties. DWT, CBN, and DRS are designated inventors of Visual Clot technology, for which the University of Zurich holds various patents and trademarks. The University of Zurich signed a letter of intent for cooperation and licensing agreement with Instrumentation Laboratory Company/Werfen Corporation, Bedford, MA, USA, and Barcelona, Spain. Under this and future agreements, they may receive royalties. DWT, CBN, and DRS received travel support for consulting Instrumentation Laboratory, Bedford, MA, USA.

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The other authors do not have any conflicts of interest.

Multimedia Appendix 1
Video sequence of an anesthesia team solving a simulated critical anesthesia event, providing a good overview of the simulation environment, the patient monitor used, and the eye-tracking footage.
[MOV File , 199528 KB - games_v10i1e35642_app1.mov]

Multimedia Appendix 2
Example sequence of the analyzed eye-tracking data.
[MP4 File (MP4 Video), 138444 KB - games_v10i1e35642_app2.mp4]

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Original Paper

A Serious Game for Performing Task-Oriented Cervical Exercises Among Older Adult Patients With Chronic Neck Pain: Development, Suitability, and Crossover Pilot Study

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Abstract

Background: There is sparse research on the effectiveness of therapeutic exercise for the treatment of neck pain in older adult populations. Moreover, there is a lack of research on the use of serious games or virtual reality for the treatment of neck pain in this population.

Objective: The primary aim of this study was to develop and assess the suitability of a serious game for performing task-oriented cervical exercises in patients with neck pain.

Methods: A serious game was designed based on the key features identified by previous studies that designed serious video games for physical and cognitive rehabilitation or exercise. The game in this study was designed to provide an interactive scenario, with the main functionality of the software solution to control a virtual airplane to reach targets using head motions. At the end of the exercise, the application stores the targets reached and missed and the airplane's trajectory. A crossover pilot study was carried out for preliminary evaluation of the suitability of the technology in the older adult population. Men and women over 65 years of age with chronic neck pain were included. Subjects were randomly assigned to two study arms; each arm consisted of a sequence of two 4-week treatments with an intermediate washout period of 4 weeks. The total study duration was 16 weeks due to a final follow-up measure 4 weeks after the end of all treatments. Treatment A consisted of the use of the serious game developed in this study, and treatment B consisted of conventional exercises. Subjects allocated to the A-B study arm received treatment A first, followed by treatment B, and vice versa in the B-A arm. The following variables were assessed: Suitability Evaluation Questionnaire (SEQ) scores, Visual Analog Scale scores, and the number of targets reached in the serious game.

Results: A total of 18 subjects were assessed for eligibility. A total of 13 subjects, aged between 71 and 92 years (mean 81.85, SD 6.82), were finally included and completed the study protocol. The global mean SEQ score was 50.38 (SD 5.35) out of 65

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points, showing good suitability of the serious game. Most patients considered the experience very enjoyable and "real" in terms of the virtual environment and found the information provided to be clear. Also, they believed that the game could be very helpful for their rehabilitation. None of the patients felt any neck pain or discomfort when playing the game, and only 2 patients out of 13 (15%) reported some degree of dizziness, eye discomfort, or disorientation, which did not limit their capacity to finish the session.

Conclusions: The serious game developed in this study showed good suitability for use in adults over 70 years of age with chronic neck pain. The game was a safe method for performing task-oriented cervical exercises, and patients reported very high levels of satisfaction and acceptance after the use of this technology.

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KEYWORDS

video games; neck pain; aged; virtual reality; exercise therapy; physical therapy modalities; technology

Introduction

Neck pain is a highly prevalent musculoskeletal disorder among populations of developed societies that leads to considerable pain, disability, and economic burden [1]. The 1-year prevalence of neck pain in the general population has been shown to be 25.8% (range 4.8%-79.5%) on average, with a point prevalence of 14.4% (range 0.4%-41.5%) [2]. It has been ranked as the 4th-greatest contributor to overall global disability and 21st in terms of overall burden [3]. Between 50% and 85% of the general population who experience neck pain at some point in their lives will report it again 1 to 5 years later [4]. Neck pain has been shown to be higher in females and to increase with age, up to 70 to 74 years, then to decrease with older age [1]. However, results from the Spanish National Health Survey showed that the age group of individuals older than 75 years had a higher prevalence of chronic neck pain (17.32% of males and 34.60% of females) compared to other age groups [5].

Clinical guidelines recommend therapeutic exercise as one of the main therapeutic options for patients with neck pain [6]. However, recent systematic reviews have highlighted the need for further research, as there has only been low- or moderate-quality evidence to support its effectiveness [7,8].

The use of technology in the context of the prescription or performance of therapeutic exercise in patients with neck pain has become more popular in recent years. Serious gaming has been described as the use of computer games where the primary goal is not pure entertainment [9]. Serious games have shown positive clinical results in physical rehabilitation [10] and pain management contexts [11]; they are believed to increase motivation and engagement in health care contexts, in which patients are required to undergo repetitive or mundane tasks that can be perceived as boring or nonmotivating. These games involve participation in challenging game environments that can potentially help patients to be more adherent to treatment regimens, as well as focus their attention on an engaging distraction away from aversive symptoms [9,12].

The use of serious games for neck pain has been evaluated in various investigations, normally described in terms of immersive virtual reality (VR) serious games using head-mounted displays or using nonimmersive flat-screen computer games [13-15]. Recent systematic reviews reported that existing evidence of VR effectiveness in patients with chronic neck pain is promising [15] but recommended further focused, high-quality research due to the low-quality evidence available [14].

Previous research studies have developed serious games or VR systems and investigated their use in terms of assessment of neck kinematics [16,17] and exercise prescription for the treatment of patients with neck pain [18,19]; these treatments showed good psychometric properties [17] and effectiveness in neck pain, disability, satisfaction, or cervical motion kinematics [18]. However, to the authors' knowledge, no previous research has investigated the suitability of the use of similar technologies in the performance of task-oriented neck exercises in older adult populations with chronic neck pain.

There is sparse research on the effectiveness of therapeutic exercise for the treatment of neck pain in older adult populations [8]. Moreover, there is a lack of research on the use of serious games or VR for the treatment of neck pain in this population [14]. Previous research has suggested that VR technology could improve variables such as functional mobility through improving gait quality and resistance in older populations [20]. A recent systematic review also suggested that VR interventions have the potential to improve health outcomes in older adults. However, factors including frailty as well as usability or acceptability of this technology need to be explored in future research in this population [21].

The use of serious video games with motion capture sensors has become popular in physical treatments in the last decade. Some pieces of commercial equipment, mainly Wii or Kinect, have been applied for clinical purposes among older adult people, especially for balance training [22,23] or pain management [24]. Most of these studies demonstrated that functions such as walking, muscle strength, and other motor functions improved. Despite their potential, these kinds of commercial devices have not been designed to monitor and register relevant parameters, such as range of motion (ROM) or movement velocity, which would be useful for quantifying the progress of the intervention. In addition, they are usually designed to train functional movements of the lower and upper limbs.

The video game in this study is controlled by the ENLAZA sensor (Werium Solutions), which consists of an inertial sensor that translates the cervical ROM into mouse pointer displacements. The ENLAZA interface has previously been used for the following purposes: as an input device [25], for

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physical rehabilitation [26], and for biomechanical assessment [27-29]. These previous studies show the potential of the use of the device in the rehabilitation of cervical movement in people with neurological disorders, such as cerebral palsy. However, this device has never been tested in the population being investigated in this paper.

The primary objective of this study was to develop and assess the suitability of a serious game for performing task-oriented cervical exercises in patients with neck pain. The secondary objective was to compare the effects of the serious game with those of conventional therapeutic exercises among older adult patients with chronic neck pain.

Methods

Sensor Description

The sensor development was based on previous work focused on head-mounted interfaces in the field of augmentative and alternative communication for children with cerebral palsy [30,31]. The ENLAZA sensor (Werium Solutions) has also been validated to measure the ROM of different body regions, such as the neck, knee, elbow, and wrist [27-29,32].

The core of the sensor is the MPU-9250 microelectromechanical systems sensor (InvenSense), which integrates a 3D accelerometer, a 3D gyroscope, and a 3D magnetometer. The information from these three sensors is combined to estimate the angular rotation of the sensor [3].

The wearable sensor unit is connected to the computer through Bluetooth connection, following the classic serial port profile of the RN42 wireless module (Microchip Technology Inc). Once the wearable sensor is paired with the computer, the sensor streams orientation data, which can be read through a virtual serial communication port.

Video Game Description: Active Airlines

The video game in this study has been designed based on the key features identified by previous studies involving the design of serious video games for physical and cognitive rehabilitation or exercise. Previous research has shown that the most relevant key feature is to keep players engaged with a challenge adapted to the skills of a particular user [33-35]. This is a critical point when the users are older adult people, due to their physical and cognitive skills.

Based on the key features described by the literature, we developed the software component of the solution, called Active Airlines. This is a Windows-based application, using the C# language in Unity's integrated development environment, designed to provide an interactive scenario for assessment and exercise of cervical ROM. The main functionality of the software solution was to control a virtual airplane to reach targets using head motions (Multimedia Appendix 1).

The key factors described in the literature were adapted to fulfill the physical and cognitive skills of our target population, following these criteria:

1. Motor control. The user performs a specific movement that requires the anticipation of feedback; as a result, outcomes may be critical to motor learning. The number of targets, the target size, and the airplane speed are customizable. These targets are shown randomly every time the game starts.
2. Cervical ROM. The distance between targets is customizable as a function of the cervical ROM required to reach them.
3. Cognitive challenge. The video game presents a simple and understandable goal-directed task.
4. Sensitivity to auditory and visual limitations of the target population. There is high contrast between the different elements of the scene and representative sounds when an event occurs.
5. Biofeedback. The airplane moves according to the user's head movement, and the video game offers visual and auditive stimuli when the user succeeds and fails.
6. Meaningful play. To provide an incentive to keep playing, besides perceiving the immediate result of the reached target via visual and auditive stimuli, a final score of the reached targets is shown.

The control algorithm follows absolute mapping, which means that a given angular orientation of the head always corresponds to the same position of the virtual airplane. Absolute mapping is more interesting than relative mapping (ie, based on a relative variable, such as movement speed or acceleration) for rehabilitation purposes, because the system demands an upright posture to control the game successfully.

The three degrees of freedom of the cervical joint (ie, 3D space), corresponding to flexion-extension, right-left inclination, and right-left rotation, have to be translated into the vertical and horizontal coordinates of the virtual airplane (ie, 2D space). The vertical coordinate (y) is always controlled by the angle of flexion-extension, and the horizontal coordinate (x) can be controlled by the angular inclination or rotation of the head. The software solution integrates a graphical user interface to configure the following options (Multimedia Appendix 2):

1. Control of the horizontal coordinate using inclination or rotational movement.
2. Control of the virtual airplane in 1D (ie, vertical or horizontal axis) or 2D (ie, vertical and horizontal axes).
3. Number of targets to reach.
4. Required cervical ROM to reach the targets (ie, angular sensibility).
5. Level of difficulty (eg, speed of target appearance).

Absolute mapping uses the Euler angles generated from the direction cosine matrix (DCM) using the YZX Euler convention. The x and y coordinates of the airplane were calculated according to the following formulas:



where R_T is the result of multiplying the R_{cal} matrix (ie, the DCM in neutral posture) by R_S (ie, the DCM in every sample). The x and y values represent the horizontal and vertical coordinates of the airplane (pixels), respectively. R_H and R_V represent the horizontal and vertical distance between targets

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(pixels), respectively. α_T and β_T represent the required ROM to reach the targets (angular degree).

Before starting the exercise, a calibration process is required to establish the R_{cal} matrix. The subject maintains a neutral posture (ie, head in the upright position) for 2 seconds, and the physiotherapist calibrates the device by clicking a specific button on the software application.

Finally, the software application includes a database to register the subjects' data. At the end of the exercise, the application stores the targets reached and missed and the airplane's trajectory (Multimedia Appendix 3). The number of reached and missed targets together represents the performance score, which is directly related to the motor control of the head.

Pilot Study Design

The usability analysis and preliminary evaluation of the effects were carried out through a randomized, single-blind, crossover clinical pilot study. Subjects were recruited from the Residencia Municipal de Griñón, a nursing home in Madrid, Spain. The trial was conducted under the criteria of the CONSORT (Consolidated Standards of Reporting Trials) statement [36]. This study was approved by the Ethics Committee of the Centro Superior de Estudios Universitarios La Salle, Universidad Autónoma de Madrid (approval code: CSEULS-PI-181/2017). All participants provided signed informed consent before participation.

As the primary objective of this study was to develop a serious game and then assess its suitability, and not to measure the outcome of the intervention through a randomized controlled trial, the study was not retrospectively registered.

Participants

Men and women over 65 years of age with chronic neck pain were included. Subjects selected for this study had to meet the following inclusion criteria: be at least 65 years of age; understand, write, and speak Spanish fluently; have suffered from neck pain for more than 12 weeks [37]; scored more than 5 points on the Neck Disability Index (NDI); have no cognitive impairment below 20 points, as assessed by the Mini–Mental State Examination (MMSE) scale; and be willing to undergo treatment. In addition, the following exclusion criteria were used: red-flagged medical history (ie, tumor, fracture, metabolic diseases, and rheumatoid arthritis), fibromyalgia syndrome, previous neck surgery, or neck pain accompanied by vertigo caused by vertebrobasilar insufficiency. The subjects were recruited by word of mouth, through individual interviews with patients.

Research Team

The research team was composed of three physiotherapists, which included two evaluators and one person who administered the treatment and was in charge of assigning the groups so that the outcome evaluators were blinded to patients' group assignments. The evaluators were in charge of recording the initial selection data and verifying that participants were eligible to participate in the study. At the end of each treatment block, they collected the data obtained from the participants. All participants were asked not to discuss the treatments they were undergoing with the evaluators so as not to influence the records. In the case of noncompliance, patients were excluded from the trial.

Randomization: Sequence Generation

All subjects who fulfilled the study selection criteria were randomly assigned to one of two study arm groups (see Interventions section below). Randomization was performed using the online computer program Prism (version 5; GraphPad Software) to assign participants to the serious game group or the conventional exercise group.

Primary Outcomes

The Suitability Evaluation Questionnaire (SEQ) was designed to test items such as satisfaction, acceptance, and security of use in virtual rehabilitation systems. It is an easy-to-understand questionnaire, with a reasonable number of straightforward and clear questions that are evaluated on a scale from 1 ("not at all" or "very easy") to 5 ("very much" or "very difficult"). The questionnaire addresses different items related to virtual rehabilitation systems, with 14 questions on feeling, satisfaction, and realism; the last question is open ended, where patients, if they felt uncomfortable, were asked the reasons why. The minimum score is 13 points, and the maximum score is 65 points. Previous research has used the SEQ to evaluate the suitability of virtual rehabilitation in older adults [38].

Secondary Outcomes

Number of Targets Reached in the Serious Game

The number of targets reached by each user in the serious game group was evaluated as a percentage in order to compare the proportion of hits across sessions, representing the performance of the craniocervical motor control. This outcome was only registered during the serious game experimental group sessions; in addition, this outcome was used as complementary data regarding whether the older adults included in the study could improve their game performance over 4 weeks of consecutive sessions. Therefore, this outcome did not allow for any comparison between groups nor for analysis that would evaluate whether improvements in the game scores were associated with changes in pain or disability.

Visual Analog Scale

The Visual Analog Scale (VAS) is a horizontal line used to grade the intensity of pain, from no pain to the maximum possible pain. Poor pain control is considered to be above 3 points on the VAS [39], and the minimum detectable change is 2 points [40]. This scale was used to measure neck pain intensity at baseline and at each of the follow-up points of the pilot study by asking each patient to mark a vertical line on the scale representing the intensity of neck pain in the last 24 hours.

Control Variables

Neck Disability Index

The NDI is a self-completed questionnaire with 10 items: intensity of neck pain, self-care, lifting, reading, headache, ability to concentrate, ability to work, ability to drive, sleep activities, and leisure activities. Each of the items has six possible responses representing six progressive levels of

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functional ability, with scores ranging from 0 to 5. The total score is expressed in percentage terms with respect to the maximum possible score. The completion time is reasonably short, and a validated Spanish version was used [41]. The NDI has been shown to be a responsive scale among older adult patients with nonspecific neck pain [42]. The minimum detectable change is 5 out of 50 points, and a change of 7 points is recommended for achieving a clinically relevant difference [43].

Mini–Mental State Examination

To measure cognitive impairment, we used an adapted and validated Spanish version of the Folstein MMSE [44]. This is a screening test for dementia that is also useful in the evolutionary follow-up of dementia. This questionnaire explores short- and long-term memory, orientation, information about everyday events, and calculation capacity. Information was collected by means of an auto-administered questionnaire. The results were evaluated according to the following number of errors: 0 to 2 (normal), 3 to 4 (mild cognitive impairment), 5 to 7 (moderate cognitive impairment), and 8 to 10 (severe cognitive impairment). When using this scale, it is important to consider the educational level of the person taking the test. In cases of low educational level (ie, elementary education), one additional error is allowed for each category. In cases of high educational level (ie, university level), one fewer error is allowed for each category (35 points maximum). Two cutoff points are considered according to age: 24 points for those 65 years of age and older, and 29 points for nongeriatric adults. The classification brackets for points are as follows: 30 to 35 (normal), 24 to 29 (borderline), 19 to 23 (mild), 14 to 18 (moderate), and less than 14 (severe) [44].

Interventions

Overview

For the crossover study, subjects were randomly assigned to one of two study groups. Group A-B started by testing the serious game for 4 weeks (8 sessions), followed by a 4-week washout period, after which they performed conventional exercises for 4 weeks (8 sessions). Group B-A started with the conventional exercises and then tested the game after the washout period. The total study duration was 16 weeks, including a final follow-up measure 4 weeks after the end of all treatments.

Serious Game: Treatment A

Treatment A consisted of the use of the Active Airlines serious game twice a week for 4 weeks. The sensor had to be held at forehead level with an elastic band and Velcro, with a Windows computer in front of it in order to run the application correctly; the computer screen was placed at eye level, and the keyboard was placed approximately in a straight line with the xiphoid process. Within the Active Airlines application, parameters could be set, such as difficulty, degrees of rotation, movement to be treated, and number of objects to be picked up. An “easy” difficulty level was selected for all subjects, with a marked maximal mobility of 20º to 30º in order to cover the entire screen (ie, flexion-extension movements moved the plane down or up, respectively, and lateral inclinations moved the plane to the sides), leaving rotation unworked in this study. The location of each of the targets was shown on the screen randomly, and the time elapsed between targets was 5 seconds. The participant performed the exercise twice (ie, two series) in each session, and the application was set up so that the participant aimed to pick up 21 targets per series, for a total of 42 points. Considering that the patient had to perform a combined movement (ie, flexion-extension combined with right-left lateral flexion) to reach each of the targets, the total number of combined movements performed by patients in each session was 42 (ie, one per target), and the total game duration was 210 seconds (ie, 5 seconds per target). At the end of each series, the targets picked up were counted and recorded as a percentage value (ie, the score for the day was recorded as the total percentage from the two series). Once the first series was finished, the exact same procedure was performed again, thus ending the serious game session for that day. In this group, the sessions included only one participant at a time.

Conventional Exercise: Treatment B

Treatment B consisted of a therapeutic exercise protocol that was based on two weekly sessions of conventional physical therapy for 4 weeks; this consisted of an exercise program of about 30 to 45 minutes in length for groups of 2 to 4 patients. This program included 5 minutes of stairs, 10 minutes of pedaling, 5 minutes of pulleys, and 5 minutes of obstacle walking. In addition, three sets of 12 repetitions of cervical joint mobility exercises in all ranges were added: cervical flexion-extension, right-left lateral flexion, and cervical rotations. The exercises were not performed with resistance, but were only self-loading at the beginning of the ROM.

Procedure

Once the informed consent forms were revised and signed by the participants, the VAS, NDI, and MMSE were administered at baseline. The study had a total duration of 16 weeks. First, the therapist assigned each study group to one study arm. One group followed the A-B sequence with an intermediate washout period of 4 weeks. The other group received the treatment in the B-A order, also with a washout period of 4 weeks. Finally, the last assessment of outcomes was carried out 4 weeks after the treatment finished. Thus, the distribution of the evaluators’ measurements was as follows: baseline (0 weeks), after first intervention (4 weeks), washout period (8 weeks), after second intervention (12 weeks), and follow-up period (16 weeks).

In the washout and follow-up weeks, no exhaustive follow-up was performed, and participants were simply reminded, sporadically, to keep up with the previously prescribed exercises. These exercises were based on cervical joint mobility.

The evaluation of the VAS was carried out at all follow-up periods, and the SEQ was included in the evaluation at the end in order to assess the degree of suitability of the inertial sensor and the Active Airlines game.

Data Analysis

All statistical tests were performed with SPSS Statistics for Windows (version 27; IBM Corp) with a significance level of $P<.05$. Demographic data were analyzed with descriptive

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statistics and were represented as mean (SD) for each of the variables. The Shapiro-Wilk statistic was used to test the normal distribution of the data. Since this was a randomized crossover clinical trial, it was necessary to analyze the difference in the variables of interest between each of the interventions. For this purpose, the Student *t* test was used for related measures, to compare between groups and within groups.

Also, based on the crossover design, other effects had to be analyzed, such as the residual effect, period effect, and sequence effect. In order to guarantee as high a quality as possible in the analysis, the following tests were performed, according to previous recommendations [45].

To verify that the interventions had an effect over time, the residual effect of the interventions was analyzed by performing a Student *t* test for related samples, comparing the initial measurement with the measurement after the washout period. In the case of statistically significant results, the Wilcoxon signed-rank test was used to repeat the analysis, subdividing by intervention group to identify the intervention that produced the residual effect. The period effect was also analyzed by performing a Student *t* test for related samples, comparing the measures after the first intervention (4 weeks) and after the second intervention (12 weeks).

Finally, to test the sequence effect, the change produced in the variables of interest with each of the interventions was analyzed by comparing the A-B sequence and the B-A sequence. For example, if there was no sequence effect, the value obtained for the VAS variable after having received the serious game intervention should be the same, either in the first period or in the second period. Therefore, the difference between baseline and postintervention for each variable was calculated for each group and compared, based on whether the A-B or B-A sequence was followed.

In addition, for the study of the control variables and variables related to the use of the technology, the Student *t* test for related measures and the repeated-measures analysis of variance (ANOVA) test were used.

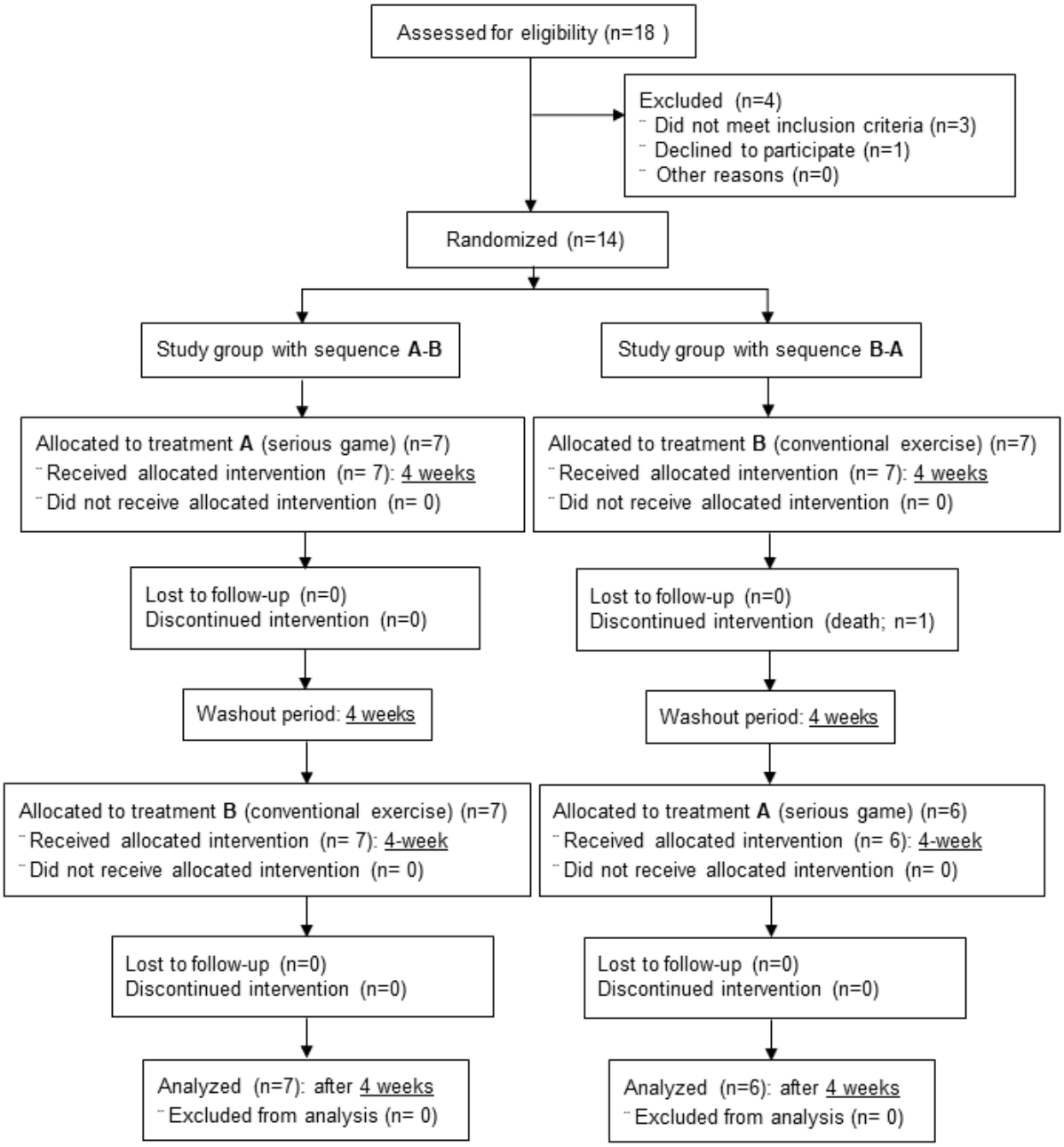
Results

Overview

A total of 18 subjects were evaluated for inclusion in the study. Of these, 14 subjects, aged between 71 and 92 years (mean 81.85, SD 6.82), were finally included (Figure 1). There was 1 participant lost due to death in the B-A sequence study group during the first 4-week period of treatment. Demographic variables and all baseline variables showed a normal distribution, with *P* values greater than .05 in the Shapiro-Wilk test. Descriptive data for the demographic variables are shown in Table 1.

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Figure 1. Participant flowchart.



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Table 1. Baseline descriptive data and normality test.

Variable	Value (N=14)	*P* value[a]
Sex (women), n (%)	9 (64)	N/A[b]
Age (years), mean (SD)	81.85 (6.82)	.31
Weight (kg), mean (SD)	68.16 (8.38)	.82
Height (cm), mean (SD)	1.54 (0.07)	.12
BMI, mean (SD)	28.65 (3.58)	>.99
Mini–Mental State Examination score[c]	31.08 (3.01)	.13
Neck Disability Index score[d]	15.77 (8.19)	.98

[a]*P* values are based on the Shapiro-Wilk test, which measures the distribution of variables; variables showed a normal distribution.

[b]N/A: not applicable; the Shapiro-Wilk test cannot be performed on categorical data.

[c]The classification brackets for this scale are as follows: 30 to 35 (normal), 24 to 29 (borderline), 19 to 23 (mild), 14 to 18 (moderate), and less than 14 (severe).

[d]The minimum detectable change for this index is 5 out of 50 points, and a change of 7 points is recommended for achieving a clinically relevant difference.

Suitability of the Technology

The scores obtained in each of the items of the SEQ are presented in Table 2. The global mean score for the SEQ was 50.38 (SD 5.35) out of 65 points, showing good suitability of the Active Airlines serious game. Most of the patients considered the experience to be very enjoyable and "real" in terms of the virtual environment, and found the information provided to be clear. Also, most of them thought that the game could be very helpful for their rehabilitation.

The results of the SEQ also showed that none of the patients felt any neck pain or discomfort when playing the game, and only 2 patients out of 13 (12%) reported some degree of dizziness, eye discomfort, or disorientation. These two events of dizziness were also recorded separately by researchers as minor adverse effects. Both subjects were able to finish the session and kept participating in the study. No other adverse events occurred during any of the treatment sessions.

Moreover, most patients considered the task to be difficult and the system difficult to use, suggesting that the game presented a challenge for them across the different treatment sessions.

Table 2. Suitability of the technology based on results from the Suitability Evaluation Questionnaire (SEQ).

Question	SEQ score, mean (SD)[a]
Q1. How much did you enjoy your experience with the system?	4.92 (0.277)
Q2. How much did you sense being in the environment of the system?	3.92 (1.115)
Q3. How successful were you in the system?	3.85 (1.214)
Q4. To what extent were you able to control the system?	3.62 (1.261)
Q5. How real is the virtual environment of the system?	4.62 (0.961)
Q6. Is the information provided by the system clear?	4.31 (0.947)
Q7. Did you feel discomfort during your experience with the system?	1.00 (0.000)
Q8. Did you experience dizziness or nausea during your practice with the system?	1.54 (1.330)
Q9. Did you experience eye discomfort during your practice with the system?	1.54 (1.330)
Q10. Did you feel confused or disoriented during your experience with the system?	1.23 (0.832)
Q11. Do you think that this system will be helpful for your rehabilitation?	4.69 (0.630)
Q12. Did you find the task difficult?	4.69 (0.855)
Q13. Did you find the devices of the system difficult to use?	4.77 (0.599)
Total for all questions	50.38 (5.35)

[a]Questions were scored on a 5-point Likert scale, ranging from 1 ("not at all") to 5 ("very much"). Reverse scoring was performed for Q7-Q10, Q12, and Q13, ranging from 1 ("very easy") to 5 ("very difficult").

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Number of Targets Reached in the Serious Game

A repeated-measures ANOVA showed that the number of targets reached during serious game–playing increased with each session. The results showed statistically significant effects over time (F_1=22.14; P<.01), as the percentage of targets reached during the game progressively increased in each session (Table 3).

Table 3. Success in the serious game during each treatment session.

Session	Success (%), mean (SD)[a]
1	68.86 (24.87)
2	71.06 (24.63)
3	82.05 (19.50)
4	82.96 (21.14)
5	85.16 (15.25)
6	83.51 (13.31)
7	86.44 (16.02)
8	89.74 (12.95)
Percentage change from session 1 to 8	24.90 (20.85)

[a]The serious game software only returns the percentage of success in the game.

Pilot Study Results for Pain

There were no significant differences between the effects of the serious game and conventional exercises when considering all subjects who received each treatment, independent of the study group sequence, but both treatments showed improvements in neck pain intensity (Table 4).

A statistically significant residual effect was found. The Wilcoxon signed-rank test, used as a secondary analysis subdividing by group, showed a statistically significant residual effect only for the conventional exercise intervention (baseline: mean 5.36, SD 1.84; washout: mean 3.21, SD 2.45; Z=–2.38, P=.02).

Table 4. Comparison between treatments, intratreatment changes, and residual effect.

Treatment[a]	Baseline VAS[b] score, mean (SD)	Posttreatment VAS score, mean (SD)	P value[c]	Washout period VAS score (residual effect), mean (SD)	P value[c]
Serious game	4.92 (1.88)	3.77 (1.92)	<.001	3.69 (2.13)	.01
Conventional exercise	4.92 (1.88)	3.46 (2.22)	<.001	3.69 (2.13)	.01

[a]No statistically significant differences between treatments were detected in the measurement after the intervention (serious game vs conventional exercise).

[b]VAS: Visual Analog Scale.

[c]P values are based on the Student t test.

Period effect analysis revealed that there were statistically significant differences between the end of the first period and the end of the second period. The mean VAS score at baseline was 4.92 (SD 1.88), the score after the first treatment was 4.15 (SD 1.57), and the score after the second treatment was 3.08 (SD 2.36; P=.003).

Finally, the sequence effect analysis for the serious game intervention showed that pain was reduced to a greater extent with the B-A sequence (VAS score mean difference –1.64, SD 0.75) than with the A-B sequence (VAS score mean difference –0.58, SD 0.49). On the other hand, for the conventional exercise treatment, pain was reduced to a greater extent with the A-B sequence (VAS score mean difference –2.08, SD 1.02) than with the B-A sequence (VAS score mean difference –0.93, SD 0.45). Table 5 shows the changes in pain that occurred after treatment in each of the study group sequences.

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Table 5. Sequence effect analysis.

Treatment and sequence[a]	VAS[b] score, mean difference (SD)[c]	*P* value[d]
Serious game		
A-B	–0.58 (0.49)	.01
B-A	–1.64 (0.75)	
Conventional exercise		
A-B	–2.08 (1.02)	.04
B-A	–0.93 (0.45)	

[a]Sequence A-B is serious game followed by conventional exercise; sequence B-A is conventional exercise followed by serious game.

[b]VAS: Visual Analog Scale.

[c]This value represents the mean difference between baseline and posttreatment measures.

[d]*P* values are based on the Student *t* test. *P* values for each group are reported in the top row of that group.

Discussion

Principal Findings

This study allowed for the development of a serious game to provide a suitable solution for the performance of task-oriented cervical exercises for people with neck pain.

The older adult population included in the study showed very good results in terms of satisfaction, acceptance, and security when using this technology. Moreover, minor adverse events were scarce in the pilot population sample included in the study. Therefore, the older adult population aged over 80 years with chronic pain might benefit from this intervention, but some factors would need further research, such as technological acceptance, visual and hearing disorders, and cognitive impairments, among others, which can become barriers for the success of the intervention.

Although the design of the study did not allow for measuring treatment adherence, the playful approach and integrated technology used may be capable of increasing adherence to the exercise treatment. Further research is needed to investigate whether these technologies are associated with higher adherence or patient motivation compared with conventional exercise programs, which can sometimes be considered more repetitive or boring [12].

The main clinical implication from this study is that patients with neck pain could safely use this serious game with high levels of satisfaction and acceptance. Although the clinical findings from the pilot study are limited and do not allow for medium- or long-term evaluation of its effects, it can be hypothesized that patients' satisfaction and adherence to exercise may be increased when performing therapeutic exercise through the serious game. Moreover, this serious game has the potential to be used in a telerehabilitation context by physiotherapists; this could result in important advantages regarding cost-effectiveness [46] and the possibility to perform therapeutic exercise at home, without having to make tiring journeys [47], which could be especially relevant at some stages of physiotherapy treatment in the older adult population with neck pain.

The main clinical findings of the pilot study are as follows: (1) both conventional exercise and the use of the serious game had the same effect in reducing neck pain in the older adult population and (2) the A-B sequence (ie, playing the serious game first followed by conventional exercise) reduced pain more than the B-A sequence (ie, conventional exercise first followed by playing the serious game).

On the one hand, the results of this study appear to support the findings of another recent study that suggested that performing exercises with immersive VR is not superior to exercises alone without VR among young adult patients with neck pain [48]. On the other hand, the results of this research are not supported by those found in another study that compared nonimmersive VR exercises with proprioceptive training in patients with neck pain, using eight sessions over a period of 4 weeks. That study observed that patients in the VR group improved more in terms of pain and disability than the group that performed proprioceptive exercises [49].

Another study in which VR was added to neck exercises in one group and compared to a group that performed exercises alone during four to six treatment sessions found that only the group that included VR improved more in terms of disability and ROM in rotation. However, there was no improvement over the exercise-only group in terms of pain intensity. Those results support the ones obtained in this study; although we did not measure the ROM variable, patients improved in accuracy when playing the video game in successive sessions [18].

The results of this study were novel in terms of the use of a serious game in a population of adults over 70 years of age, but we must analyze a series of important limitations for their possible applicability in clinical practice. First, the characteristics of the pilot study with a reduced sample size limit the generalizability of the results in terms of the suitability of the serious game in this older adult population and its effects on the treatment of neck pain. Second, the study had a crossover versus parallel design; therefore, it is more difficult to demonstrate the isolated effects of each therapy. Third, a control group was not included to investigate whether the therapies used had a greater effect than the natural evolution of neck pain. Fourth, psychological variables such as kinesiophobia or anxiety, which have been shown to influence the effects of interventions

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for neck pain in other studies with VR, were not measured. The fifth limitation is that the washout period was shown to be ineffective according to the statistical analysis of this study; for future studies, washout periods longer than 4 weeks should be considered.

Conclusions

The serious game developed in this study showed good suitability when used in a population of adults over 70 years of age with chronic neck pain. It was a safe method for performing task-oriented cervical exercises, and patients reported very good levels of satisfaction and acceptance after the use of this technology. Although preliminary results on the effects of using the serious game showed short-term improvements in pain intensity, further research with larger samples is needed.

Acknowledgments

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Conflicts of Interest

RR is the CEO of Werium Solutions.

Multimedia Appendix 1
Screenshot of the Active Airlines serious game.
[PNG File , 1397 KB - games_v10i1e31404_app1.png]

Multimedia Appendix 2
Settings for the graphical user interface of the Active Airlines serious game.
[PNG File , 156 KB - games_v10i1e31404_app2.png]

Multimedia Appendix 3
Subjects' data regarding targets reached and missed in the Active Airlines serious game.
[PNG File , 135 KB - games_v10i1e31404_app3.png]

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Abbreviations

ANOVA: analysis of variance
CONSORT: Consolidated Standards of Reporting Trials
DCM: direction cosine matrix
MMSE: Mini–Mental State Examination
NDI: Neck Disability Index
ROM: range of motion
SEQ: Suitability Evaluation Questionnaire
VAS: Visual Analog Scale
VR: virtual reality

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Original Paper

Viewpoint: Virtual and Augmented Reality in Basic and Advanced Life Support Training

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Abstract

The use of augmented reality (AR) and virtual reality (VR) for life support training is increasing. These technologies provide an immersive experience that supports learning in a safe and controlled environment. This review focuses on the use of AR and VR for emergency care training for health care providers, medical students, and nonprofessionals. In particular, we analyzed (1) serious games, nonimmersive games, both single-player and multiplayer; (2) VR tools ranging from semi-immersive to immersive virtual and mixed reality; and (3) AR applications. All the toolkits have been investigated in terms of application goals (training, assessment, or both), simulated procedures, and skills. The main goal of this work is to summarize and organize the findings of studies coming from multiple research areas in order to make them accessible to all the professionals involved in medical simulation. The analysis of the state-of-the-art technologies reveals that tools and studies related to the multiplayer experience, haptic feedback, and evaluation of user's manual skills in the foregoing health care-related environments are still limited and require further investigation. Also, there is an additional need to conduct studies aimed at assessing whether AR/VR-based systems are superior or, at the minimum, comparable to traditional training methods.

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KEYWORDS

basic and advanced life support; first aid; cardiopulmonary resuscitation; emergency; training; simulation training; medical simulation; healthcare simulation; virtual reality; augmented reality

Introduction

Life support training has become more important in recent decades, creating mass training possibilities that have the potential to significantly reduce the number of deaths due to sudden cardiac arrest [1,2]. In emergency health care, it is crucial to know the differences between advanced training targeted at qualified professionals and training of the general population and paramedics [3]. Qualified professionals need to know how to use mechanical tools and drugs, in addition to performing lifesaving tasks, and general population cohorts need to know and understand how to perform basic manual skills (eg, maintaining an open airway and performing chest compressions) while waiting for professional help. It is important that both professionals and untrained rescuers are able to train with safe and realistic emergency medical scenarios. Training should provide opportunities for frequent rehearsal and assessment of a required core knowledge base in order to achieve optimal levels of practical expertise in stressful situations [4]. Life support training is typically accomplished via the use of manikins and simulated scenarios; moreover, the use of disruptive technologies like virtual reality (VR) and augmented reality (AR) have garnered more interest in training [5-7], beginning with nonimmersive serious games, up to immersive

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VR, AR, and mixed reality (MR) that provides haptic feedback and realistic interactions. This is probably due to the fact that these technologies can enhance immersivity, defined as the subjective impression to be part of a realistic experience [8], which further strengthens medical learning [9-11]. That said, efficacy studies on VR and AR simulations for emergency training have not been sufficiently performed, as the majority of the research studies in the area are proofs-of-concept. In fact, studies in the field have been presented in scientific journals and conferences that include many different research areas, such as computer science, engineering, medicine, and simulation. The resulting fragmentation and mix-and-match of studies in immersive medical emergency training have resulted in a jumble of different terminologies and aims, making it difficult to have a comprehensive overview of many existing immersive applications to date.

Our goal for this paper is to provide a comprehensive analysis and review of state-of-the-art of VR- and AR-based simulators for life support training. Our intention is to target professionals involved in medical simulation (ie, physicians, medical instructors, simulation specialists, engineers, technicians, computer scientists, and VR and AR developers).

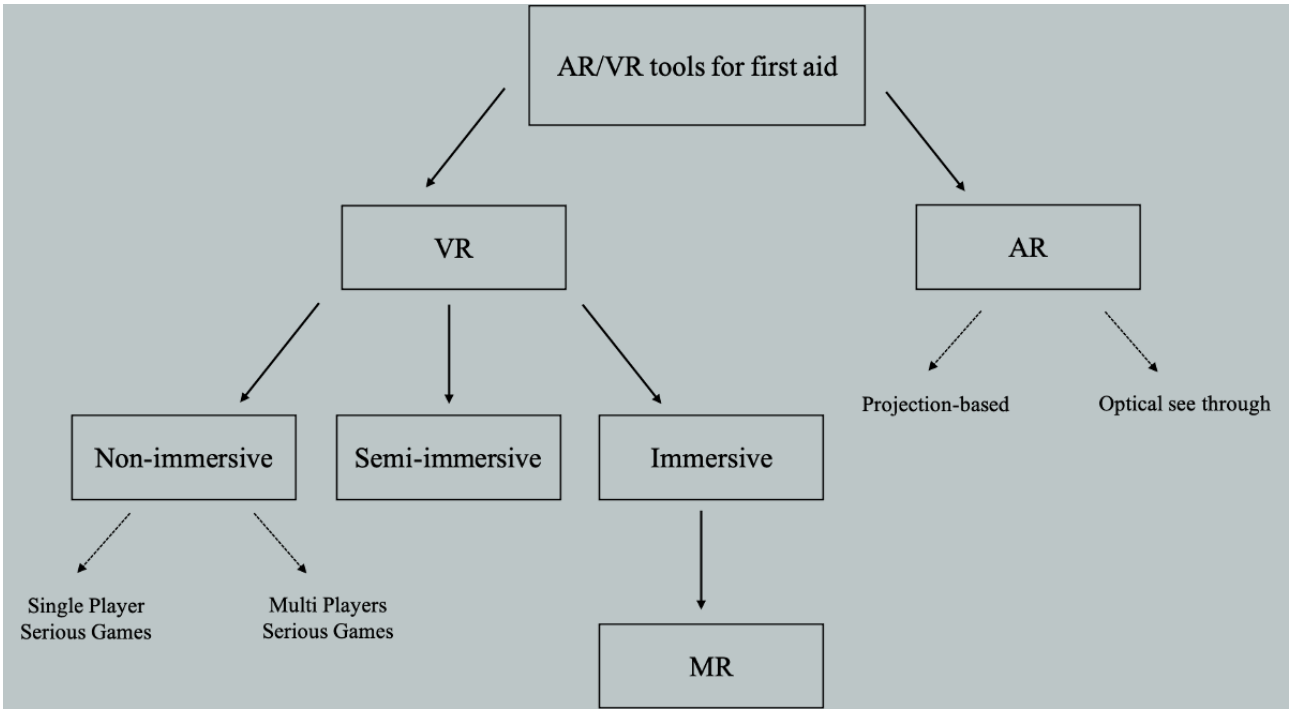
We include, in our review, studies from multiple research areas, such as medicine, engineering, and computer science (Multimedia Appendix 1). First, we provide a description of VR- and AR-based tools used for first aid training, classifying them according to their technology, main features, and appropriate end-users; we also emphasize the advantages and limitations of the foregoing technologies. Following this, we pursue a discussion of the primary properties a simulator should have for optimizing trainee and instructor educational needs.

As the different studies cited are not of the same quality—some of them are well-designed randomized controlled trials, whereas others are prepost studies with surrogate outcomes and few subjects—we classified the studies according to the model of Kirkpatrick for the evaluation of outcomes [12], as this model is commonly used in the field of medical education [13]. Briefly, education outcomes can be classified in different levels as follows:

- Level 1: reaction to learning experience.
- Level 2a: modification of attitudes and perceptions.
- Level 2b: acquisition of knowledge and skills.
- Level 2c: retention of knowledge and skills over a period of time.
- Level 3: behavioral change.
- Level 4a: change in organizational practice.
- Level 4b: benefits to patients/clients, families, and communities.

The review is organized as shown in Figure 1. We provide an overview of VR, AR, and MR; then, the first part encompasses the primary research studies for VR for life support training. The second part of our review covers AR applications for emergency care training and assessment.

Figure 1. Organization of the review. AR: augmented reality; MR: mixed reality; VR: virtual reality.



Overview of VR and AR Technology

VR can be divided into nonimmersive, semi-immersive, and immersive VR (Textbox 1) [14,15].

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Textbox 1. Definitions of virtual reality and augmented technology

Virtual reality: computer-generated simulation:

- Nonimmersive: the virtual environment is accessed through a display, and interaction is limited to keyboard and mouse
- Semi-immersive: the setup includes projections or multiple screens
- Immersive: a head-mounted display isolates the user from the real world
    - Mixed reality: virtual and real worlds are overlapped such that the user sees the virtual world and interacts with the real one

Augmented reality: integration of 3D virtual objects into a real environment in real time:

- Optical see through: semi-transparent glasses to combine the virtual content with the real view of the world
- Video see-through: cameras to show the user the real world, augmented with virtual elements
- Projection-based: the virtual elements are projected in the real world

Nonimmersive VR includes desktop applications, in which the virtual environment is accessed through a screen, and interaction is usually limited to the keyboard and mouse, but it can also involve other devices such as gaming controllers, joysticks, or graphic tablets. Semi-immersive VR allows the user to experience a 3D environment through projections or multiple screens, while immersive VR requires a wired or wireless head-mounted display (HMD) that can fully isolate the user from the real environment [16]. In VR, interactions can occur in multiple ways: by using controllers, motion tracking devices, or data gloves which also provide haptic feedback such as vibrations. In addition, supplementary devices such as Leap Motion (Ultraleap) or external cameras track the users' movements, thus allowing them to naturally interact with the VR without wearing or holding external devices.

Recently, immersive VR has further evolved into mixed reality (MR), combining virtual and real information, such that the virtual and real worlds can interact [17]. In particular, MR allows the users to be immersed in a virtual world and to interact with the virtual objects as they would normally do in the real world (eg, by grasping or handling real objects) [18,19], given that the virtual and real worlds are overlapped.

Another approach to "augment" the environment information is by using AR. In particular, AR can be defined as the integration of 3D virtual objects into a real environment in real time [20-23]. AR can be divided into (1) optical see through using semi-transparent glasses to combine the virtual content with the real view of the world; (2) video seen through taking advantage of cameras to show the user the real world, augmented with virtual elements; (3) projection-based which does not need any wearable device, as the virtual elements are projected (Textbox 1).

The main difference between AR and MR is the visual feedback provided: the former combines real and virtual elements in the user's field of view; the latter shows a completely virtual world. In addition, with AR, the interaction with virtual objects is limited to simple gestures; conversely, MR guarantees a realistic interaction with virtual objects as the virtual and real world are overlapped.

Virtual Reality

The studies are organized into nonimmersive, semi-immersive, and immersive VR categories (Figure 1). For the sake of clarity, nonimmersive systems are defined as serious games throughout the text, as this term is most commonly used in health care simulation for the applications under study. Further, the immersive VR section contains a part about MR systems with haptic feedback, commonly referred to as hybrid tools.

Nonimmersive Systems or Serious Games

The early definitions of serious games described them as games with an educational purpose not primarily intended for entertainment [24]. Conversely, [25] suggests that the educational purpose of these games was most commonly deployed in a way that made them entertaining. More recently, the term serious game has been associated with videogames that include scoring systems that challenge users [26]. In particular, serious games are educational computer applications that teach a specific skill that can be transferred into real life [26,27]. With serious games, students can deal with a challenging situation by learning from mistakes [28,29]. They also find different strategies and can be rewarded by a score and through the possibility of exploring levels having increasing difficulty [27]. In 2021, Bedwell et al [30] defined the characteristics a serious game should have that can be summarized as such: rules and a specific challenging goal, a story told during the game, actions that the user can control, communication between the player and the game characters, and a scoring system.

Within the foregoing context, medical education is particularly suited for the development of serious games ranging from 2D applications to teach anatomy to 3D applications that train triage or surgery [31]. For the purpose of this review, we will discuss only VR-based serious games, specifically designed for life support training, with a specific focus on the difference between single-player and multiplayer tools (Table 1).

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Table 1. Serious games specifically designed for emergency training.

Study	Topic	Target	Players	Features	Study design (N)	Kirkpatrick's level
Youngblood et al [32], 2008	CRM[a]	HCP[b]	4	Users can communicate vocally in real time and can perform clinical actions only if they are properly positioned with respect to the patient who responds to treatments and actions	Prepost (30)	2b
Creutzfeldt et al [33], 2012 *CPR-MVW*	CPR[c]	HP, NCP[d]	3	Trainees are avatars in the virtual world who need to cooperate to perform BLS	Case control (30)	2b
Buttussi et al [34], 2013 *EMSAVE*	ALS[e]	HCP	1	User plays the leader of an ALS team. When a correct task is selected, its execution and effects are shown. Otherwise, the game provides hints for self-correction. Debriefing at the end of the simulation	Prepost (40)	2c
Ribeiro et al [35], 2014 *SeGTE*	CPR	NP	1	Training and evaluation modes; debriefing	Prepost (31)	2b
Vankipuram et al [36], 2014	ALS	HCP	6	Each role receives specific feedback and can perform certain actions. The player responsible for compression interacts with the system using a haptic joystick that mimics the patient's chest	Usability (96)	2a
Boada et al [37], 2015 *LISSA*	CPR	HCP, NP	1	The player has to save the victim applying CPR. Scoring system with penalties for wrong actions and delays. Two types of users: teacher and learner	Randomized trial (109)	2b
Drummond et al [38], 2017 *Staying Alive*	CPR	HCP, NP	1	The player learns the appropriate tasks to manage SCA. Actions are guided throughout the game	Randomized trial (79)	1
Latif et al [39], 2017 *LA-VIE*	CPR	NP	1	Serious game usable to test the CPR knowledge of nonprofessional laypersons. The user is presented with different situations and needs to perform the correct action.	Prepost (52)	2b
Gerard et al [40], 2018 *PediatricSim*	PALS[f]	HCP	1	User plays the role of a code leader, selecting assessments and treatments performed by avatars. Two modes: tutorial, which provides real-time feedback; nontutorial with feedback at the end of the simulation	Prepost (60)	2a
Aksoy et al [41], 2019 *3DMedSim tablet-based BLS*	CPR	HCP	1	Usable with a tablet. Two modes: training which guides the trainees during the emergency and self-test	Randomized trial (40)	2b

[a]CRM: crisis resource management.

[b]HCP: health care providers.

[c]CPR: cardiopulmonary resuscitation.

[d]NP: nonprofessionals.

[e]ALS: advanced life support.

[f]PALS: pediatric advanced life support.

Single Player

Single player is the most common type of serious games used for life support training. Typically, a trainer assesses a first aid scenario and decides which treatments the rescue team needs to perform. Serious games are mainly used by medical students, paramedics, and medical doctors to train and refresh decision-making and teamwork skills [40,41]. Nevertheless, some of these serious game applications have been designed for laypersons (Table 1) [35,39]. Several studies report these tools to be superior to traditional teaching methods. For instance, a study carried out on nursing students revealed that those who had access to a serious game after a theoretical presentation had better practical performance outcomes [37]. However, it was unclear whether performance improvements were due to exposure to serious games or simply a result of overall increased training time. Another study targeted at advanced life support (ALS) experts focused on the role of serious games as refresher tools (ie, courses were specifically designed for health care providers [HCP] familiar with a particular procedure, but required a review of basic conceptual and practical learning skills to maintain a high proficiency level on that skill) [34,42]. ALS performance was assessed before and 3 months after a serious game session. Results showed that performance at follow-up was significantly higher than performance outcomes at the beginning of the experiment [34]. Hence, serious games

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may be effective tools to enhance skill retention between practical courses. Another study compared a cardiopulmonary resuscitation (CPR) serious game with a traditional online course and found no difference between the two teaching modalities [38]. These results support the hypothesis that serious games can be valuable tools for first aid training, being at the minimum comparable to traditional methods in terms of outcomes. Furthermore, it is important that these applications are carefully designed in order to be engaging, motivating, and as realistic as possible. In fact, simulation games are preferable to passive instructions only if they provide active commands that motivate the learner's immersion into content [38,43].

Multiplayers

Serious games involving multiple players are usually called collaborative virtual environments or multiplayer virtual worlds [44,45]. Typically, users are given specific roles within the game (eg, team leader, nurse, etc; Figure 2) with successful outcomes resulting from designed-in collaboration and communication goals.

As for single-player systems, analyses on multiplayer applications yielded results that are limited and difficult to compare. For example, two studies assessing self-efficacy of medical and high-school students using a commercial serious game detected an increase of confidence [46,47]. Unfortunately, the experimental design included both a lecture and serious game practice, thus making it impossible to discriminate whether the self-efficacy increase in procedure confidence was the result of a single training modality. The same research group also explored whether knowledge acquired through multiplayer games would be retained and transferred to manual practice [33]. Briefly, groups of medical students were trained using serious games 6 and 18 months prior to a high-fidelity simulation. Data from these participants were compared to a control group that had not practiced prior to the simulation [33]. Interestingly, all groups showed an improvement in theoretical knowledge. The effect of prior practice became a study factor when the authors took into consideration the number of violations to the CPR guidelines [33], further supporting the idea that serious games are helpful learning tools to learn and refresh CPR algorithm, but not for enhancing the theoretical and practical knowledge related to life-saving skills. Finally, comparing team-leadership skills following either virtual practice or high-fidelity simulation resulted in similar improvements [32,48].

One of the biggest limitations of serious games is the lack of physical practice, as the interaction is limited to keyboard and mouse clicks. To overcome this constraint, a research group added a haptic device (providing physical feedback) to simulate chest compression, thus allowing for a more realistic simulation and improved manual skills [36,45,49]. Yet, since multiple users are assigned different roles, some did not have access to haptic feedback; this resulted in different simulation experiences among trainees. In fact, multiplayer serious games raise an important question: how can students who are practicing different tasks retain the same skills? In other words, it is important to study whether skills acquisition is similar when learners are actively involved in the task, as well as during observational sessions of their practicing peers. On the one hand, team training may be beneficial, as it makes the learning experience more engaging and unpredictable. This is also supported by a qualitative study assessing medical students' experiences during serious game practice where learners found team simulation challenging, competitive and rewarding, thus leading to better retention [44]. On the other hand, students might be easily distracted when not directly involved in the case presented in the simulation. A study comparing the outcome of students playing different roles during a high-fidelity simulation reported that operative roles enhanced problem-solving, support, and guided reflection abilities [50]. Also, the learning attitude seems related to the role played during the simulation [50]. Further, it is important that medical students learn how successfully be part of a team, as health care is currently provided by multidisciplinary teams who need to work together, and lack of communication and poor teamwork have been related to poor medical care [51]. Within this framework, simulation roles should be rotated, assigning students different roles, so that by the end of the practice session, all participants had experienced the same situations, learning either different skills or the same one from different perspectives. However, in order for the training to be effective, it should not be boring [9-11]. Indeed, one of the main advantages of serious games, and more generally of VR, is the unpredictability embedded within the simulation, thus compelling an increased level of focus and attention on the part of the learner, resulting in better outcomes. Given the foregoing, it appears to be a need for additional studies assessing whether serious games are superior to traditional teaching methods after the "wow" effect has subsided in order to accurately determine the real learning improvement potential of these tools.

Semi-Immersive Experiences

The first example of a semi-immersive VR tool was JUST VR, a semi-immersive tool used for the training of nonprofessionals [3]. In this simulation, users face a screen that presents an interactive medical emergency. During the simulation, trainees can move; this is enabled by a magnetic sensor placed on their head; also, they can vocally interact with a virtual assistant (controlled by a technician) who is giving commands on how to manage the emergency situation [3]. Even though this proof of concept might be helpful for learning within the CPR algorithm, it does not provide haptic feedback or effectively train for manual skills.

A recent study presented a CPR training simulation that occurred in the Octave VR facility at the University of Salford, Manchester, United Kingdom [52]. The Octave VR facility is an evolved version of a VR Cave, which is a room equipped with either projectors or screens covering three to six walls of a room. The Octave is defined by an octagonal space that displays an outdoor environment projected onto the walls and floor of the room; students can view a functional CPR manikin at the room's center and, through shutter glasses, they experience 3D visual cues [52]. Confidence levels in performing lifesaving tasks and performance of second-year nursing students were compared in three environments: the Octave, a skill room (ie, a simulated hospital room), and a simulation room equipped with projectors displaying realistic images and audio of an outdoor urban environment [52]. Surprisingly, self-confidence

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was lower when students experienced the Octave with respect to the other environments, although students' performance outcomes improved. One possible explanation of these results is that students were unfamiliar with the Octave technology and thus felt less confident than they actually were due to the novelty of the simulation. Indeed, the Octave challenged the trainees more than other simulation technologies, proving to be an effective way to prepare learners for real-life scenarios [52]. However, the Octave technology is expensive and requires dedicated equipment, space, and trained technicians to operate, making it impractical for medical simulation centers to deploy for the immediate future.

A very different application of VR for CPR training is CPRBuddy proposed by [53]; it consists of a virtual avatar displayed on a screen. CPRBuddy follows the users' performance on a manikin, providing real-time audio and gestural feedback. Interestingly, the avatar is able to illustrate an incorrect action committed by the student before showing him/her the correct procedure. CPRBuddy was tested on a sample of nine novice learners who were asked to perform chest compression before and after the training with the system, showing improved performance after the training. Similarly, Tian et al [54] presented a proof of concept of a CPR trainer which used a Microsoft Kinect and a haptic device. The Kinect captured the user's movements while performing CPR with the haptic device, which provided the realistic physical feedback of a chest compression procedure. A virtual representation of the user reanimating a virtual patient was displayed on a screen; visual and audio cues were also provided [54]. Even if these are preliminary studies, they suggest that a virtual trainer can effectively support live tutors, reducing their effort during CPR courses and increasing learning outcomes.

Immersive Applications

The first example of an immersive VR application for first aid training was presented at the IEEE Virtual Reality Annual International Symposium of 1998 [55]. The first prototype called MediSim was developed to train front-line medical personnel in battlefield medicine. The prototype included a VR HMD, four trackers positioned on the user's body, and a dynamic causality model that provided simulated changes in a patient's condition according to the learner's actions [55]. From the position of the trackers, MediSim reconstructed the trainee body configuration and position, creating a virtual avatar that could interact with a virtual patient and other objects (eg, surgical gloves). No tests studies were reported on the effectiveness of simulated patients or student learning performance, as the main goal of this study was to integrate the system into a battlefield simulator. MediSIM eventually evolved into BioSimMER [56], an application used to train medical first responders to an act of bioterrorism. With BioSimMER, trainees learned how to triage and treat different injuries related to a terroristic attack while at the same time protecting themselves from harm.

After these pioneer studies, research on semi-immersive and immersive VR/MR tools for life support training has been sparse, with only two main studies published between 2000 and 2014 [3,57].

VR applications lacking haptic feedback prove to be efficient learning tools for HCPs who need to refresh skills, be informed of new guidelines, and train for leadership or communicative skills. Moreover, VR applications are promising tools for teaching nonexperts, especially younger people, how to manage medical emergencies. In particular, young people are more prone to use mobile and gaming apps for learning new skills, thus making them a good way to reach them and raise awareness on the importance of first aid knowledge among the general population. In fact, as HMDs have become more common, game developers and designers have begun to create games that increase awareness of life-saving skills. Among these toolsets is *Relieve* (Studio Evil), a science fiction adventure game published by the company that developed VR CPR [58], and an MR application in collaboration with the Italian Resuscitation Council. Other examples include *Accident: The Pilot* (Duality SA), *Ambulance Simulator* (Image Power SA), *Reanimation Inc.* (Nuclear Games), and *Lifesaver VR app* endorsed by the UK Resuscitation Council [59].

Despite growing interest in immersive simulators for CPR training, few studies have assessed their potentialities. Table 2 summarizes the main immersive VR and MR tools for first aid training. A German group has recently implemented VReanimate II, an immersive tool for first aid and reanimation training [60,61]. This application provides different modalities, including a tutorial and two levels of exercises covering different scenarios. The application was tested on users who had limited first aid experience, resulting in a 20% increase in CPR knowledge after training; this suggests that VR has a strong potential to increase functional first aid knowledge. In addition, two studies from 2019 compared VR with a video-based and tablet-based serious game application in order to assess whether people retained more knowledge when trained using the VR system [41,62]. Results showed that the VR application led to increased knowledge of CPR steps [41,62] but a worsening outcome in chest compression technique after training [62]. Altogether, literature on VR for first aid training supports the claim that such technology can be a powerful tool that increases public awareness and learning of life-saving skills, primarily due to the high level of immersivity, perceptual access to real-time scenarios, and impersonation [63]. Further, VR appears to be highly valued by both untrained and expert users who can use it in different ways: the former can learn how to react to a medical emergency, memorizing the CPR algorithm and thus acquiring communicative skills; the latter can easily and rapidly refresh previously acquired knowledge [60,62,64].

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Table 2. Virtual reality and mixed reality simulations.

Study	Target	Type	Setup	Skill	Status	Design (# subjects)	Kirkpatrick's level
Blome et al [61], 2017; Bucher et al [20], 2019 *VReanimate*	NP[a]	VR[b]	HTC Vive	Chest compression (qualitative); defibrillation	Tutorial and exercises modes; simple instructions without complex text; qualitative evaluation	Usability (8); pre-post (22)	1
Wong et al [64], 2018; *CPR + AEDVR*	HCP[c]	VR	HTC Vive	CPR[d] algorithm	Tutorial and simulation modes; training on AED[e]; manual skills are performed by an avatar and not by the user; qualitative evaluation	Usability (30)	2b
Aksoy et al [41], 2019; *3DMedSim VR-based BLS*	HCP	VR	HMD[f]	CPR algorithm	Two modes: training which guides the trainees during the emergency and self-test; quantitative Evaluation	Randomized (40)	2b
Leary et al [62], 2019 *VR mApp*	NP	VR	Smartphone (VR), HMD and manikin (MR)	CPR algorithm; defibrillation	Portable and low-cost; quantitative evaluation	Randomized (103)	2a
Vaughan et al [65], 2019	NP	VR, MR[g]	HMD and manikin (MR) or smartphone (VR)	None	Portable; proof of concept	N/A[h]	N/A
Buttussi et al [66], 2020	NP	VR, MR	HTC Vive and manikin (for MR only)	CPR algorithm; chest compression	Training and evaluation modes; training mode provides progressively decreasing clues; quantitative evaluation	Prepost (30)	2b
Semeraro et al [57], 2009 *VREM*	HCP	MR	Physical manikin, data gloves and HMD	None	Proof of concept	N/A	N/A
Almousa et al [67], 2019	HCP, NP	MR	HTC Vive and physical manikin	Chest compression; defibrillation	Multiple scenarios and increasing difficulty levels; animations controlled by a technician; qualitative evaluation	Usability (20)	N/A
Bench et. al [68], 2019 *Code Blue*	NP	MR	HTC Vive and physical manikin	Chest compression	Qualitative evaluation;quantitative evaluation	Prepost (23)	2a
Girau et al [69], 2019	HCP	MR	HTC Vive, Leap Motion, and physical manikin	None	Interactions between the virtual patient and the trainees; proof of concept	N/A	N/A
Leary et al [70], 2019 *VR SCA*	NP	MR	HTC Vive and physical manikin (MR)	CPR; algorithm	Manual and vocal interaction; quantitative evaluation	Prepost (119)	1
Liyanage et al [71], 2019	HCP	MR	HTC Vive, Leap Motion, and physical manikin	Chest compression	Proof of concept	N/A	N/A

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Study	Target	Type	Setup	Skill	Status	Design (# subjects)	Kirkpatrick's level
Semeraro et al [58], 2019	HCP, NP	MR	HTC Vive and physical manikin	Chest compression	Quantitative evaluation	N/A	N/A

[a]NP: nonprofessionals.

[b]VR: virtual reality.

[c]HCP: health care providers.

[d]CPR: cardiopulmonary resuscitation.

[e]AED: automated external defibrillator.

[f]HMD: head-mounted display.

[g]MR: mixed reality.

[h]N/A: not applicable.

Mixed Reality Devices

Currently, literature on virtual reality for life support training is focused on MR systems for CPR training. In other words, many research groups have been trying to "enhance" VR by combining physical elements with a virtual environment. This way, the user interaction is more realistic than by using VR alone. On the one hand, MR tools may be more desirable for life support training, given their inherent advantage of haptic feedback combined with VR; on the other hand, a recent study comparing VR and MR CPR training reported no differences relative to procedural knowledge and self-efficacy [37].

In general, MR tools (Table 2) provide realistic feedback into an immersive environment (Figure 2), being more desirable than AR. By definition, AR integrates virtual and real elements in the learner's field of view, presenting these elements as two separate layers [72]; However, in order for a technology to be truly immersive, the human brain should not be able to determine the difference between virtual and real elements [73,74]. In this context, MR seems more appropriate since the brain can perceive the environment as it would normally do in the real world, given that all the elements of the scene are virtual [73]; in addition, users perceive haptic feedback and perform actions in a realistic way.

Figure 2. Examples of immersive tools. Left: VR application without haptic feedback. Center: MR system which combines an HMD with a manikin for a more realistic simulation experience. Right: AR application (Holo BLSD) designed to augment a physical manikin with a virtual representation [75]. AR: augmented reality; HMD: head-mounted display; MR: mixed reality; VR: virtual reality.



The first example of an MR tool for CPR training is the virtual reality enhanced mannequin (VREM), which combines a half-body manikin with HMD, data gloves, and tracking devices [57]. During the simulation, the user is immersed in a VR environment, but at the same time, they can physically interact with the manikin, as his/her hands' movements are tracked in real time [57]. Despite having some limitations, such as the lack of performance evaluation, VREM was the first example of MR that combined immersive VR with manikins traditionally used to teach lifesaving skills. VREM was the sole example of an MR simulator until 2018 when new developments and tools appeared. In particular, several research groups implemented MR prototypes that share the same concept of augmenting a VR application with a manikin (Table 2). All these examples combine a manikin, either half-body or full-body, with an HMD device (typically HTC Vive) and a VR application developed in Unity game engine. Despite some differences among the projects, the main idea is to overlap a manikin with its virtual representation in ways that enable trainees to be immersed in a realistic virtual environment accompanied by realistic haptic feedback (Figure 2). The majority of these tools use trackers provided by the VR setup to monitor chest compressions by

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virtue of their direct placement into the physical hands and/or on the wrists of learners [58,66-68]. To prevent obstruction of the user's hands, two setups include a Leap Motion device, specifically designed to track the hands in real time [69,71,76]. Leap Motion is attached to the HMD and combines infrared cameras with light-emitting diodes. A proprietary software analyzes the frames captured to extract hand-movement information [76]. These projects are proofs of concept which do not monitor CPR performance but address different challenges of MR, such as the interaction between the user and the manikin [69] and the monitoring of user's performance via Leap Motion data [71]. Another project [65] attempted to import an MR application designed to be used with an HMD into a Google Cardboard VR platform in order to demonstrate that MR can be used with a smartphone, thus making it even more accessible.

MR solutions highlight an important point that there is a lack of integration between VR and CPR manikin equipped with sensors. In other words, the projects aim at combining VR with physical manikins into a single learning tool, but the two parts remain disconnected, with no data-sharing between them. To overcome this limitation, some research groups used trackers to monitor performance, while others added sensors into the manikin. CPR manikins are largely distributed by a few companies, and this may have caused a lack of communication between hardware and software, suggesting an investigation into how we might better integrate these learning toolsets is necessary. Data recorded by the manikins are protected; therefore, using manikins in combination with VR requires more successful collaborations between research groups and companies. It is unclear whether companies are not interested in providing secure access to their data or, instead, if universities are not willing to share their ideas with commercial, for-profit enterprises. In any case, university and for-profit enterprise collaborations are desirable for various reasons: first, the integration of performance data with VR leads to improved user experiences, as the learner would not be required to wear additional tracking devices; further, the virtual manikin can react more accurately to maneuvers performed by the learner during first aid training. Second, CPR manikins have been used for a long time, meaning that the hardware is stable with standardized performance indexes. The use of these devices would make comparisons with traditional methods more valuable than designing custom-made manikins that require validation prior to being integrated into the VR. Additionally, VR is becoming a common technology within medical simulation environments, as it provides riskless experiences that are controlled and scaled to the user's ability. Hence, it is likely that companies need to look further into the integration of VR into first aid training scenarios in the near future. Initiating collaborations with universities would speed up this much-needed technological evolution; in particular, commercial and nonprofit collaborations can lead to now medical training opportunities and additional profit for commercial enterprise.

Augmented Reality

Projection-Based Systems

The use of AR within the context of first aid training is a recently recognized challenge. The first AR application to CPR training combined a physical manikin with AR interactive projections [77]. Briefly, sensors located on the manikin were used to monitor chest compression, head position, and airflow; an RGB-D (red, green, blue-depth) camera recorded the user's position. Finally, a realistic scenario was projected in the simulation room to increase realism and immersivity. This system combined data from the camera and the manikin, giving real-time feedback about the trainee's performance and position. Similarly, Kwon [78] implemented a portable version of the above prototype where projections are replaced by a mobile phone screen. However, the study did not include any demographic information for study participants; therefore, it is not known whether novice or expert learners can benefit from the AR projections in similar ways.

Low-Cost Prototypes

There is increasing awareness that first aid training should be affordable and easy to access, given that a medical emergency can occur anywhere, at any time. Also, CPR training should be tailored to the audience, with high-fidelity, highly functional simulations designed for HCPs in simulation centers and low-cost solutions devoted to the general population or to guarantee optimal training in low-income countries and rural areas. Within the foregoing contexts, some recent proofs of concept have appeared even though validation studies assessing the efficacy of such ideas are still missing. In 2016, Philips presented a low-cost project for automated external defibrillator placement training [79]. The system included a cloth sheet representation of a patient and a camera that monitored the correct positioning of the electrode pads. Feedback on the pads' location and hand position were shown on a monitor. The rationale behind the project was that an effective CPR response in untrained personnel should be automatic and related to muscle memory rather than abstract cognitive learning. In this model, resistance that mimics chest stiffness should be included, in addition to hand and pad positioning. A more recent study presented the first prototype of an AR application usable with a smartphone [80]. The system combined two markers with a pillow mimicking the chest via a mobile application and a smartphone. The application computes chest compression depth and rate using markers and projects information via smartphone to a body over the pillow, blending the digital body into the real world. Altogether, studies showing the potentialities of low-cost AR applications suggest that further validation and efficacy studies are required prior to using these systems for CPR training. As an example, [80] have neither tested the system with experts nor compared their system with a traditional manikin. Hence, it is difficult to foresee the near-term role that these applications may play in increasing CPR knowledge among the general population.

Optical See-Through Applications

In recent years the majority of research studies have focused on AR in emergency training designed applications, taking

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advantage of optical see-through AR devices like the Microsoft HoloLens and Google Glass (Figure 2) [75,81-86]. AR-based tools can be divided into (1) applications that assist a user who needs to perform a life-saving task [81,85] and (2) applications that augment the simulation experience with virtual elements, giving real-time performance feedback during training [75,82,83]. The first group of tools aims at shortening the rescue time through cues appearing in an emergency setting. So far, in the latter context, experimental study results have been controversial. Siebert [81] compared the time required to provide defibrillation in two groups of pediatric residents. The first group could follow the pediatric advanced life support algorithm on a pocket reference card; the second group used Google Glasses to access the same information. Results show a similar shocking time in the two groups, but a better defibrillation dose delivered by residents using Google Glasses. Conversely, a study carried out on untrained subjects revealed that participants wearing HoloLens reacted faster and better than those having access to an instruction checklist on a tablet [85]. One possible explanation for these results is that AR may be beneficial for novice learners who do not have any previous experience with algorithms and instructions; however, HCPs may get distracted by information appearing in their field of view because they may look for confirmation of their prior knowledge [87]. Another variable may be that health professionals are familiar with the checklists. All of this suggests that AR could be a valuable tool for novice first aid rescuers and could be included in first aid kits. Indeed, further studies are required to (1) assess the acceptance rate of AR among the general population, (2) define its benefits and limitations, and (3) determine whether the efficient use of optical see-through systems to perform lifesaving tasks requires training.

Another class of AR-based applications includes CPR trainers that provide real-time feedback on users' performance during simulations by combining a real manikin with AR optical see-through devices. Recently, two research groups have implemented similar tools: HoloBLSD [75,86] and CPReality [82,84]. HoloBLSD is a self-instruction basic life support defibrillation trainer having three modalities: learning, rehearsal, and evaluation, allowing the user to practice prior to evaluation [75,86]. CPReality is intended for hands-only CPR training; briefly, information on chest compression is measured by the manikin and integrated into the AR application, which displays, in real time, how the blood flows into the circulatory system as a result of the compression [82]. Both systems have been recently tested among HCPs, comparing the performance of participants who use AR with the performance of subjects undergoing traditional manikin-based training [70,86]. Results show that both HoloBSLD and CPReality lead to performance outcomes similar to those obtained with traditional training methods [84,86]. From a theoretical standpoint, self-learning AR tools can be at the minimum comparable to traditional training methods. However, one important factor should be taken into account: the biggest difference between instructor-guided courses and self-learning is the customization of the courses based on the learner's difficulties and abilities (ie, individualized learning). In particular, during a traditional course, an instructor can adjust the content of a simulation according to audience needs. This means tailoring courses to the audience's skills, needs, and background. For this reason, it is important to further investigate the role of personalized training as to its impact on learning and retention outcomes. At this time, no current available AR or VR tools provide personalized and self-adjustable programs, as opposed to instructor-led training.

General Discussion

This review has summarized the main scientific studies related to first aid training using VR and AR. Some of the prototypes investigated have been designed by medical groups, others by technicians. Some of the prototypes focus on leadership and teamwork training, and others have been implemented to enhance the practice of manual skills.

The analysis of the existing AR- and VR-based systems has helped us to identify the primary features that a simulator should have in order to increase individualized outcomes. These studies highlight the importance of choosing the end user prior to defining the main features of a training toolset. In fact, nonprofessionals have little to no medical background, whereas medical students and HCPs require advanced training. Also, the general public is trained at far less frequent rates than medical caregivers. The general public needs more and better information—both theoretical and practical—in learning how to deal with stressful medical emergency situations without the immediate aid of a medical professional. Advanced life support instead requires coordination and cooperation, with everyone involved performing as optimally as possible (Textbox 2).

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Textbox 2. Main features an augmented reality or virtual reality-based simulator should have according to its users and purpose.

Nonprofessional:

- Procedures:
  - Environmental safety
  - Chain of survival activation
  - Cardiopulmonary resuscitation performance
  - Automatic medical instrument management
- Training:
  - Knowledge of procedures
  - Stress management
  - Manual skills
- Assessment:
  - Guarantee safety
  - Procedure correct execution
  - Manual skills.

Health care providers:

- Procedures
  - Environmental safety
  - Basic life support defibrillator
  - Advanced life support
  - Manual instrument management
  - Diagnostic skills in emergency
  - Invasive procedures performance
  - Drugs administration
- Training:
  - Crisis resource management
  - Stress management
  - Familiarity with instruments
  - Procedure knowledge
  - Manual skills
  - Diagnostic skills
  - Drugs management
  - Teamwork
- Assessment:
  - Guarantee safety
  - Procedure correct execution
  - Ability in performing invasive procedures
  - Diagnostic performance
  - Decision making
  - Drugs effects and indication knowledge

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Aside from defining the end user, it is important to establish whether the simulation tool is intended for training, assessment, or both, as training and evaluation tools should have different features. For instance, a training tool used by nonmedical learners should include information about how to communicate with paramedics or where to place one's hands to optimally perform chest compression (Textbox 2). An evaluation instrument should simulate an emergency occurring in a nonhospital setting, also including distractors. In addition, chest compression should be assessed in a quantitative way, measuring compression rate, depth, and recoil. A simulator for HCPs should include pathology and pharmacology notions, as well as diagnostic skills used in emergency and invasive procedures performance (Textbox 2).

At the present time, we are unable to find a clear distinction between nonmedical and training and assessment tools. We believe this is a crucial point in order to effectively design AR/VR-based simulators for life support training. In fact, instructors should tailor the content they are delivering to their audience, in the same way first aid tools should be adapted to the end users, in order to guarantee engaging and challenging training.

A distinctive feature of simulation toolsets is the ability to train small groups of medical students, either in person or via distance learning; this is important for three reasons. First, every participant can take a specific, assigned role during the training. Presently, several multiplayer serious games have been implemented and introduced as medical training tools [32,44,45,48]; further, few multiplayer VR platforms with multiple cases designed for HCPs are available (eg, *SimX*, *OMS Interprofessional*, and *ORama VR*). Still, multiplayer AR and MR tools have not yet been designed. Second, the debriefing phase following the simulation training is more effective if the clinical case study is analyzed from multiple perspectives [88-92]. The majority of the studies we analyzed did not consider the possibility of providing the debriefing phase via the simulator itself, other than giving performance scores or video recordings of the simulation. We believe this would be a feature that would innovate medical simulation as an optimal training strongly affected by an organized debriefing phase that takes into consideration learner's performance, errors, divergent behaviors, and user experience. Thirdly, at the time of writing, the way medical education is delivered has strongly changed due to the COVID-19 pandemic. Changes include the need to train smaller groups of students, thus replicating the same clinical case scenarios multiple times, and the need to deliver content online, taking advantage of distance learning but maintaining the same level of content quality and engagement. Another point to consider is the importance of designing AR- and VR-based simulators providing haptic feedback and monitoring the user's manual skills. Among the basic tasks a user needs to perform during first aid, there is chest compression and bag-mask ventilation, in addition to more complex task knowledge required by HCPs (eg, invasive procedures, drugs administration, etc). At present, performance monitoring is sparse and typically limited to hands-only CPR [53,54,57,67,75]. Indeed, research studies in the field should focus more on realistic feedback and performance monitoring systems, considering all the maneuvers associated with optimal first aid.

Importantly, it is also necessary to carry out detailed learning outcome studies aimed at assessing whether AR- and VR-based systems are comparable to traditional training methods. In fact, if VR is equivalent to traditional methods, medical simulation can benefit from VR in terms of setting space, flexibility, and training time. This review indicates that many research studies report proof of concepts without comparing them to the most popular in-use manikin-based simulators [93,94]; specifically, very few studies compared VR/AR tools with traditional training methods, reporting controversial or inconsistent results.

Conclusions

Research on VR and AR for basic and advanced life support training is heterogeneous in terms of users, type of technology, experimental design, and metrics. Analysis of the existing studies revealed the importance of defining the end user and the purpose of the simulator during the design phase, as professionals and nonprofessionals need to learn different skills. Also, this review highlights a few limitations of the current devices that should be addressed to improve the learning outcome. These include the possibility to develop multiplayer tools, the inclusion of the debriefing phase within the simulation, the ability to monitor users' performance, and the possibility to provide realistic haptic feedback. In this context, standardized tests are required to assess the benefits of new technologies in life support and, more generally, in medical training.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary materials.

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Abbreviations

ALS: advanced life support
AR: augmented reality
CPR: cardiopulmonary resuscitation
HCP: health care provider
HMD: head-mounted display
MR: mixed reality
VR: virtual reality
VREM: virtual reality enhanced mannequin

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Original Paper

Serious Game for Change in Behavioral Intention Toward Lifestyle-Related Diseases: Experimental Study With Structural Equation Modeling Using the Theory of Planned Behavior

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Abstract

Background: Health activities should be tailored to individual lifestyles and values. To raise awareness of health behaviors, various practices related to health education, such as interactive activities among individuals with different backgrounds, have been developed. Moreover, serious games have been used as a tool for facilitating communication. However, there have been few investigations that are based on the framework of the theory of planned behavior on the mechanisms of health-related behavioral intention change from playing serious games.

Objective: We aimed to investigate the mechanisms of behavioral intention change among various age groups after an intervention using a serious game to increase awareness of lifestyle-related diseases.

Methods: Adults, undergraduates, and high school students played a serious game, called Negotiation Battle, and answered a questionnaire—Gaming Event Assessment Form for Lifestyle-related Diseases—before, immediately after, and 2-4 weeks after the game. The questionnaire was composed of 16 items based on the theory of planned behavior. We used structural equation modeling to compare responses from the 3 groups.

Results: For all 3 age groups (adults: mean 43.4 years, range 23-67 years; undergraduates: mean 20.9 years, range 19-34 years; high school students: mean 17.9 years, 17-18 years), perceived behavior control was the key factor of behavioral intention change. Immediately after the game, causal relationships between perceived behavioral control and behavioral intention were enhanced or maintained for all groups—adults (before: path coefficient 1.030, $P<.001$; after: path coefficient 2.045, $P=.01$), undergraduates (before: path coefficient 0.568, $P=.004$; after: path coefficient 0.737, $P=.001$), and high school students (before: path coefficient 14.543, $P=.97$; after: path coefficient 0.791, $P<.001$). Analysis of free descriptions after intervention suggested that experiencing dilemma is related to learning and behavioral intention.

Conclusions: The study revealed that the serious game changed the behavioral intention of adolescents and adults regarding lifestyle-related diseases, and changes in perceived behavioral control mediated the alteration mechanism.

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KEYWORDS

lifestyle-related disease; mechanism of behavior change; serious game; theory of planned behavior

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Introduction

Noncommunicable diseases, such as cardiovascular disease, cancer, diabetes, and chronic respiratory disease, are the leading cause of mortality worldwide and accounted for 71% of 41 million deaths in 2018 [1]. The major risk factors of mortality that contribute to noncommunicable diseases and are modifiable, given effective interventions [2], are high blood pressure, tobacco use, high blood glucose levels, physical inactivity, and being overweight or obese. In Japan, the current leading causes of death are malignant neoplasm, heart disease, and cerebrovascular diseases, which accounted for more than 50% of total deaths in 2017 [3]. Therefore, preventing deaths due to lifestyle-related diseases is a major concern. In Japan, lifestyle-related diseases cause major medical and economic problems [4]. Notably, however, lifestyle-related diseases are primarily dependent on individual values and attitudes and it is difficult to intervene. To prevent such diseases, people must balance unhealthy and healthy behaviors while conforming to their values and lifestyle. To encourage awareness and behavior changes, methods of health communication, such as interactive dialog between individuals with different backgrounds, have been proposed [5-7]. Applying a combination of health communication models, including serious games, has proven effective in improving knowledge and self-management [8,9].

Serious games are useful as a communication tool. They are designed for teaching, training, and changing knowledge, attitudes, and behavior while remaining entertaining [10]. Moreover, the design and practicability of serious games have been evaluated in the fields of health care [8-10]. Although serious games are simulated, they can provide real-world experiences to participants through role-playing [11].

The theory of planned behavior is a hypothesis on health behavior [12-14] and has been widely applied to motivation analyses of health-related behaviors [15-17]. The theory of planned behavior postulates that 3 factors influence behavioral intention: (1) attitude toward behavior, that is, the belief that healthy behavior leads to health and appreciation of the consequences of such behavior; (2) the subjective norm, the realization that other people believe that healthy behavior is desirable and conform to this social expectation; and (3) perceived behavioral control, which is the belief that one possesses the resources and skills necessary for healthy behavior. Therefore, the theory of planned behavior postulates that individuals are likely to engage in a health behavior if they believe that (1) it will lead to particular outcomes they appreciate, (2) people important to them think they should engage, and (3) they have the necessary resources and opportunities to perform the behavior.

Many studies [18-20] have reported on the development of serious games based on theory of planned behavior that target chronic diseases or disease prevention and have mainly focusing on the game design and the interventions. Serious games have been designed on the basis of behavioral models to highlight chronic diseases in children [18]; for the prevention and rehabilitation of diseases, such as asthma, diabetes, or HIV [19]; or to encourage healthy lifestyles [20]. However, to date, no studies have investigated the mechanism of behavioral intention change through serious games using the theory of planned behavior framework as a basis. Moreover, little is known about differences in the effects of health-targeted serious games on various age groups. To address this research gap, we aimed to identify on which behavior change mechanisms a serious game for lifestyle-related diseases has an effect and to elucidate differences according to various age groups.

Serious games are frequently used in combination with educational activities, especially in health care fields, with positive outcomes [21,22]. For example, serious games targeting health behaviors can improve cognitive abilities in older adults [23] or improve neuropsychological abilities of alcoholic patients [24]. Unlike regular computer and video games, serious games have dual goals of entertaining and promoting behavior change [10]. Face-to-face serious games (eg, board games) combined with health education may also achieve similar benefits [25].

Methods

Negotiation Battle

We employed a serious game called *Negotiation Battle* (Figure 1), which is a board game developed by a nonprofit organization called Citizen's Science Initiative Japan [26]. We chose Negotiation Battle because it is a board game in which 2 teams with different views on lifestyle-related diseases can discuss the issues while playing the game, and we thought it would have an educational effect through discussion.

Negotiation Battle is played by 6 people on 2 sides, with one side playing the seducer (3 people) and one side playing the human (3 people). The seducer team persuades the human team, but the seducer team also exchange opinions with each other and with the human team. The duration of the game is 20 to 30 minutes per set, and the game set includes a dilemma card (Figure 2) and health sheet (Figure 3). For the dilemma situation, unhealthy points and happy points are listed on the card about each specific behavior. On the health sheet (one for each seducer role and only the seducer team can record on and view the sheet), unhealthy values of the human team are recorded. When the health points reach a certain value, the seducer is hospitalized.

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Figure 1. Negotiation Battle serious game.



Figure 2. Dilemma cards regarding behaviors such as whether to season meals at home more, use a juicer to eat more vegetables, eat out at high-calorie restaurants, or eat convenience store lunches every day. Example: “07. I want to eat what I like when eating out.” You are told to avoid overly seasoned and salty foods, so your meals at home are tasteless. So, at least when you eat out, you want to eat what you want without worrying about the label. Do you eat like that? A: Yes, B: No. Temptation Tip: You'll be happier if you eat what you like.



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Figure 3. Health sheet with blood pressure, blood sugar, and cholesterol. Points accumulate depending on the results of each behavior. When points reach a threshold, the human is hospitalized, which is game over.



The goal of the seducer is to add up the unhealthy points of the person he is in charge of, while the goal of the human is to accumulate happy points without being hospitalized. (1) The seducer reads out the card's dilemma situation and seduces the human to focus on work, hobbies, and relationships and continue with behaviors that are unhealthy. (2) The human decides whether or not to accept the temptation while negotiating and interacting with the seducer and other human players. (3) If the human accepts the temptation, the seducer adds the value of the unhealthy points on the dilemma card to the health sheet at hand. (4) The human earns happy points. (5) After each human's decision is made on one card, the player moves on to the next card and repeats steps 1 through 4. The health sheet shows the threshold of ill health (ie, hospitalization, which is game over for the human), but the human cannot know the current value of ill-health points. (6) At the end of the game, the seducer discloses the information on the health sheet to the human, and (7) together they reflect on and discuss the types of temptations to which they were vulnerable. Thus, participants are stimulated to engage in interactive communication by applying the imaginary dilemma to real-life situations.

Participants

We recruited participants from 3 age groups—adults (including postgraduate students), undergraduate students, and high school students—because behaviors and attitudes toward lifestyle-related diseases could differ between adults and young people. In addition, among young people, we expected that there would be differences between high school students, who mainly live with their parents, and university students, who are often independent from their parents (living alone).

Adults, who were invited to participate and applied through a social networking service (Facebook, mailing list), attended a total of 3 Negotiation Battle sessions held between November and December 2016. For university students, we invited second-year students of the Tokyo University to participate in January 2017, and for high school students, we invited third-year students of a high school in Tokyo to participate as part of their classes in January 2017.

Data Collection

The participants were asked to submit a questionnaire (Gaming Event Assessment Form for Lifestyle-related Diseases) before, immediately after, and 2 to 4 weeks after the intervention. Prior to the intervention, an instruction document that described the survey was given to each participant, with the questionnaire and a return envelope to be filled in 2 to 4 weeks after the intervention and returned by mail.

There is a rule of thumb regarding sample size in structural equation modeling analysis that the sample size should be at least 5 times the number of parameters [27]. In this study, the questionnaire had 16 items (on the theory of planned behavior), and the minimum required sample size was estimated to be 80. However, since this study was conducted in the context of actual classes for university students and high school students, feasibility was given priority, and it was considered inevitable that there would be some groups below that size in each age group.

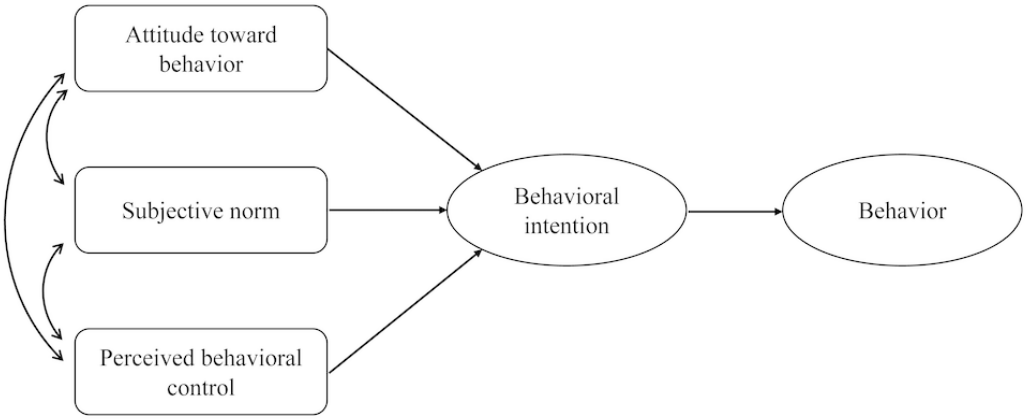
Questionnaire Composition

The questionnaire was constructed to assess components of the theory of planned behavior (Figure 4) to allow structural equation modeling of before-and-after comparisons, and additional items were inserted to obtain background information on the participants (age, family composition, occupation, and history of lifestyle-related diseases as a background profile of the participants). The questionnaire was scaled according to previous studies that examined 4 aspects, namely, attitude

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toward behavior [28], subjective norm [29], perceived behavioral control [30], and behavioral intention [31]. The questionnaire included additional items for free description of what the participants learned or whether they newly started healthy behaviors afterward: "What was your learning or awareness about healthy lifestyle?" (for both time points) and "What kind of healthy behaviors have you recently started?" (2 to 4 weeks after).

Figure 4. Theory of planned behavior diagram.



Data Analysis

Responses were analyzed using SPSS Statistics and Amos software (version 23; IBM Corp). Structural equation modeling was performed to determine the relationship (causality or correlation) between factors of the theory of planned behavior. We used the comparative fit index (CFI), Tucker-Lewis index (TLI), and root mean square error of approximation (RMSEA) as fitness indices. Missing values were imputed (using means within each item). Statistical significance was set to $P<.05$. Content analysis was used for the free descriptions; characteristic concepts were extracted from entire free descriptions, and the frequency with which these concepts were observed was counted for each category.

Ethical Consideration

Participants were given a written and verbal explanation of the study protocol, and only those who consented were included in the study. Anonymity was ensured; the contents of the questionnaire were viewed only by the researchers, and no identifiable information was disclosed. The researchers securely stored collected data. The undergraduate and high school students were assured that their responses would not place them at any academic disadvantage. Ethical procedures [32] of the Ministry of Education, Culture, Sports, Science, and Technology and Ministry of Health, Labor, and Welfare in Japan were followed; formal ethical approval is not mandated for this type of study under these guidelines.

Results

Participant Characteristics

The adult group ranged in age from 23 to 67 years, university students ranged in age from 19 to 34 years, and high school students ranged in age from 17 to 18 years (Table 1).

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Table 1. Demographic characteristics.

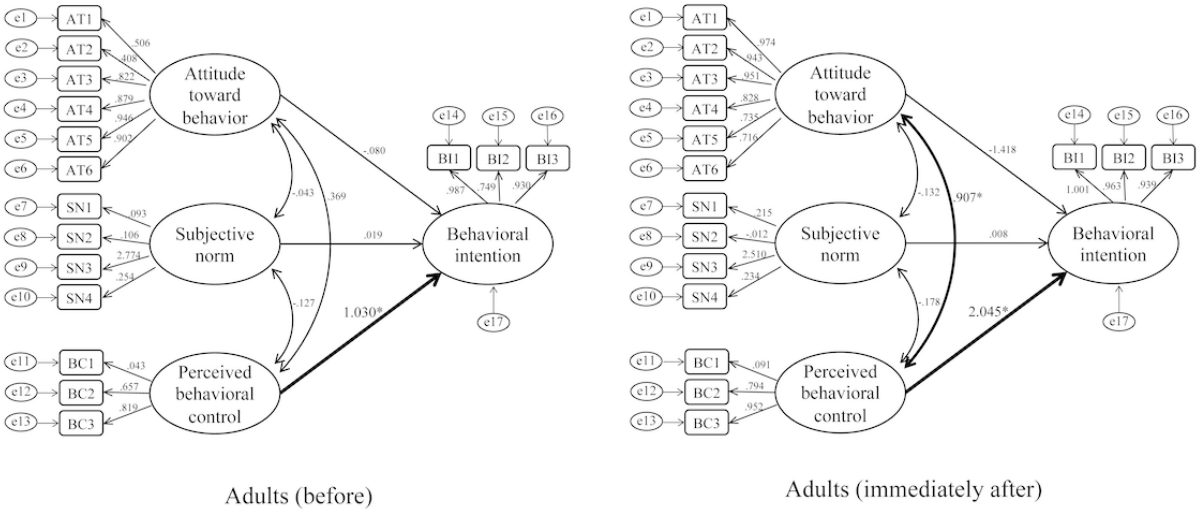
Characteristic	Adults (n=22)	Undergraduate students (n=76)	High school students (n=24)
Age, mean (SD)	43.4 (14.4)	20.9 (2.6)	17.9 (0.3)
Household, n (%)			
Living alone	4 (18)	38 (50)	0 (0)
Only a couple	3 (14)	1 (1)	0 (0)
Parent and child	11 (50)	30 (40)	22 (92)
Three generations	3 (14)	4 (5)	2 (8)
Unknown	1 (4)	3 (4)	0 (0)
Occupation, n (%)			
Medical and welfare specialists	7 (32)	—[a]	—
Nonmedical and welfare specialists	4 (18)	—	—
Graduate students	5 (23)	—	—
Others	5 (23)	—	—
Unknown	1 (4)	—	—
Experience of illness, n (%)			
Self			
Positive	4 (18)	1 (1)	0 (0)
Negative	17 (77)	72 (95)	22 (92)
Unknown	1 (4)	3 (4)	2 (8)
Family member			
Positive	8 (36)	22 (29)	1 (4)
Negative	12 (55)	50 (66)	23 (96)
Unknown	2 (9)	4 (5)	0 (0)

[a]No data.

Structural Equation Models of Behavioral Decision-making Mechanisms

In adult participants, structural equation models demonstrated that there was a significant causal relationship between perceived behavioral control and behavioral intention both before (path coefficient 1.030, $P<.001$; CFI 0.562; TLI 0.464; RMSEA 0.259) and immediately after (path coefficient 2.045, $P=.01$; CFI 0.755, TLI 0.700, RMSEA 0.223) the intervention (Figure 5).

Figure 5. Structural equation model: adult participants before and immediately after participation. Standardized coefficients are shown on each path.



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In undergraduate students, before the intervention, significant causal relationships between perceived behavioral control and behavioral intention (*P*=.004; CFI 0.781; TLI 0.731; RMSEA 0.138) and between attitude toward behavior and behavioral intention (*P*=.04) were evident. In contrast, however, the relationship between attitude toward behavior and behavioral intention was no longer significant immediately after the intervention (*P*=.22; CFI 0.785; TLI 0.701; RMSEA 0.140), which suggests that perceived behavioral control alone influences behavioral intention (Figure 6).

In high school students, prior to the intervention, no factors significantly influenced behavioral intention (CFI 0.785, *P*=.97; TLI 0.701, *P*=.97; RMSEA 0.154, *P*=.97); however, a significant causal relationship (*P*<.001; CFI 0.709; TLI 0.596; RMSEA 0.210) was observed between perceived behavioral control and behavioral intention immediately after the intervention (Figure 7).

Figure 6. Structural equation model: undergraduate students before and immediately after participation. Standardized coefficients are shown on each path.

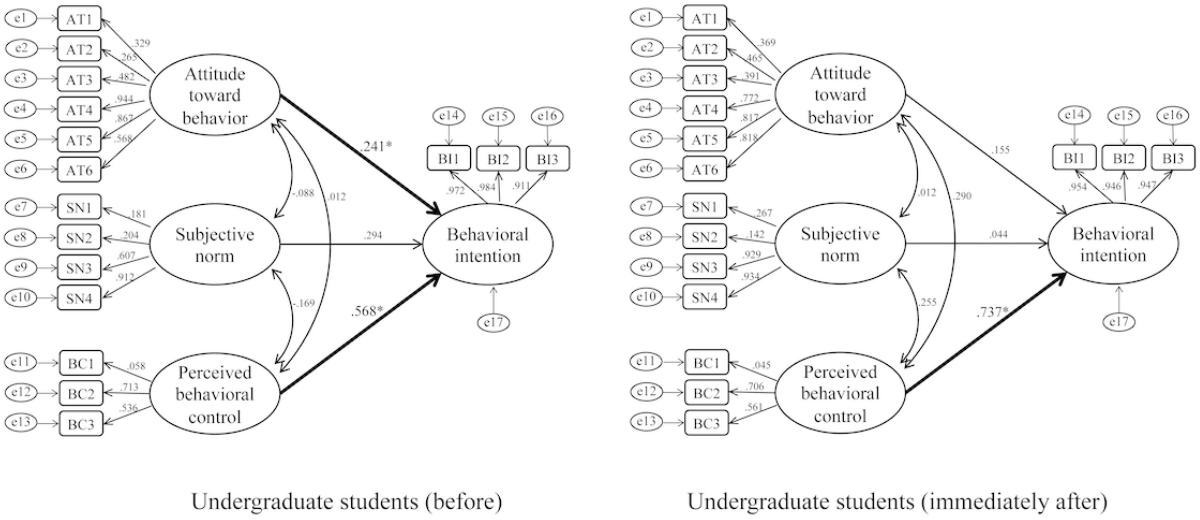
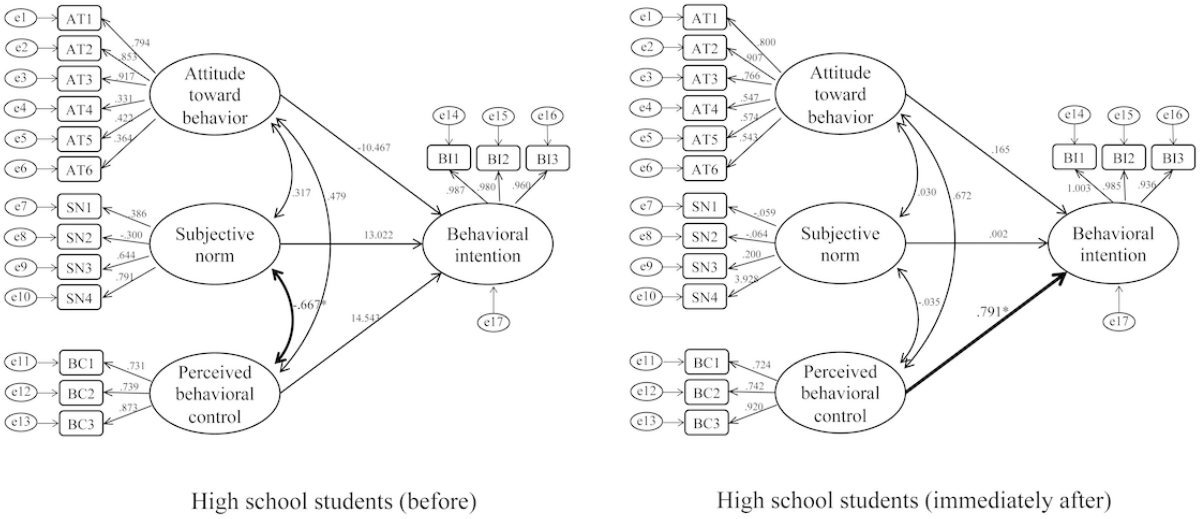


Figure 7. Structural equation model: high school students before and immediately after participation. Standardized coefficients are shown on each path.



Analysis of Free Descriptions

The number of valid responses for free descriptions immediately after the intervention were 20, 66, and 19 for adults, undergraduate students, and high school students, respectively; the number of valid responses for free descriptions 2 to 4 weeks after the interventions were 12, 54, and 16 for adults, undergraduate students, and high school students, respectively. A total of 8 concepts were observed (Table 2): dilemma, intention, learning, and status quo explanation with dilemma and learning description as dominant descriptions.

Responses 2 to 4 weeks after the intervention contained descriptions of behavior (adults: 10/17 concepts, 59%; undergraduates: 42/74 concepts, 57%; high school students: 14/18 concepts, 78%) with less descriptions of dilemma (adults: 3/17 concepts, 18%; undergraduates: 3/74 concepts, 4%; high school students: 2/18 concepts, 11%) or other concepts (Table 3).

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Table 2. Extracted concepts and examples from free descriptions.

Concept	Sentence pattern	Examples
Dilemma	Want to do something but cannot	"When I prioritize fun activities and socializing, it leads to an action that is unhealthy in many cases."
Intention	Want to continue doing something	"I want to start engaging in healthy activities and want to keep improving health awareness so that I can encourage others."
Learning	Noticed something	"I came to realize my tendency to be worried about whether to prioritize career or health."
Status quo explanation	Understood why	"I became aware that I am unhealthy."
Behavior	Did something	"I started recording weights and diet using the body support app."
Cognitive change	Adopted a new thought	"I became more positive about outlooks."
Social pressure	Affected by others	"My health conditions could be affected by others."
Game-related description	N/A[a]	"I want to use it in my study group." "This game realizes us that health is a tradeoff with comfort rather than happiness."

[a]N/A: not applicable.

Table 3. Concepts observed immediately after and 2 to 4 weeks after the game.

Concept	In Adults' responses, n (%)		In undergraduate students' responses, n (%)		In high school students' responses, n (%)	
	Immediately after (n=44)	2 to 4 weeks after (n=17)	Immediately after (n=111)	2 to 4 weeks after (n=74)	Immediately after (n=30)	2 to 4 weeks after (n=18)
Dilemma	13 (30)	3 (18)	39 (35)	3 (4)	10 (33)	2 (11)
Intention	5 (11)	0 (0)	13 (12)	6 (8)	2 (7)	0 (0)
Learning	14 (32)	1 (6)	39 (35)	11 (15)	14 (47)	0 (0)
Status quo explanation	7 (16)	0 (0)	11 (10)	5 (7)	2 (7)	0 (0)
Behavior	0 (0)	10 (59)	0 (0)	42 (57)	0 (0)	14 (78)
Cognitive change	0 (0)	1 (6)	3 (3)	3 (4)	0 (0)	2 (11)
Social pressure	0 (0)	2 (12)	1 (1)	4 (5)	1 (3)	0 (0)
Game-related description	5 (11)	0 (0)	5 (5)	0 (0)	1 (3)	0 (0)

Discussion

Principal Findings

Our findings suggest that perceived behavioral control is a determinant of behavioral intention in adult participants who played Negotiation Battle, a game in which players face an imagined situation that induces dilemma and engage in dialog. Free descriptions revealed that adults frequently experienced dilemma (13/44, 30%) and learning (14/44, 32%), which were the expected characteristics of the game. Thus, it seems that exposure to different perspectives during dilemmas in the simulated scenarios and the subsequent dialog led to self-reflection and transformative learning, which reinforced their perceptions that they can control health-related behaviors.

Transformative learning pertains to "a deep, structural shift in basic premises of thought, feelings, and actions [33]." According to transformative learning theory, critical self-reflection on the assumptions of learners facing disorienting dilemma may occur, which leads them to explore new options regarding roles, relationships, and actions. After undergoing such phases, they build competence and self-confidence in new roles and relationships [34]. In the game, players faced imaginary dilemma situations, which may lead to critical self-reflection and cognitive change in their perceptions of their health behaviors.

For undergraduate students, 2 factors—namely, attitude toward behavior (path coefficient 0.241; P=.04) and perceived behavioral control (path coefficient 0.568; P=.004)—influenced behavioral intention prior to the intervention. Immediately after the intervention, the influence of perceived behavioral control on behavioral intention was maintained (path coefficient 0.737; P=.001), whereas that of attitude toward behavior was not (path coefficient 0.155; P=.22). This finding indicates that undergraduate students also reinforced perceived behavioral control toward healthy behavior by facing dilemmas and undergoing transformative learning.

For high school students, no significant factors for behavioral intention were observed prior to the intervention (P=.97). Afterward, perceived behavioral control contributed to behavioral intention (P<.001). Descriptions of dilemma (10/30, 33%) and learning (14/30, 47%) were mainly observed

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immediately after the intervention, whereas those of behavior (14/18, 78%) and cognitive change (2/18, 11.1%) appeared after 2 to 4 weeks, suggesting that playing Negotiation Battle triggered transformative learning in high school students as it did in adults and undergraduate students.

Notably, the serious game related to lifestyle-related diseases resulted in transformative learning even in high school students, with the majority of concepts (14/18, 78%) suggesting that participants started a new behavior after 2 to 4 weeks. All high school students who participated in the study lived with and were dependent on their parents; thus, we assumed that they would pay less attention to the context of their diet or health behaviors. However, our findings revealed that the game can increase health awareness even among high school students. This finding is in line with those of previous studies [35-37], which demonstrated that serious games designed for health behavior change can be effective for adolescents.

Moreover, we observed that Negotiation Battle reinforced perceived behavior control out of all factors of theory of planned behavior, which led to behavioral intention change. The findings of previous studies [38,39], that digital serious games for health promotion among older adults enhanced perceived behavioral control, support this.

Strengths and Limitations

The study has 3 major strengths. First, we used the theory of planned behavior framework to reveal which factors led to change of behavioral intention after playing Negotiation Battle, which revealed that perceived behavioral control was a major influencing factor. Second, we found that Negotiation Battle can induce critical reflection and transformative learning by placing learners in simulated dilemmas. If transformative learning can be triggered, then the health consciousness transformed by learning will be likely sustained. Third, we compared the effects of Negotiation Battle on adults and on younger people (high school students); thus, the findings are observable across ages.

The study's limitations are the relatively small sample size, which limits the generalizability of this study, and the lack of a control group in the study's design to see the true effect of the intervention.

Conclusions

Through the simulation of dilemma and dialog in Negotiation Battle, participants were encouraged to reflect on their health behaviors, and enhanced perceived behavioral control contributed to the change in health consciousness. Serious game interventions based on the framework of cognitive change processes appear to foster self-reflection and dialog, which encourages transformative learning and the improvement of specific lifestyle behaviors.

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Conflicts of Interest

None declared.

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Abbreviations

CFI: comparative fit index
HIV: human immunodeficiency virus
RMSEA: root mean square error of approximation
TLI: Tucker-Lewis index

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Original Paper

A Virtual Reality Game Suite for Graded Rehabilitation in Patients With Low Back Pain and a High Fear of Movement: Within-Subject Comparative Study

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Abstract

Background: Complex movement pathologies that are biopsychosocial in nature (eg, back pain) require a multidimensional approach for effective treatment. Virtual reality is a promising tool for rehabilitation, where therapeutic interventions can be gamified to promote and train specific movement behaviors while increasing enjoyment, engagement, and retention. We have previously created virtual reality–based tools to assess and promote lumbar excursion during reaching and functional gameplay tasks by manipulating the position of static and dynamic contact targets. Based on the framework of graded exposure rehabilitation, we have created a new virtual reality therapy aimed to alter movement speed while retaining the movement-promoting features of our other developments.

Objective: This study aims to compare lumbar flexion excursion and velocity across our previous and newly developed virtual reality tools in a healthy control cohort.

Methods: A total of 31 healthy participants (16 males, 15 females) took part in 3 gamified virtual reality therapies (ie, Reachality, Fishality, and Dodgeality), while whole-body 3D kinematics were collected at 100 Hz using a 14-camera motion capture system. Lumbar excursion, lumbar flexion velocity, and actual target impact location in the anterior and vertical direction were compared across each virtual reality task and between the 4 anthropometrically defined intended target impact locations using separate 2-way repeated measures analysis of variance models.

Results: There was an interaction between game and impact height for each outcome (all P<.001). Post-hoc simple effects models revealed that lumbar excursion was reduced during Reachality and Fishality relative to that during Dodgeality for the 2 higher impact heights but was greater during Reachality than during Fishality and Dodgeality for the lowest impact height. Peak lumbar flexion velocity was greater during Dodgeality than during Fishality and Reachality across heights. Actual target impact locations during Dodgeality and Fishality were lower relative to those during Reachality at higher intended impact locations but higher at lower intended impact locations. Finally, actual target impact location was further in the anterior direction for Reachality compared to that for Fishality and for Fishality relative to that for Dodgeality.

Conclusions: Lumbar flexion velocity was reduced during Fishality relative to that during Dodgeality and resembled velocity demands more similar to those for a self-paced reaching task (ie, Reachality). Additionally, lumbar motion and target impact location during Fishality were more similar to those during Reachality than to those during Dodgeality, which suggests that this new virtual reality game is an effective tool for shaping movement. These findings are encouraging for future research aimed at developing an individualized and graded virtual reality intervention for patients with low back pain and a high fear of movement.

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KEYWORDS

virtual reality; reaching; intervention; rehabilitation; exergaming; biomechanics; serious games; gamification; movement; physiotherapy; lumbar

Introduction

Virtual reality (VR) has emerged as a promising tool for psychological and movement-based rehabilitation. For example, VR has been used to improve gait adaptability and stability in populations with mobility impairment and a heightened risk for falls [1,2], alleviate phantom limb pain in patients with upper extremity amputation [3], reduce combat-related posttraumatic stress in active duty service members [4], and improve proprioception, mobility, and muscle strength in older adults with knee osteoarthritis [5]. A clear advantage of the VR environment is that it can provide a gamified intervention that is designed to increase enjoyment, motivation, and retention. This can be particularly beneficial when the goal of the intervention is to stimulate movements that may be associated with pain and fear. Based on these unique advantages and the increase in user-friendly VR systems that continue to reduce in cost, it is likely that VR could become a fundamental component of psychological and movement-based rehabilitation programs.

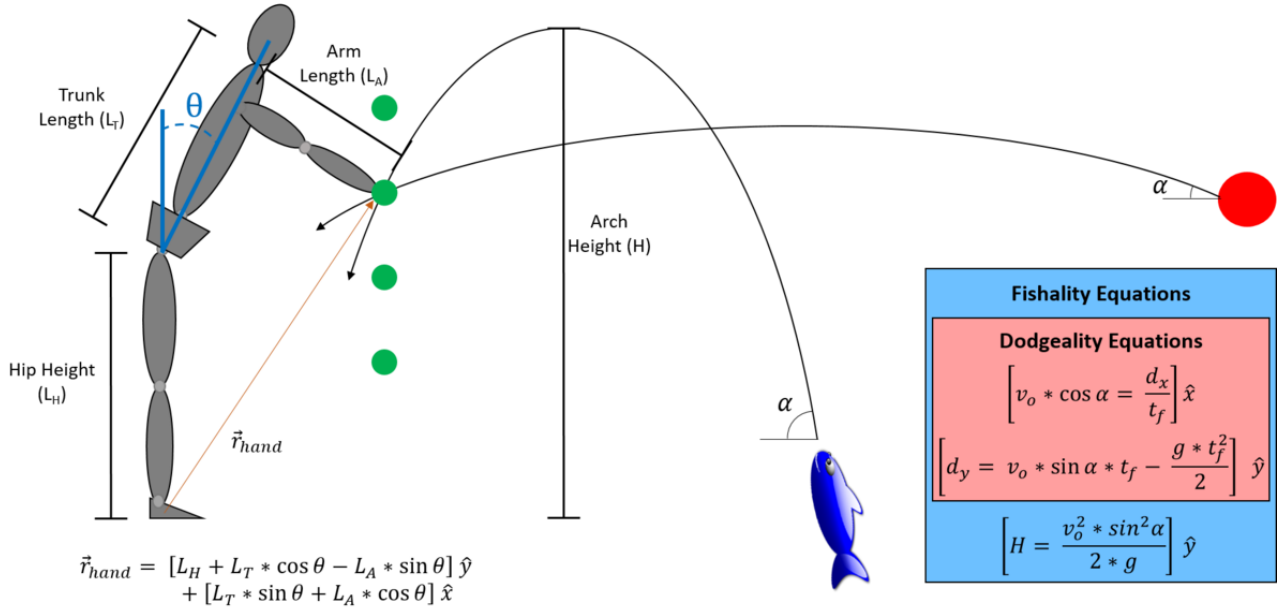
Our group has been developing and testing novel VR games to assess and improve movement deficits in patients with low back pain (LBP) [6]. LBP is the most common source of pain among middle-aged and older adults, resulting in significant financial impact through both health care costs and pain-related work absences [7,8]. Much of these health care costs are driven by the approximately 10% of patients who develop chronic LBP that lasts for many years [9]. Many patients with LBP will develop kinesiophobia, which is fear of movement due to expectations of pain and harm [10]. Among patients with LBP, kinesiophobia is associated with reduced physical activity and particularly reduced spine motion and is a strong predictor of chronic LBP development [10-14]. In brief, kinesiophobia is central to the development of chronic pain through a vicious cycle of pain catastrophizing, hypervigilance regarding pain-related threat, fear-related avoidance of movement, and a resultant combination of disuse, physical deconditioning, and depression, which serve to further amplify pain [10,11,13].

A common method to quantify avoidance behavior is through the assessment of motor control during functional tasks that involve kinematic redundancy [12-14]. Our lab uses a standardized reaching task to compare forward reaching across participants with various body anthropometrics [12-14]. This standardized reaching task uses hip height, trunk length, and arm length to compute 4 points in space that would require exactly 15°, 30°, 45°, and 60° of trunk flexion (θ) to reach, if the participant were to move only at the trunk (Figure 1). While these points are computed based on isolated trunk flexion, participants are not instructed as to how they should reach each target. By assessing how an individual chooses to reach each target, this kinematically redundant task is well positioned to identify avoidance behavior (eg, reduced trunk motion and increased motion at the ankle, knee, and hips) [12-14]. While we originally implemented this reaching task with physical targets, we have recently developed a VR version of the task, hereby referred to as "Reachality" (Figure 2A) [15]. In Reachality, participants are immersed in a virtual environment using a head-mounted display, where their body is represented as an avatar and the participants are instructed to reach their hand through targets that appear in front of them (eg, at the 4 aforementioned locations).

Common interventional approaches for patients with LBP and a high fear of movement include graded exposure therapy, wherein patients gradually confront increasingly feared movements, and motor control exercises, wherein existing movement patterns are retrained with a specific focus on restoring trunk control [16-18]. Our group recently developed a VR dodgeball game, hereby referred to as "Dodgeality," with the goal of creating a gamified intervention that incorporates principles of these classic interventional approaches that are known to be successful [6,19]. In Dodgeality, participants are immersed in a virtual gymnasium and hold a plastic 3D-printed dodgeball, which is tracked and visualized as a dodgeball in the avatar's hand within the virtual environment. There are 4 opposing players who randomly take turns throwing dodgeballs at the participants, who are instructed to block the balls thrown at them with the ball held in their hand. Each dodgeball is launched at a constant velocity and is modeled as a point-mass projectile with only gravitational forces acting upon it, resulting in a parabolic flight path. Through manipulating only launch angle, we are able to force the dodgeballs' trajectory to intercept the same 4 locations in space that are presented as targets during Reachality (Figure 1), thereby enticing the participants to reach those locations during gameplay. In a recent phase I clinical trial, our group found that lower intercept locations resulted in increased lumbar flexion excursion in patients with chronic LBP [6]. As avoidance behavior is more prominent when reaching for lower targets [14], the ability to increase the magnitude of trunk flexion needed for gameplay throughout an intervention is essential. Other important findings from the phase I clinical trial were that participants viewed the game as "distracting from their back pain" and "fun to play," that they were "not worried about hurting their back during gameplay," and that the game "did not increase their back pain" [6]. Based on the findings from this phase I trial, we believe that Dodgeality could be a useful component of rehabilitation for patients with chronic LBP and a high fear of movement, and we are currently evaluating the efficacy of this intervention in a phase II randomized clinical trial [20].

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Figure 1. Diagram of the physics equations used in the different VR games. Four target contact locations (shown in green) are computed for each subject based on anthropometrics and a trunk flexion angle (θ) of 15°, 30°, 45°, and 60° and presented as a static target during Reachality. During Dodgeality, targets are launched with a constant initial velocity (vo), and the launch angle (α) is modified to ensure that the launch trajectory intercepts an intended target contact location. During Fishality, the launch velocity and angle are manipulated to ensure that the launch trajectory reaches a target height (H) and intercepts the intended target contact locations. VR: virtual reality.



While our recent findings indicate that we are able to successfully manipulate the amount of trunk flexion needed during gameplay [6], Dodgeality is inherently a fast-paced game that requires quick reactions. In open-ended survey responses, some participants indicated a desire for more practice in the virtual environment at slower speeds [6]. Importantly, a primary principle of graded exposure therapy is to begin with patients' least feared movement and gradually work toward their most feared movement [16-18]. Patients with LBP and a high fear of movement not only restrict the amount of trunk motion during forward reaching but also the speed at which they flex their trunk [12]. Therefore, to improve our ability to gradually increase mechanical demands of the trunk throughout an intervention, we sought to create a new game that required similar amounts of trunk flexion as Dodgeality but with lower velocity demands. We developed a virtual fish-catching game, hereby referred to as "Fishality," which is intended to precede Dodgeality in a graded intervention (Figure 2B-2D). In the Fishality virtual environment, participants are standing on a dock overlooking a pond and have a basket in their dominant hand (which is tracked with a controller in the real world). Fish swim toward participants, with an indicator above the level of the water to alert participants to an approaching fish. The fish then jump out of the water toward participants at a high parabolic arc, and participants are instructed to catch the fish in their bucket. This trajectory is intended to give participants more time to react, thereby requiring decreased trunk flexion velocities. Through prescribing the height of the trajectory and resolving the kinematic equations, initial launch angle and launch velocity can be computed to ensure that the fish intercept the same 4 points in space that are used during Reachality and Dodgeality (Figure 1).

The purpose of this study was to compare lumbar kinematics across Reachality, Dodgeality, and Fishality in healthy control participants. Our first hypothesis was that lumbar flexion velocity would be increased during Dodgeality relative to that during Fishality. Our second hypothesis was that the extent of lumbar flexion would not be different between virtual games. While Dodgeality and Fishality are designed such that the trajectories of the launched objects intersect each of the 4 static target locations presented during Reachality, the participants are allowed to intercept the launched objects at any point along their trajectory. Considering that the objects' trajectories are markedly different between Dodgeality and Fishality, it is possible that observed differences in lumbar kinematics may be explained through differences in the actual interception location (rather than the intended location from which trajectories are initially derived). Therefore, we present the following exploratory third hypothesis: participants would reach further in the forward direction during Fishality and Reachality than during Dodgeality.

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Figure 2. Visual depiction of Reachality (A), Fishality (B), and Dodgeality (C) gameplay, the avatar that participants controlled (D), and the motion analysis data collected during the experiment (E).



Methods

Participants and Ethical Considerations

A total of 31 healthy, unimpaired participants (16 males, 15 females; mean age 24.7 years, SD 3.3 years; mean weight 76.05 kg, SD 12.24 kg; mean height 172.5 cm, SD 9.8 cm) completed an informed consent process approved by the Virginia Commonwealth University Human Research Protection Program (HM20014879) and then participated in the present study. Inclusion criteria for the study mandated that all participants be between 18 and 35 years of age. Individuals who were pregnant or had a history of spine or hip surgery, LBP in the previous 6 months, a diagnosis of a neurological, cardiovascular, or musculoskeletal disorder that would interfere with the ability to participate in movement-based VR games, alcohol or drug dependence, significant visual impairment, or a history of motion sickness that would prevent the use of a VR head-mounted display were excluded from participating.

Gameplay

The order of gameplay was fixed such that Reachality was followed by Fishality and then Dodgeality. During Reachality, participants reached virtual targets that were located in the midsagittal plane at heights that would theoretically elicit 15°, 30°, 45°, and 60° of isolated trunk flexion (Figure 1) [21]. The order of the reaching heights was fixed, starting with the highest target and ending with the lowest target. At each height, participants completed 5 reaches with their right hand, followed by 5 reaches with their left hand. A short rest of approximately 15 seconds was provided between reaches and approximately 2 minutes between heights. For each reach, participants were instructed to stand upright until the virtual target changed color (red to green), after which they were instructed to reach their hand through the virtual target and hold it there for 2 seconds, which was timed and displayed visually using a status bar above the target. After the 2 seconds, the target and status bar disappeared, and the participant was instructed to return to upright stance and wait for the next target to appear.

During Fishality, participants held a controller in their right hand, which was visualized as a basket in the virtual environment, and were instructed to catch fish that jumped out of the water toward them in a path that followed a high parabolic arc. The trajectory of each fish was prescribed such that the fish would intercept the same 4 points in space that were used to theoretically elicit 15°, 30°, 45°, and 60° of isolated trunk flexion; however, the participants were not instructed as to where to catch the fish along its trajectory. Along with catching the fish at different heights, participants were occasionally presented with an ominous audio cue followed by a large shark jumping out of the water toward their head, and they were instructed to duck to avoid the shark.

During Dodgeality, participants held a 3D-printed dodgeball, which was tracked and visualized in the virtual environment, and were instructed to use the ball to block incoming dodgeballs that were thrown at them by 4 opponents. Again, the trajectory of the thrown dodgeball was prescribed to intercepts with the 4 aforementioned points in space, and the participants were free to intercept the dodgeball at any point along its trajectory. Dodgeality also involved occasional ducking, with participants

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instructed to duck and avoid the incoming dodgeball if they heard a quacking sound, and the color of the incoming ball was black instead of red.

Each participant played Reachality, followed by 1 level of Fishality and then 1 level of Dodgeality. Fishality and Dodgeality each consisted of 2 sets of 15 launched fish (or dodgeballs), with an equal and randomized distribution across the 4 target heights and ducking.

Instrumentation

Whole body kinematics were collected in 3D at 100 Hz using a 14-camera passive motion capture system (Vero v1.3, Vicon Motion Systems Ltd.) and rigid tracking clusters placed on the head over the thoracic spine, lumbar spine, and pelvis and bilaterally on the feet, shank, thigh, arm, forearm, and hands. Each rigid cluster was 3D printed (Taz 6, LulzBot Inc.), contained 4-7 spherical retroreflective markers (9.5 mm Pearl Markers, B&L Engineering), and was affixed to the body using Velcro straps (Fabrifoam ProWrap, Applied Technology International, Ltd.). The 3D position and orientation of each rigid cluster were recorded at 100 Hz and streamed to a Transmission Control Protocol (TCP) socket port in real time using Vicon Tracker software.

Motion monitor software (MotionMonitor xGEN, Innovative Sports Training Inc.) was used to read the rigid cluster kinematics and kinetic data obtained from 2 embedded force plates (Bertec Inc.). Segment orientations were defined in MotionMonitor xGEN through digitizing anatomic landmarks during quiet stance using a custom 3D-printed stylus pen that contained 5 reflective markers. Segments were then tracked in 6 degrees of freedom during motion, and joint angles were computed between adjacent segments using an Euler angle sequence of rotations in the sagittal, frontal, and transverse planes. All kinematic and kinetic data were recorded for each trial using MotionMonitor xGEN and exported for further analyses.

Along with the motion capture system, participants held a 3D-printed dodgeball, which had a wireless HTC Vive tracker (HTC America Inc.) attached to it, during Dodgeality and held a wireless HTC controller in their right hand during Fishality. The 3D position and orientation of the Vive tracker and controller were tracked using 2 HTC Base Stations, which emit infrared light that is sensed by multiple photodiode detectors on the tracker and the controller to determine orientation. The kinematics of the Vive tracker and controller were also streamed to a TCP socket port in near real time using SteamVR software (Valve Inc.).

The VR environments and games were custom-built using Unity game engine (version 3.9, Unity Technologies). The Unity program read incoming data from Vicon Tracker, MotionMonitor xGEN, and SteamVR from the TCP socket ports and used these data to build and control the participants' avatar in the virtual environment. Along with reading incoming data, the Unity program also sent data to MotionMonitor xGEN regarding the timing of game events (eg, when the virtual target appeared, cued reaching by changing colors, and was first contacted during Reachality). Participants were immersed in the virtual environment using an HTC Vive-wired, head-mounted display, which presented them with a first-person perspective of their avatar. The head-mounted display had a resolution of 1080 × 1200 per eye, with a refresh rate of 90 Hz and a field of view of 110°.

Analysis

Joint kinematics exported from MotionMonitor xGEN were further reduced using a custom-built MATLAB program (version 2020a, The MathWorks Inc.). Joint angle time series were smoothed and differentiated using a 41-point, fourth-order Savitzky-Golay filter, which computes polynomial coefficients to fit a least-squares solution to the data [22,23]. Lumbar flexion excursions and peak lumbar flexion velocity were computed for each forward reaching movement. As fishing was played with the right hand, joint kinematics were assessed on the right side and only right-handed reaching trials were analyzed. Joint excursion and velocity were computed between the time when each movement began (eg, target appeared in Reachality, opponent began winding up in Dodgeality, or fish began swimming toward the participant in Fishality) and 200 milliseconds after the participant contacted the target (or fish/dodgeball). Trials where the targets were not successfully intercepted (ie, the fish was not caught in the basket) were included in the analyses as long as the participant did react to the launch and attempted to intercept it. Each trial was visually reviewed by a member of the study team, and if there was an apparent lack of lumbar motion in response to a launched target, that trial was excluded from analysis. Along with lumbar excursion and velocity, hand location at target contact was computed relative to the midpoint of the participants' feet. Outcomes were computed for each movement and then averaged across reaching height for each game.

Statistical Analysis

Data were tested for normality using Shapiro-Wilk tests before separate 2-way repeated measures analyses of variance were performed for each outcome measure, with game (Reachality, Fishality, and Dodgeality) and height (target location for 15°, 30°, 45°, and 60° of trunk flexion) as within-subject variables. Greenhouse-Geisser corrections were applied when the assumption of sphericity was not met. Effect sizes (via partial Eta-squared values) were computed for each analysis of variance model, with values greater than 0.25 indicating a moderate effect and values greater than 0.64 indicating a strong effect [24]. Post-hoc analyses were performed using the method of least significant differences for significant main effects, and interactions were analyzed using a simple effects model. Significance was set at an α level of .05, and all statistical analyses were performed using SPSS (version 27, IBM Inc.).

Results

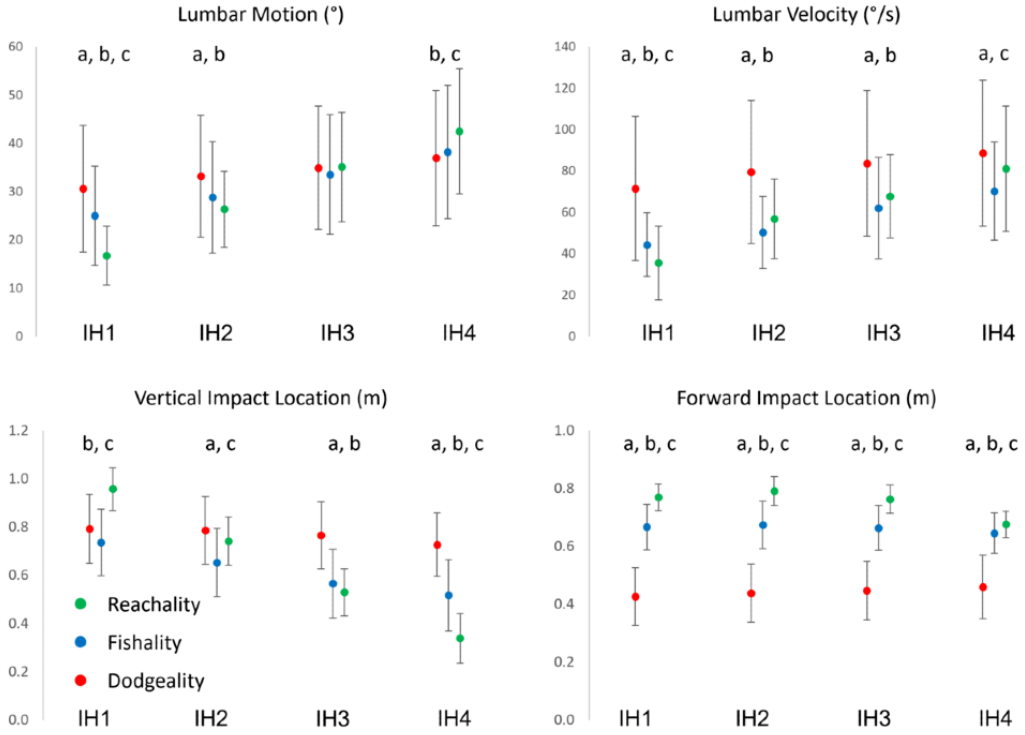
The raw data and results for the repeated measures analysis of variance are presented in Table 1. There was an interaction between game and impact height for each outcome (Figure 3, all P<.001). Therefore, post-hoc simple effects models (ie, 1-way analysis of variance) were performed to compare the 3 games across each impact height.

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Table 1. Outcome measures compared across games and impact heights.

Outcome measures	Game	Impact height	Interaction between game and impact height
Lumbar motion (°)	• F(2,48)=2.739 • *P*=.08 • η^2=0.102	• F(1.4,33.9)=110.41 • *P*<.001 • η^2=0.821	• F(2.9,69.7)=22.092 • *P*<.001 • η^2=0.479
Lumbar velocity (°/s)	• F(2,48)=17.002 • *P*<.001 • η^2=0.415	• F(1.4,34.2)=108.151 • *P*<.001 • η^2=0.818	• F(3.4,82.6)=9.366 • *P*<.001 • η^2=0.281
Anterior-posterior impact location (m)	• F(1.4,32.4)=136.48 • *P*<.001 • η^2=0.85	• F(3,72)=29.704 • *P*<.001 • η^2=0.553	• F(4.1,97.9)=12.188 • *P*<.001 • η^2=0.561
Vertical impact location (m)	• F(1.6,37.8)=16.653 • *P*<.001 • η^2=0.41	• F(2.1,51.1)=493.625 • *P*<.001 • η^2=0.954	• F(3.8,91.0)=150.701 • *P*<.001 • η^2=0.863

Figure 3. Study outcomes compared across intended impact heights (IH1–IH4) and virtual reality games (Reachality, Fishality, and Dodgeality). Error bars represent 1 standard deviation. a: significant difference between Dodgeality and Fishality; b: significant difference between Dodgeality and Reachality; c: significant difference between Fishality and Reachality.



Lumbar Excursions

On examination of the effects of game type on lumbar excursions, the effects were found to be different at each intended impact height. Specifically, at intended impact height 1, lumbar flexion excursion was greater during Dodgeality than during Fishality and Reachality and greater during Fishality than during Reachality. At intended impact height 2, lumbar flexion excursion was greater during Dodgeality than during Fishality and Reachality. There were no significant differences between the games at intended impact height 3, but at intended impact height 4, lumbar flexion excursion was greater during Reachality than during Dodgeality and Fishality.

Lumbar Flexion Velocity

On examination of the effects of game type on lumbar flexion velocity, the effects were found to be different at each intended impact height. Specifically, at intended impact height 1, lumbar flexion velocity was greater during Dodgeality than during Fishality and Reachality and greater during Fishality than during Reachality. At intended impact heights 2 and 3, lumbar flexion velocity was greater during Dodgeality than during Fishality and Reachality. Finally, at intended impact height 4, lumbar flexion velocity was greater during Dodgeality and Reachality than during Fishality.

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Impact Location

The differences between games for actual impact location in the vertical direction varied across intended impact heights. At intended impact height 1, actual impact location was lower during Dodgeality and Fishality than during Reachality. At intended impact height 2, actual impact location was lower during Fishality than during both Dodgeality and Reachality. At intended impact height 3, actual impact location was lower during Fishality and Reachality than during Dodgeality. Finally, at intended impact height 4, actual impact location was lower during Reachality than during Dodgeality and Fishality and lower during Fishality than during Dodgeality. At each intended impact height, the actual impact location in the anterior-posterior direction was greater during Reachality than during Dodgeality and Fishality and greater during Fishality than during Dodgeality.

Discussion

Gamified movement-based intervention is a promising approach for rehabilitation in patients with LBP and a high fear of movement. Our group recently developed Dodgeality, a virtual dodgeball game where patients are encouraged to bend forward to block incoming balls thrown at them by opposing players [6]. While we are able to influence the amount of trunk flexion needed for successful gameplay by modifying the intended impact location of launched balls, Dodgeality is inherently a fast-paced game with large movement velocity demands. We sought to supplement our VR game suite by developing a game to encourage patients to flex their trunk at a slower speed. We therefore developed Fishality, a novel VR game where fish jump out of a body of water with a high parabolic arc, and the patients have to bend forward to catch the fish before they land back in the water.

This study sought to compare movement biomechanics across Dodgeality, Fishality, and a standardized virtual reaching task (Reachality). Our first hypothesis was supported, as lumbar flexion velocity was greater during Dodgeality than during Fishality. While flexion velocity during Fishality was less than that during Dodgeality at each intended impact height, differences were greater for higher impact heights (requiring less motion). Specifically, lumbar flexion velocity reduced by 38% at intended impact height 1 (Dodgeality: mean 71.5°, SD 35.8°; Fishality: mean 44.3°, SD 15.4°) and 21% at intended impact height 4 (Dodgeality: mean 88.7°, SD 35.3°; Fishality: mean 70.2°, SD 23.7°). Our second hypothesis was not supported, as lumbar motion was different between games. Specifically, Fishality resulted in 13%-18% less lumbar motion relative to Dodgeality for higher targets, resulting in magnitudes of movement that were more similar to those for Reachality. It is unclear why lumbar flexion was increased for higher targets during Dodgeality; however, it is likely that participants began moving downward before they identified the target of the incoming ball because of the fast speeds at which the dodgeballs were launched. This finding suggests that Fishality is better than Dodgeality for manipulating trunk flexion during gameplay. As the magnitude of lumbar flexion and lumbar flexion velocity across VR games and impact heights were comparable between this study and prior research conducted in a real-world environment [12,21], the findings of this study were likely not due to the VR environment itself. Additional evidence for this notion comes from a prior study that found limited differences in lumbar motion and velocity when reaching tasks were compared between a virtual environment and real-world setting [15]. Because a major goal of graded intervention is to increase movement demands throughout the course of an intervention [16-18], the ability to modulate lumbar motion and velocity is essential. Hence, the results of this study are encouraging when considering the development of an individualized, graded intervention program for patients with LBP who have low physical activity and a high fear of movement.

Another important finding from this study was that participants did not reach as far forward when playing Dodgeality and Fishality relative to when making contact with the targets during Reachality. This finding intuitively makes sense, as projectiles (dodgeball and fish) can be intercepted at any point along their trajectory for successful gameplay during Dodgeality and Fishality (compared to static target positions used in Reachality). Reach distance was increased during Fishality compared to that during Dodgeality, which is also to be expected given the different requirements of the 2 games. Specifically, incoming dodgeballs have a flat trajectory that will contact participants' bodies if not blocked, whereas incoming fish have a high parabolic trajectory and will land in the water between the participant and intended intercept target if not caught. Based on these findings, feature modifications to our VR games, such as interception boundaries, could be introduced to ensure greater forward movement during gameplay, which would improve our ability to specifically target lumbar flexion appropriately across all target heights.

This study had limitations that should be considered when interpreting the findings. First, as our sample consisted of young healthy participants, these findings should be repeated in a cohort of participants with a broad range of ages and spine impairments to determine the robustness of the findings. However, for this study, we intentionally included healthy participants without impairment to ensure that the task demands aligned with how we had developed the VR games. A second potential limitation is that the gameplay order was not randomized, which could have introduced an ordering effect into our data. However, as the games are designed to be used in an ordered fashion for interventional purposes, we wished to investigate movement behaviors within this context.

In conclusion, the present study sought to compare a virtual dodgeball game, a newly developed virtual fish-catching game, and a virtual reaching task in a healthy sample. We found that lumbar flexion velocities were reduced in Fishality compared to those in Dodgeality and resembled velocity demands more similar to those in a self-paced reaching task (ie, Reachality). These findings are encouraging for future research aimed at developing individualized, graded VR interventions for patients with LBP and a high fear of movement.

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Acknowledgments

JST, CRF, and PEP developed the testing paradigm, were responsible for project conceptualization, and provided lab space; ATP, SvdV, and AS performed data collection; ATP, SVDV, and AS performed data analysis; ATP wrote the manuscript; and SvdV, AS, PEP, CRF, and JST proofread the work.

Conflicts of Interest

None declared.

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Abbreviations

LBP: low back pain
TCP: Transmission Control Protocol
VR: virtual reality

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Original Paper

Gaming Activity and Possible Changes in Gaming Behavior Among Young People During the COVID-19 Pandemic: Cross-sectional Online Survey Study

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Abstract

Background: Young people's daily lives and social interactions changed remarkably during the COVID-19 pandemic as schools and cinemas closed, leisure activities were cancelled, and gatherings were regulated. Questions have been raised by the media, schools, policy makers, and research communities about the effect on young people's online behaviors.

Objective: This cross-sectional study aimed to study self-reported changes in gaming, focusing on a younger section of the population during the COVID-19 pandemic in Sweden. We also wanted to look at potential risk factors behind problematic gaming during the pandemic, including gaming patterns, gambling behavior, psychological distress, certain sociodemographic characteristics, health factors, and school situation.

Methods: This was an anonymous online survey study of web panel participants in Sweden (n=1501) to study changes in gaming behaviors during the COVID-19 pandemic. Self-reported increases in gaming were analyzed in logistic regression analyses against sociodemographic and health factors.

Results: Within the study population that reported changes in gaming activity, we found significant differences in age, employment status, disposable income, whether they ever played on loot boxes, time spent at home, school attendance, psychological distress, and gambling and gaming problems, as well as significant differences in changes in alcohol consumption and exercise habits. When examining the 16–24-year-old age group who reported changes in gaming activity, we found significant differences within the group in disposable income, time at home, and school attendance. When examining the 25–39-year-old age group who reported changes in gaming activity, we found significant differences within the group in employment status, disposable income, time spent at home, whether the respondents were studying, school attendance level, psychological distress, and gaming problems, as well as significant differences in changes in alcohol consumption and exercise habits. Psychological distress (all age groups analyzed together; 25–39-year-old age group), drinking less alcohol (all age groups analyzed together), spending more time at home (all age groups analyzed together), gaming problems, and exercising less (25–39-year-old age group) were positively correlated with a self-reported increase in gaming activity. Being employed (25–39-year-old age group) and being over 40 years of age (all age groups analyzed together) were negatively correlated with increased gaming. We found no significant correlations in the 16–24-year-old age group.

Conclusions: Those who reported increased gaming during the COVID-19 pandemic were more likely to be 16 years to 39 years old. In the age group of 25 years to 39 years old, the increase was associated with psychological distress, reporting less exercise, and being unemployed. COVID-19 may present as a risk factor of increased online gaming in a small but vulnerable group. More research and preferably longitudinal studies are needed in the field of gaming and effects of the COVID-19 pandemic.

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KEYWORDS

COVID-19 pandemic; gaming; screen time; psychological distress

Introduction

The index case of the now widespread COVID-19 pandemic caused by the SARS-CoV-2 virus originated in Wuhan, the capital of Hubei Province, China, on December 8, 2019 [1]. On January 31, 2020, the first confirmed case of SARS-CoV-2 viral infection was recorded in Sweden. In subsequent months, COVID-19 reached most countries in Europe [2], and on March 11, 2020, the World Health Organization (WHO) declared the outbreak a pandemic.

As well as physiological harm, the COVID-19 pandemic has also had an enormous effect on people's mental health [3,4]. Research has confirmed that rates of depression, addiction, anxiety, and other psychiatric disorders rose during the pandemic [5-10]. Research has shown an increase in screen time and the consumption of digital entertainment during the pandemic, particularly online gaming and related activities such as video game streaming [4,9,11-13]. This phenomenon has been seen worldwide. In India, for example, WinZO Games reported 300% greater user engagement, 30% higher traffic in online mobile gaming, and 35% higher usage in multiplayer modes [14], and another Indian mobile-based online gaming platform reported an almost 200% increase in the user base during the pandemic, with 75,000 new users [15]. A 70% increase in Fortnite gaming has been seen in Italy [16]. In the United States, one of the largest telecom providers reported a 75% rise in online activity [17]. In 2020, the world's largest video game digital distribution service, Steam, reported 20 million active users, an all-time high [18]. The WHO has supported gaming as an activity that promotes social distancing and reduces the loneliness that might follow, including the gaming industry's media campaign #PlayApartTogether, which mixes guidelines to prevent the spread of COVID-19 with messages encouraging online gaming [19-22]. It has been suggested that online gaming could be psychosocially beneficial to young people—cognitively, motivationally, emotionally, and socially [23,24]—and especially so in the COVID-19 pandemic, when recommendations and regulations to stop the spread of the virus have affected everyone's lives. Gaming has been shown to reduce loneliness [25,26] and, even though concerns have been raised about its addictive potential, research has shown that frequent gaming does not have to be problematic [27] and most gamers' gaming habits are changeable and not fixed [28,29]. It has also been suggested that gaming could work as a coping mechanism against stress [30,31]. However, excessive screen time has been shown to be associated with a range of negative mental health outcomes, including anxiety and depression, in adolescents considered particularly vulnerable to a problematic use of online media [32-34]. Softening its excessively positive initial message about gaming, the WHO's mental health information (#HealthyAtHome—Mental Health) recommended a *balance* between time spent on screens—and gaming in particular—and offline activities [22].

Governmental virus protection strategies have differed around the world from recommendations to more mandatory interventions [35]. Sweden's approach to prevent virus spread has not included lockdown or stay-at-home orders but rather recommendations. Most workplaces encouraged their workers to work from home, and regulations in opening hours have been in effect for places such as restaurants and shopping malls, leading people in general to spend a lot more time inside with possible access to screens.

Young people's daily lives and social interactions have changed remarkably in the COVID-19 pandemic because of school and cinema closures, the cancellation of leisure activities, and restrictions on gatherings. Without the daily routine of going to school, young people had unlimited opportunities to play video games, making them vulnerable to developing problems related to excessive gaming.

Internet gaming disorder (IGD), it should be noted, is included in the 11th revision of the International Classification of Diseases (ICD 11), defined as a gaming behavior of sufficient severity to result in significant impairment in areas of function [36]. However, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) has described IGD as "necessitating further clinical experience and research before inclusion as a formal disorder" [37].

With regard to gambling habits, there has also been considerable research on the impact of the COVID-19 pandemic [38]. Our research in this area has shown that the increase in gambling in the general population in Sweden is limited, but the group who does report increased gambling activity also reports psychosocial problems [38-41]. Researchers have raised the concern that more time spent at home *could* increase gaming and its possible negative side effects, but there is very little research on the *actual* situation [18]. We thus set out to see if gaming habits changed during the COVID-19 pandemic in the same way as gambling habits.

The aim of this cross-sectional study was thus to study self-reported changes in gaming during the COVID-19 pandemic, focusing on a younger section of the Swedish population. We also considered the potential risk factors for problematic gaming during the pandemic, including gaming patterns, gambling behavior, psychological distress, certain sociodemographic characteristics, health factors, and school situation.

Methods

Setting

The first wave of the COVID-19 pandemic in Sweden was in the spring of 2020. In the summer of 2020, virus transmission decreased, and the second wave started in the autumn of 2020. After only a partial decrease in virus transmission in the winter of 2020-2021, early 2021 saw a third wave of virus transmission and an increased hospital-admitted disease burden in Sweden [42]. This study was cross-sectional and based on a self-report online survey study carried out in Sweden in March 2021 during the third wave of the ongoing COVID-19 pandemic in the

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country. At the time of the study, secondary schools in Sweden had started to open up for on-site teaching, but the national COVID-19 strategies regarding leisure activities and restrictions on gatherings of more than 8 people were still in effect.

Participants and Procedures

We used the market survey company Ipsos and their online web survey panel. Ipsos is a market survey company that has broad experience in conducting survey studies in the area of addictive disorders. Ipsos abides by the International Chamber of Commerce (ICC)/ESOMAR Code. The Ipsos web panel has previously been used for online surveys in the course of our research [43]. In this study, we invited respondents from the general population, aged 16 years and older. Participants for the Ipsos web panel were invited with the information that the survey would address "computer gaming, gambling for money and other behavioral patterns in Sweden during COVID-19—association with mental health, social situation and attitudes to the pandemic." The survey was made accessible only when the respondent provided electronic informed consent. Participants on the Ipsos web panel enroll voluntarily to take market surveys, political opinion polls, and similar surveys, for which they earn points they can redeem as goods or services. Most surveys are worth a point and each point is worth approximately €1 (US $1.14). The survey is sent out to different age groups of web panel participants until a gender and age distribution close to that of the general population is achieved. In this study, invitations were sent until some 1500 complete answers were obtained. In addition, in this study, the final distribution of age groups, gender, and geographical location (regions) was compared by Ipsos with those of the general population, such that the data set was weighted according to a summarized weighting score derived from these 3 variables. When the survey was halted, the final sample consisted of 1501 individuals. The study was carried out from March 19, 2021 through March 29, 2021. The study was reviewed and approved by the Swedish Ethical Review Board (File: 2021/00369).

Measures

Basic sociodemographic variables comprised gender (female or male), age (divided into 2 age groups: 16-24 years; ≥25 years), monthly income (divided into 3 groups: SEK 10,000-20,000 [US $1107.48-$2214.97]; SEK 20,000–40,000 [US $2214.97-$4429.94]; SEK ≥40,000 [US ≥$4429.94]), level of education (university, secondary school [age 16-19 years], primary school [age 6-16 years], other), employment status (studying, employed, unemployed, retired, other). The questionnaire began with questions about changes in the respondent's personal behavior during the COVID-19 pandemic ("since these changes in Sweden started"); whether they, during this period, had spent more or less time at home (much more, slightly more, unchanged, or less time at home); and whether they had consumed more or less alcohol (more, less, unchanged, or don't drink at all). Thereafter, questions were asked regarding schooling situation—whether the respondents attended school of any kind including university (yes or no) and whether their level of achievement had been affected by the remote learning situation during the pandemic (for the better, for the worse, or not affected). Finally, the participants were asked if their school attendance had been affected by the remote learning situation during the COVID-19 pandemic (less absence, more absence, or not affected). The final questions were about gaming, specifically whether their personal gaming habits had changed, excluding games for money (more, no change, less, I do not engage in gaming). We also asked about loot boxes: whether in the last 12 months they had engaged in gaming involving currency inside a video game, with the purpose to either gain money or advantages in the video game (yes, no).

The Game Addiction Scale for Adolescents (GASA) is one of the most frequently used questionnaires for gaming addiction [44-47]. The scale was theoretically based on the DSM-5 criteria for pathological gambling [47]. Each question covers 1 criterion, answered on a 5-point continuum scale: 1 (never), 2 (rarely), 3 (sometimes), 4 (often), 5 (very often). It should, according to the developer, be accounted as endorsed when rated 3 or higher. The DSM-5 requires half (or more) of their criteria to be met, while scholars within the field of gaming suggest a ranking of the criteria: the "core approach." The criteria tolerance, mood modification, and cognitive salience are said to be associated with engagement rather than addiction, while the contrary applies for the criteria withdrawal, relapse, conflict, and problems [47-49]. In order to distinguish between levels of severity within the group of gamers, the core approach was applied, whereby the individuals who met all the core criteria (relapse, withdrawal, conflict, and problems) constituted the group *addicted gamers*. The respondents who endorsed 2 or 3 of the core criteria but none of the peripheral criteria (salience, tolerance, mood modification) were grouped as *problem gamers*, and those that endorsed all 3 of the peripheral criteria but not more than one of the core criteria were grouped as *engaged gamers* [46,50]. The remaining respondents comprised the group "*noproblem" gamers*, as individuals below the cut-off for engaged gaming.

Since both the problem gamers and the addicted gamers were assumed to be associated with more severe gaming behavior as well as more negative outcomes [46,51], these 2 groups also constituted one combined group (2-4 endorsed core criteria): *addicted/problem gamers*.

Psychological distress was measured using the Kessler-6 scale [52]. This scale measures symptoms of depression and anxiety perceived during the past 6 months. The Kessler scores (0-4 for each question) were summed, and a total score of 5 or more was classified as psychological distress [52].

The level of potential gambling problems was measured with the 9-item Problem Gambling Severity Index (PGS-I) [53], where each of the statements addresses the preceding 12 months. For the PGS-I scale, the scores of 0-3 for each question were summed: A score of 0 indicated no problem with gambling; a score of 1-2 indicated a low risk of gambling problems; 3-7 indicated a moderate risk of gambling problems; and 8 or more indicated gambling problems.

Statistical Analysis

Weighting adjustments were applied to compensate for nonresponse and noncoverage and to make the sample estimates conform to external values. The reporting of prevalence

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measures and group-wise comparisons related to the weighted data and statistical tests were applied using the Chi-square test, while binary logistic regression analyses were carried out using the unweighted data. Binary logistic regression analyses were carried out with increased changes in gaming behavior (yes/no) as the dependent variable in order to study potential independent variables associated with the outcome. For all models, odds ratios (ORs) with 95% CIs are presented. For all statistical analyses, SPSS version 25.0 (IBM Corp, Armonk, NY) was used [54].

Results

Descriptive Data on Changes in Gaming Behavior by Demographic and Socioeconomic Factors (Weighted Data)

Overview

The descriptive data for the sample are shown in Table 1. The questionnaire was answered by 1501 participants, of whom 37.9% (569/1501) answered they had never played video games, neither now nor before the pandemic, and were therefore removed from further analysis. The remaining study population (932/1501) was used for further analysis. We chose to study the younger section of the population. Of the population who did game, 16.4% (153/932) were in the 16–24-year-old age group, and 30.8% (287/932) were in the 25–39-year-old age group. Gender was equally distributed in both age groups. We then looked at the various demographic and socioeconomic factors described in the previous sections and their relationships with self-reported changes in gaming activity (increased, decreased, unchanged).

Table 1. Survey respondents and the final study populations by age group.

Characteristics	Total sample (n=1501), n (%)	Age groups	
		16-24 years (n=190), n (%)	25-39 years (n=392), n (%)
Never gamed	569 (37.9)	37 (19.5)	105 (26.8)
Study population	932 (62.1)	153 (80.5)	287 (73.2)
Gender			
Female	452 (48.5)	68 (44.4)	152 (53.0)
Male	480 (51.5)	85 (55.6)	135 (47.0)

All Age Groups

We found significant differences according to age group (P<.001), employment status (P<.001), disposable income (P<.001), whether respondents ever played on loot boxes (P=.002), time spent at home (P<.001), changes in alcohol consumption (P<.001), changes in exercise habits (P<.001), whether the respondents were studying (P<.001), school attendance (P<.001), Kessler score (P<.001), PGS-I score (P<.001), and GASA score (P<.001; Table 2).

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Table 2. Gaming behavior by demographic characteristics among all participants.

Characteristics	Gaming behavior, n (%)			*P* value	Participants, n (%)
	Increased	Unchanged	Decreased		
Total sample	357 (38.3)	541 (58.0)	34 (3.6)	N/A[a]	932 (100)
Gender					
Female	179 (39.6)	259 (57.3)	14 (3.1)	.55	452 (48.5)
Male	178 (37.1)	282 (58.8)	20 (4.2)		480 (51.5)
Age group (years)					
16-24	87 (56.9)	59 (38.6)	7 (4.6)	<.001	153 (16.4)
25-39	146 (50.9)	126 (43.9)	15 (5.2)		287 (30.8)
40-59	77 (25.8)	213 (71.2)	9 (3.0)		299 (32.1)
≥60	47 (24.4)	143 (74.1)	3 (1.6)		193 (20.7)
Employment status					
Studying	93 (61.2)	52 (34.2)	7 (4.6)	<.001	152 (16.3)
Employed	174 (33.4)	325 (62.4)	22 (4.2)		521 (55.9)
Unemployed	34 (54.0)	28 (44.4)	1 (1.6)		63 (6.8)
Retired	48 (27.7)	122 (70.5)	3 (1.7)		173 (18.6)
Other	8 (34.8)	14 (60.9)	1 (4.3)		23 (2.5)
Level of education					
Primary school	37 (43.5)	47 (55.3)	1 (1.2)	.60	85 (9.1)
Secondary school	135 (36.9)	214 (58.5)	17 (4.6)		366 (39.3)
University	173 (38.4)	261 (58.0)	16 (3.6)		450 (48.3)
Other	12 (38.7)	19 (61.3)	0 (0.0)		31 (3.3)
Disposable income (SEK[b])					
<20,000	150 (48.7)	146 (47.4)	12 (3.9)	<.001	308 (33.0)
20,000-40,000	157 (34.5)	284 (62.4)	14 (3.1)		455 (48.8)
>40,000	50 (29.6)	111 (65.7)	8 (4.7)		169 (18.1)
Loot box					
Yes	54 (51.9)	45 (43.3)	5 (4.8)	.002	104 (11.2)
No	208 (35.3)	363 (61.6)	18 (3.1)		589 (63.2)
Missing	95 (39.7)	133 (55.6)	11 (4.6)		239 (25.6)
Time at home					
Much more	269 (47.4)	284 (50.0)	15 (2.6)	<.001	568 (60.9)
Slightly more	71 (28.2)	168 (66.7)	13 (5.2)		252 (27.0)
Unchanged	15 (14.0)	86 (80.4)	6 (5.6)		107 (11.5)
Less time	2 (40.0)	3 (60.0)	0 (0.0)		5 (0.5)
Change in alcohol habits					
More alcohol	49 (50.5)	43 (44.3)	5 (5.2)	<.001	97 (10.4)
Unchanged	133 (27.7)	339 (70.6)	8 (1.7)		480 (51.5)
Less alcohol	117 (51.1)	98 (42.8)	14 (6.1)		229 (24.6)
Does not drink	58 (46.0)	61 (48.4)	7 (5.6)		126 (13.5)
Change in exercise habits					

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Characteristics	Gaming behavior, n (%)			*P* value	Participants, n (%)
	Increased	Unchanged	Decreased		
More exercise	87 (35.5)	147 (60.0)	11 (4.5)	<.001	245 (26.3)
Unchanged	89 (29.1)	208 (68.0)	9 (2.9)		306 (32.8)
Less exercise	168 (49.3)	161 (47.2)	12 (3.5)		341 (36.6)
Never	13 (32.5)	25 (62.5)	2 (5.0)		40 (4.3)
In school					
Yes	107 (59.4)	66 (36.7)	7 (3.9)	<.001	180 (19.3)
No	250 (33.2)	475 (63.2)	27 (3.6)		752 (80.7)
School performance					
Unchanged	26 (47.3)	28 (50.9)	1 (1.8)	.08	55 (5.9)
Better	26 (65.0)	11 (27.5)	3 (7.5)		40 (4.3)
Worse	55 (64.7)	27 (31.8)	3 (3.5)		85 (9.1)
Missing	250 (33.2)	475 (63.2)	27 (3.6)		752 (80.7)
School attendance					
Unchanged	61 (57.0)	44 (41.1)	2 (1.9)	<.001	107 (11.5)
Less	25 (69.4)	11 (30.6)	0 (0.0)		36 (3.9)
More	21 (56.8)	11 (29.7)	5 (13.5)		37 (4.0)
Missing	250 (33.2)	475 (63.2)	27 (3.6)		752 (80.7)
PGS-I[c]					
No problem with gambling	157 (32.6)	310 (64.3)	15 (3.1)	<.001	482 (51.7)
Low risk of gambling problems	40 (43.0)	48 (51.6)	5 (5.4)		93 (10.0)
Moderate risk of gambling problems	39 (52.7)	34 (45.9)	1 (1.4)		74 (7.9)
Gambling problems	18 (56.3)	14 (43.8)	0 (0.0)		32 (3.4)
Missing	103 (41.0)	135 (53.8)	13 (5.2)		251 (26.9)
Kessler-6					
Score 0-4: no psychological distress	79 (20.8)	286 (75.3)	15 (3.9)	<.001	380 (40.8)
Score 5-24: moderate psychological distress	273 (50.5)	251 (46.4)	17 (3.1)		541 (58.0)
Missing	5 (45.5)	4 (36.4)	2 (18.2)		11 (1.2)
GASA[d]					
Addicted/problem gamer	40 (66.7)	17 (28.3)	3 (5.0)	<.001	60 (6.4)
Engaged gamer	36 (66.7)	17 (31.5)	1 (1.9)		54 (5.8)
No problem	281 (34.4)	507 (62.0)	30 (3.7)		818 (87.8)

[a]N/A: not applicable.

[b]A currency exchange rate of SEK 1=US $0.11 is applicable.

[c]PGS-I: Problem Gambling Severity Index.

[d]GASA: Game Addiction Scale for Adolescents.

Ages of 16 Years to 24 Years

In this age group, we found significant differences in disposable income (*P*=.04), time spent at home (*P*=.002), and school attendance (*P*=.02; Table 3).

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Table 3. Gaming behavior by demographic characteristics among participants 16 years to 24 years of age.

Characteristics	Gaming behavior, n (%)			*P* value	Participants, n (%)
	Increased	Unchanged	Decreased		Total
Total sample	87 (56.9)	59 (38.6)	7 (4.6)	N/A[a]	153 (100)
Gender					
Female	34 (50.0)	31 (45.6)	3 (4.4)	.27	68 (44.4)
Male	53 (62.4)	28 (32.9)	4 (4.7)		85 (55.6)
Employment status					
Studying	59 (57.3)	38 (36.9)	6 (5.8)	.89	103 (67.3)
Employed	22 (56.4)	16 (41.0)	1 (2.6)		39 (25.5)
Unemployed	5 (62.5)	3 (37.5)	0 (0.0)		8 (5.2)
Retired	—[b]	—	—		—
Other	1 (33.3)	2 (66.7)	0 (0.0)		3 (2.0)
Level of education					
Primary school	27 (71.1)	10 (26.3)	1 (2.6)	.25	38 (24.8)
Secondary school	43 (53.8)	32 (40.0)	5 (6.3)		80 (52.3)
University	17 (48.6)	17 (48.6)	1 (2.9)		35 (22.9)
Other	—	—	—		—
Disposable income (SEK[c])					
<20,000	64 (53.8)	48 (40.3)	7 (5.9)	.04	119 (77.8)
20,000-40,000	23 (74.2)	8 (25.8)	0 (0.0)		31 (20.3)
>40,000	0 (0.0)	3 (100)	0 (0.0)		3 (2.0)
Loot box					
Yes	16 (69.6)	6 (26.1)	1 (4.3)	.19	23 (15.0)
No	33 (49.3)	32 (47.8)	2 (3.0)		67 (43.8)
Missing	38 (60.3)	21 (33.3)	4 (6.3)		63 (41.2)
Time at home					
Much more	68 (64.8)	35 (33.3)	2 (1.9)	.002	105 (68.6)
Slightly more	18 (47.4)	17 (44.7)	3 (7.9)		38 (24.8)
Unchanged	0 (0.0)	7 (77.8)	2 (22.2)		9 (5.9)
Less time	1 (100)	0 (0.0)	0 (0.0)		1 (0.7)
Change in alcohol habits					
More alcohol	8 (42.1)	10 (52.6)	1 (5.3)	.14	19 (12.4)
Unchanged	24 (54.5)	20 (45.5)	0 (0.0)		44 (28.8)
Less alcohol	35 (57.4)	23 (37.7)	3 (4.9)		61 (39.9)
Does not drink	20 (69.0)	6 (20.7)	3 (10.3)		29 (19.0)
Change in exercise habits					
More exercise	30 (53.6)	25 (44.6)	1 (1.8)	.22	56 (36.6)
Unchanged	13 (43.3)	15 (50.0)	2 (6.7)		30 (19.6)
Less exercise	40 (67.8)	16 (27.1)	3 (5.1)		59 (38.6)
Never	4 (50.0)	3 (37.5)	1 (12.5)		8 (5.2)
In school					

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Characteristics	Gaming behavior, n (%)			*P* value	Participants, n (%)
	Increased	Unchanged	Decreased		Total
Yes	58 (56.9)	39 (38.2)	5 (4.9)	.96	102 (66.7)
No	29 (56.9)	20 (39.2)	2 (3.9)		51 (33.3)
School performance					
Unchanged	9 (36.0)	15 (60.0)	1 (4.0)	.15	25 (16.3)
Better	13 (61.9)	7 (33.3)	1 (4.8)		21 (13.7)
Worse	36 (64.3)	17 (30.4)	3 (5.4)		56 (36.6)
Missing	29 (56.9)	20 (39.2)	2 (3.9)		51 (33.3)
School attendance					
Unchanged	30 (53.6)	25 (44.6)	1 (1.8)	.02	56 (36.6)
Less	16 (66.7)	8 (33.3)	0 (0.0)		24 (15.7)
More	12 (54.5)	6 (27.3)	4 (18.2)		22 (14.4)
Missing	29 (56.9)	20 (39.2)	2 (3.9)		51 (33.3)
PGS-I[d]					
No problem with gambling	24 (53.3)	20 (44.4)	1 (2.2)	.76	45 (29.4)
Low risk of gambling problems	7 (43.8)	8 (50.0)	1 (6.3)		16 (10.5)
Moderate risk of gambling problems	13 (65.0)	7 (35.0)	0 (0.0)		20 (13.1)
Gambling problems	2 (40.0)	3 (60.0)	0 (0.0)		5 (3.3)
Missing	41 (61.2)	21 (31.3)	5 (7.5)		67 (43.8)
Kessler-6					
Score 0-4: no psychological distress	10 (40.0)	14 (56.0)	1 (4.0)	.16	25 (16.3)
Score 5-24: moderate psychological distress	74 (60.7)	44 (36.1)	4 (3.3)		122 (79.7)
Missing	3 (50.0)	1 (16.7)	2 (33.3)		6 (3.9)
GASA[e]					
Addicted/problem gamer	13 (76.5)	3 (17.6)	1 (5.9)	.20	17 (11.1)
Engaged gamer	9 (75.0)	3 (25.0)	0 (0.0)		12 (7.8)
No problem	65 (52.4)	53 (42.7)	6 (4.8)		124 (81.0)

[a]N/A: not applicable.

[b]No responses to this category.

[c]A currency exchange rate of SEK 1=US $0.11 is applicable.

[d]PGS-I: Problem Gambling Severity Index.

[e]GASA: Game Addiction Scale for Adolescents.

Ages of 25 Years to 39 Years

In this age group, we found significant differences in employment status (*P*=.004), disposable income (*P*=.01), time spent at home (*P*=.005), changes in alcohol consumption (*P*=.003), changes in exercise habits (*P*=.001), whether the respondents were studying (*P*=.007), and Kessler score (*P*<.001; Table 4).

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Table 4. Gaming behavior by demographic characteristics among participants 25 years to 39 years of age.

Characteristics	Gaming behavior, n (%)			*P* value	Participants, n (%)
	Increased	Unchanged	Decreased		
Total sample	146 (50.9)	126 (43.9)	15 (5.2)	N/A[a]	287 (100)
Gender					
Female	81 (53.3)	65 (42.8)	6 (3.9)	.48	152 (53.0)
Male	65 (48.1)	61 (45.2)	9 (6.7)		135 (47.0)
Employment status					
Studying	33 (76.7)	9 (20.9)	1 (2.3)	.004	43 (15.0)
Employed	93 (44.3)	104 (49.5)	13 (6.2)		210 (73.2)
Unemployed	15 (68.2)	7 (31.8)	0 (0.0)		22 (7.7)
Retired	—[b]	—	—		—
Other	5 (41.7)	6 (50.0)	1 (8.3)		12 (4.2)
Level of education					
Primary school	5 (50.0)	5 (50.0)	0 (0.0)	.74	10 (3.5)
Secondary school	53 (46.1)	54 (47.0)	8 (7.0)		115 (40.0)
University	80 (54.1)	61 (41.2)	7 (4.7)		148 (51.6)
Other	8 (57.1)	6 (42.9)	0 (0.0)		14 (4.9)
Disposable income (SEK[c])					
<20,000	52 (66.7)	21 (26.9)	5 (6.4)	.01	78 (27.2)
20,000-40,000	82 (45.3)	91 (50.3)	8 (4.4)		181 (63.1)
>40,000	12 (42.9)	14 (50.0)	2 (7.1)		28 (9.8)
Loot box					
Yes	28 (58.3)	17 (35.4)	3 (6.3)	.45	48 (16.7)
No	84 (49.7)	77 (45.6)	8 (4.7)		169 (58.9)
Missing	34 (48.6)	32 (45.7)	4 (5.7)		70 (24.4)
Time at home					
Much more	105 (59.3)	65 (36.7)	7 (4.0)	.005	177 (61.7)
Slightly more	33 (38.8)	45 (52.9)	7 (8.2)		85 (29.6)
Unchanged	8 (32.0)	16 (64.0)	1 (4.0)		25 (8.7)
Less time	—	—	—		—
Change in alcohol habits					
More alcohol	20 (62.5)	9 (28.1)	3 (9.4)	.003	32 (11.1)
Unchanged	53 (41.4)	73 (57.0)	2 (1.6)		128 (44.6)
Less alcohol	49 (58.3)	28 (33.3)	7 (8.3)		84 (29.2)
Does not drink	24 (55.8)	16 (37.2)	3 (7.0)		43 (15.0)
Change in exercise habits					
More exercise	32 (47.8)	29 (43.3)	6 (9.0)	.001	67 (23.3)
Unchanged	34 (37.4)	53 (58.2)	4 (4.4)		91 (31.7)
Less exercise	77 (65.3)	37 (31.4)	4 (3.4)		118 (41.1)
Never	3 (27.3)	7 (63.6)	1 (9.1)		11 (3.8)
In school					

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Characteristics	Gaming behavior, n (%)			*P* value	Participants, n (%)
	Increased	Unchanged	Decreased		
Yes	43 (68.3)	18 (28.6)	2 (3.2)	.007	63 (22.0)
No	103 (46.0)	108 (48.2)	13 (5.8)		224 (78.0)
School performance					
Unchanged	15 (65.2)	8 (34.8)	0 (0.0)	.13	23 (8.0)
Better	10 (66.7)	3 (20.0)	2 (13.3)		15 (5.2)
Worse	18 (72.0)	7 (28.0)	0 (0.0)		25 (8.7)
Missing	103 (46.0)	108 (48.2)	13 (5.8)		224 (78.0)
School attendance					
Unchanged	26 (66.7)	12 (30.8)	1 (2.6)	.80	39 (13.6)
Less	8 (80.0)	2 (20.0)	0 (0.0)		10 (3.5)
More	9 (64.3)	4 (28.6)	1 (7.1)		14 (4.9)
Missing	103 (46.0)	108 (48.2)	13 (5.8)		224 (78.0)
PGS-I[d]					
No problem with gambling	55 (45.8)	59 (49.2)	6 (5.0)	.48	120 (41.8)
Low risk of gambling problems	23 (56.1)	15 (36.6)	3 (7.3)		41 (14.3)
Moderate risk of gambling problems	18 (58.1)	12 (38.7)	1 (3.2)		31 (10.8)
Gambling problems	12 (66.7)	6 (33.3)	0 (0.0)		18 (6.3)
Missing	38 (49.4)	34 (44.2)	5 (6.5)		77 (26.8)
Kessler-6					
Score 0-4: no psychological distress	21 (29.6)	43 (60.6)	7 (9.9)	<.001	71 (24.7)
Score 5-24: moderate psychological distress	124 (57.7)	83 (38.6)	8 (3.7)		215 (74.9)
Missing	1 (100)	0 (0.0)	0 (0.0)		1 (0.3)
GASA[e]					
Addicted/problem gamer	21 (65.6)	9 (28.1)	2 (6.3)	.14	32 (11.1)
Engaged gamer	16 (66.7)	7 (29.2)	1 (4.2)		24 (8.4)
No problem	109 (47.2)	110 (47.6)	12 (5.2)		231 (80.5)

[a]N/A: not applicable.

[b]No responses to this category.

[c]A currency exchange rate of SEK 1=US $0.11 is applicable.

[d]PGS-I: Problem Gambling Severity Index.

[e]GASA: Game Addiction Scale for Adolescents.

Comparison of Increased Gaming in Different Outcomes (Unweighted Data)

The multivariable analysis using binary logistic regression models of the potential predictors of increased changes (yes versus no) are presented in the following sections.

All Age Groups

Increased gaming was significantly negatively correlated with the age group of 40 years to 59 years (OR 0.43, 95% CI 0.27-0.68) and ≥60 years (OR 0.57, 95% CI 0.33-0.97) as well as with much more time spent at home (OR 3.96, 95% CI 2.15-7.28). We also found a significant correlation with drinking less alcohol (OR 1.93, 95% CI 1.34-7.28) and self-reported not drinking alcohol (OR 1.66, 95% CI 1.05-2.61). Increased gaming was also significantly correlated with a Kessler score greater than 5 (OR 2.44, 95% CI 1.73-3.44) and with the GASA categories of engaged gamer (OR 2.27, 95% CI 1.23-4.20) and addicted/problem gamer (OR 2.37, 95% CI 1.26-4.47; Table 5).

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Table 5. The likelihood of increased gaming behavior (increased vs unchanged/decreased) among all participants (n=932).

Characteristics	OR[a] (95% CI)
Age groups (years)	
16-24	Reference
25-39	0.97 (0.63-1.50)
40-59	0.43 (0.27-0.68)
≥60	0.57 (0.33-0.97)
Time at home	
Unchanged	Reference
Much more	3.96 (2.15-7.28)
Slightly more	1.72 (0.89-3.31)
Less time	3.54 (0.44-28.28)
Change in alcohol habits	
Unchanged	Reference
More alcohol	1.62 (0.99-2.67)
Less alcohol	1.93 (1.34-2.78)
Does not drink	1.66 (1.05-2.61)
Kessler-6	
Score 0-4: no psychological distress	Reference
Score 5-24: moderate psychological distress	2.44 (1.73-3.44)
GASA[b]	
No problem	Reference
Engaged gamer	2.27 (1.23-4.20)
Addicted/problem gamer	2.37 (1.26-4.47)

[a]OR: odds ratio.

[b]GASA: Game Addiction Scale for Adolescents.

Ages of 16 Years to 24 Years

In this age group, no correlations were found (Table 6).

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Table 6. The likelihood of increased gaming behavior (increased vs unchanged/decreased) among participants 16 years to 24 years of age

Characteristics	OR[a] (95% CI)
Disposable income (SEK[b])	
<20,000	Reference
20,000-40,000	5.69 (0.5-65.0)
>40,000	__[c]
Loot box	
Yes	Reference
No	0.66 (0.15-2.89)
Time at home	
Unchanged	Reference
Much more	—
Slightly more	—
Less time	—
School attendance	
Unchanged	Reference
Less	2.5 (0.61-10.3)
More	1.39 (0.33-5.85)

[a]OR: odds ratio.

[b]A currency exchange rate of SEK 1=US $0.11 is applicable.

[c]Could not be estimated.

Ages of 25 Years to 39 Years

In this age group, employment was negatively correlated with a self-reported increase in gaming (OR 0.41, 95% CI 0.18-0.92). Self-reporting less exercise was positively correlated with increased gaming (OR 2.27, 95% CI 1.20-4.27), and Kessler scores greater than 5 were positively correlated with a self-reported increase in gaming activity (OR 2.36, 95% CI 1.27-4.41; Table 7).

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Table 7. The likelihood of increased gaming behavior (increased vs unchanged/decreased) among participants 25 years to 39 years of age.

Characteristics	OR[a] (95% CI)
Employment status	
Studying	Reference
Employed	0.41 (0.18-0.92)
Unemployed	0.82 (0.24-2.74)
Retired	__[b]
Other	0.30 (0.07-1.30)
Change in alcohol habits	
Unchanged	Reference
More alcohol	1.49 (0.62-3.58)
Less alcohol	1.61 (0.88-2.97)
Does not drink	1.65 (0.77-3.55)
Change in exercise habits	
Unchanged	Reference
More	1.29 (0.64-2.59)
Less	2.27 (1.20-4.27)
Never	0.60 (0.14-2.60)
Time at home	
Unchanged	Reference
Much more	1.60 (0.59-4.32)
Slightly more	0.94 (0.34-2.64)
Less time	—
Kessler-6	
Score 0-4: no psychological distress	Reference
Score 5-24: moderate psychological distress	2.36 (1.27-4.41)

[a]OR: odds ratio.

[b]Could not be estimated.

Discussion

This cross-sectional study aimed to look at self-reported changes in gaming behavior during the third wave of the COVID-19 pandemic in Sweden. We also wanted to look at potential risk factors for problematic gaming during the pandemic, including gaming patterns, gambling behavior, psychological distress, a number of sociodemographic characteristics, health factors, and school situation during the pandemic. We used data from a web panel of 1501 respondents who answered questions on gaming and gambling. The results on gambling are presented elsewhere.

Principal Findings

We found several factors associated with changed gaming behavior, but on further analysis, only psychological distress (all age groups analyzed together and the 25–39-year-old age group), drinking less alcohol (all age groups analyzed together), spending more time at home (all age groups analyzed together), gaming problems (all age groups analyzed together), and exercising less (25–39-year-old age group) were positively correlated with a self-reported increase in gaming activity. Being employed (25–39-year-old age group) and being over 40 years of age (all age groups analyzed together) were negatively correlated with increased gaming. We did not find any significant correlations in the 16–24-year-old age group.

Comparison With Prior Work

Research from the early phases of the COVID-19 pandemic showed worrying figures for increased screen time among young people, raising questions about whether this would continue and how it would affect the younger population [55-57]. Gaming disorder has been recognized as a public health problem of importance, but the majority of people who engage in gaming do not fulfil the criteria for gaming disorder [58]. In most studies, the overall prevalence of gaming disorder is around 3% [48]. In our study, 62% of respondents self-reported that they sometimes played video games. We found 38% self-reported an increase in gaming since the start of the COVID-19 pandemic. When looking at gaming and possible changes in the younger population, in the 16–24-year-old age group, 57% self-reported an increase in gaming, and in the 25–39-year-old

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age group, 51% reported an increase in gaming. Other researchers have seen similar results. Frequencies and screen time had increased during the COVID-19 pandemic when Paschke et al [59] looked at those aged 10 years to 17 years and compared their usage frequency and screen time from before the pandemic with their behavior in lockdown. Lemenager et al [60] found the same tendency: 71.4% of participants estimated a general increase in their online media consumption during the lockdown, and some 10% self-reported a rise in gaming activity during the COVID-19 pandemic, of whom men aged between 18 years and 24 years showed the highest increase in gaming. Studies from before the COVID-19 pandemic had shown the same tendency, with young men reported to play computer games more frequently and for longer duration [61,62], making them vulnerable to developing addictive gaming behaviors [63-65]. Balhara et al [58] looked at university students' gaming behavior during the COVID-19 pandemic and found those who used gaming as a tool to reduce stress showed an increase in gaming activity during the pandemic. Before the COVID-19 pandemic, it was known that gamers who gave escapism (a coping technique to handle negative emotions) as a reason for gaming were more commonly problem gamers [66,67].

When analyzing the whole sample who reported increased gaming, we found positive associations with engaged gaming but also with addicted/problem gaming; this relationship was not seen in the 2 younger groups. Increased time spent gaming is a risk factor for developing gaming problems/addiction [63-65]. Previous studies have shown a huge male predominance in problematic gaming behavior [27,68,69]. Men have been reported to play computer games more frequently and for longer duration [61,62], whereas there is a female predominance in smartphone use [70]. Massively multiplayer online role-playing games (MMORPGs) and multiplayer online battle arenas (MOBAs), both with a predominance of male players, have been found to have an addictive potential due to their specific structural characteristics of advancement and social interactions [28,29,71-74]. Researchers have also looked at the cortical region and found that gender differences in IGD might be associated with different cortical thickness in and around the posterior cingulate cortex, the region thought to be involved in cognitive control and reward/loss processing and hence thought to play a role in addiction [68]. These are plausible explanations for the gender differences. In this study, we did not see that gender was associated with self-reported increased gaming, possibly because the numbers were too small.

During the COVID-19 pandemic, the media, schools, and parents all wondered whether remote learning would see schoolchildren spending more time using digital media, not including homework. This was to some extent true for April 2020 to June 2020, when a 69%-76% rise in online media use was reported for children in the United Kingdom, Spain, and Belgium compared with a 36% rise in the Swedish population [56,57]. Although not immediately comparable, the difference can to some extent be explained by the fact that, in the Swedish material, the majority of pupils were aged 13 years to 16 years, compared with an age range of 5 years to 12 years in the other countries, and while the Swedish children were online for the whole school day, the children in the other countries did their schoolwork under their parents' supervision [56,57].

In India, which has seen intermittent total lockdowns throughout the pandemic, meaning people have had to stay at home, an increase in gaming has been seen in those aged 25 years to 35 years [14]. There have also been public health efforts by the WHO to encourage people to engage in gaming (#PlayApartTogether) to promote social distancing and prevent the virus spread [21]. In our study, looking at all age groups together, we saw a correlation between staying home much more and self-reporting an increase in gaming. The relationship was not found in the 2 age groups under 40 years of age. It is important to bear in mind that our sample was rather limited in size, and possibly a larger sample size would show additional correlations.

Being 40 years old or more seemed to reduce the reporting of increased gaming, not surprisingly since gaming is more common in younger people [61,62]. We found a positive correlation between less exercise and increased gaming in the age group of 25 years to 39 years. Sedentary lifestyles and increased gaming have been known to co-occur during the COVID-19 pandemic, making researchers call for parents, schools, and decision makers to mandate physical activity and keep outdoor facilities open as long as possible, even in lockdowns [55,75]. Psychological distress was positively associated with increased gaming in the whole sample as well as in those aged 25 years to 39 years. The association of excessive gaming with comorbidities such as sleeping disorders, obesity, depression, and anxiety is well known [68,76-78], marking out the group who self-reported increased gaming *and* psychological distress as vulnerable and a focus of concern. The same was observed by King et al [18]: Some individuals may develop an increasingly unhealthy pattern of gaming due to pandemic-related psychological distress, because they find gaming relieves stress. We found respondents aged 25 years to 39 years who reported increased gaming during the pandemic were less likely to be in work. Unemployment might facilitate their gaming activities, enabling them to spend more time at home, possibly under greater stress.

When examining those aged 16 years to 24 years who reported increased gaming, we did not find any correlations with associated factors. One possible reason why those in this age group who reported increased gaming did not seem to suffer from psychological distress could be that gaming involves social aspects and thus increased their ability to cope with social isolation in a functional way. This would seem to be confirmed by a report by Bora [14] showing higher usage in multiplayer modes. Playing video games together helped people reduce feelings of loneliness and stress and to stay in touch with friends [58].

Gaming was already viewed by some in a positive light for helping to develop cognitive skills such as reasoning, spatial awareness, and problem-solving [74], and it is now also considered a way of maintaining social contact during lockdown. It would be desirable for authorities to issue recommendations for preferred types of video games that enhance social activity

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and physical health while avoiding the pitfalls of unhealthy gaming.

Limitations

This study has several limitations. The study was based on a self-assessment questionnaire, rather than a standardized, structured clinical interview that would allow a more accurate assessment. Against that, questionnaires are widely used in epidemiological studies, and in other studies, they have been considered to give a satisfactory picture of the situation [39,41]. Our data were based on a web panel survey, and although the study sample was designed and weighted to represent the general population, it is hard to know whether the respondents' original choice to enroll in a web panel is associated with other characteristics and, in this case, with gaming habits that differ from those of their peers in the general population. Our sample size is too small to draw generalized conclusions.

Strengths

Despite the extreme interest in the possible increase in gaming during the COVID-19 pandemic, whether in popular science or more clinical and scientific contexts, there is still a significant lack of studies focusing on the younger population. This study contributes important information about possible changes in gaming behavior during the COVID-19 pandemic.

Conclusion

Those who reported increased gaming during the COVID-19 pandemic were more likely to be 16 years to 39 years old. In those aged 16 years to 24 years, increased gaming was not associated with any risk factors. In the 25–39-year-old age group, the increase was associated with psychological distress, reporting less exercise, and being unemployed. COVID-19 may present a risk factor for increased online gaming in a small but vulnerable group. More research and preferably longitudinal studies are needed in the field of gaming and the effects of the COVID-19 pandemic.

Conflicts of Interest

AH has a researcher position at Lund University, which is sponsored by the Swedish state-owned gambling operator, AB Svenska Spel. He also has research funding from the research councils of AB Svenska Spel and the Swedish alcohol monopoly Systembolaget AB. None of these organizations were involved in the present research in any way.

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Abbreviations

DSM-5: *Diagnostic and Statistical Manual of Mental Disorders*
GASA: game addiction scale for adolescents
ICC: International Chamber of Commerce
ICD: International Classification of Diseases
IGD: internet gaming disorder

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MMORPG: massive multiplayer online role-playing game
MOBA: multiplayer online battle arena
OR: odds ratio
PGS-I: Problem Gambling Severity Index
WHO: World Health Organization

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Letter to the Editor

Serious Games Without Screens. Comment on “Involvement of End Users in the Development of Serious Games for Health Care Professions Education: Systematic Descriptive Review”

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KEYWORDS

game-based learning; health professions education; participatory design; systematic review; user-centered design; serious games; game development; end users; education

Maheu-Cadotte et al [1] reviewed end user involvement in the development of serious games for health professionals' education. They identified 45 games that were evaluated in randomized controlled trials for efficacy, of which only 21 reported on end user involvement during development. Citing a 2012 review, the authors included serious games defined as “video games designed with a primary educational purpose” [2]. This definition misses a large category of games whose review could provide important insights on the topic.

The term “serious games” likely originated from the 1970 monograph of the same name by Clark Abt [3]. The book concerns “*serious games* in the sense that these games have an explicit and carefully thought-out educational purpose and are not intended to be played primarily for amusement” [3]. Abt explored a number of examples including a card game to learn math, a board game to teach color mixing using transparent sheets, as well as a number of simulations of historic events and economies. He discussed a case with a component of computer-based simulation; however, the bulk of the book was dedicated to analog experiences.

We would like to challenge the persistent usage of the narrow digital-only definition of a serious game seen in health professionals' education, often citing the same 2012 review or its source, a 2006 book about the design of serious video games [4]. While the focus of *JMIR Serious Games* may be digital games and gamification, not all games are digital, and similarly, not all serious games are digital. As designers of card and board games used for health professionals' education, we invite those in our field to reconsider this narrow definition. With its origin in mind, a more inclusive definition of serious games would be any standalone game designed with a specific purpose beyond entertainment *regardless of medium.*

We applaud Maheu-Cadotte et al [1] for highlighting the importance of end users' contributions to game development, which applies to analog games as much as digital ones, with similar questions regarding balancing cost and possible benefit for consideration. Our experience has been variable: students (the target audience) co-designed *GridlockED* along with faculty but were only involved in playtesting during early design work on *Empiric* [5]. For *Clinical Coaching Cards*, the game underwent iterative rule changes based on observations of end user play and feedback collected during workshop sessions [6]. As Maheu-Cadotte et al [1] have shown, this is generally not well-reported, and we agree that end user involvement and feedback is a key component of demonstrating the validity of a game as an educational intervention.

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We are appreciative of the insight provided by this review and hope the journal can prompt authors of future submissions to provide information pertaining to end user involvement on reports of serious games. We encourage other researchers to expand their definition of serious games and specify the focus on digital games when appropriate.

Conflicts of Interest

MC is the designer of *Empiric Game* and receives minor royalties from the sales of this card game. TMC is a cocreator of the *GridlockED* and *TriagED* serious board games. While she does not receive proceeds from these games (this has been donated generously to McMaster University), this does pose an intellectual conflict of interest. The other author declares no conflicts of interest.

Editorial Notice

The corresponding author of "Involvement of End Users in the Development of Serious Games for Health Care Professions Education: Systematic Descriptive Review" declined to respond to this letter.

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Review

How, for Whom, and in Which Contexts or Conditions Augmented and Virtual Reality Training Works in Upskilling Health Care Workers: Realist Synthesis

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Abstract

Background: Using traditional simulators (eg, cadavers, animals, or actors) to upskill health workers is becoming less common because of ethical issues, commitment to patient safety, and cost and resource restrictions. Virtual reality (VR) and augmented reality (AR) may help to overcome these barriers. However, their effectiveness is often contested and poorly understood and warrants further investigation.

Objective: The aim of this review is to develop, test, and refine an evidence-informed program theory on how, for whom, and to what extent training using AR or VR *works* for upskilling health care workers and to understand what facilitates or constrains their implementation and maintenance.

Methods: We conducted a realist synthesis using the following 3-step process: theory elicitation, theory testing, and theory refinement. We first searched 7 databases and 11 practitioner journals for literature on AR or VR used to train health care staff. In total, 80 papers were identified, and information regarding context-mechanism-outcome (CMO) was extracted. We conducted a narrative synthesis to form an initial program theory comprising of CMO configurations. To refine and test this theory, we identified empirical studies through a second search of the same databases used in the first search. We used the Mixed Methods Appraisal Tool to assess the quality of the studies and to determine our confidence in each CMO configuration.

Results: Of the 41 CMO configurations identified, we had moderate to high confidence in 9 (22%) based on 46 empirical studies reporting on VR, AR, or mixed simulation training programs. These stated that realistic (high-fidelity) simulations trigger perceptions of realism, easier visualization of patient anatomy, and an interactive experience, which result in increased learner satisfaction and more effective learning. Immersive VR or AR engages learners in *deep immersion* and improves learning and skill performance. When transferable skills and knowledge are taught using VR or AR, skills are enhanced and practiced in a safe environment, leading to knowledge and skill transfer to clinical practice. Finally, for novices, VR or AR enables repeated practice, resulting in technical proficiency, skill acquisition, and improved performance. The most common barriers to implementation were up-front costs, negative attitudes and experiences (ie, cybersickness), developmental and logistical considerations, and the complexity of creating a curriculum. Facilitating factors included decreasing costs through commercialization, increasing the cost-effectiveness of training, a cultural shift toward acceptance, access to training, and leadership and collaboration.

Conclusions: Technical and nontechnical skills training programs using AR or VR for health care staff may trigger perceptions of realism and deep immersion and enable easier visualization, interactivity, enhanced skills, and repeated practice in a safe

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environment. This may improve skills and increase learning, knowledge, and learner satisfaction. The future testing of these mechanisms using hypothesis-driven approaches is required. Research is also required to explore implementation considerations.

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KEYWORDS

realist synthesis; realist review; review; virtual reality; augmented reality; simulation; training; health; health personnel; education; mobile phone

Introduction

Background

As in most businesses, upskilling health care workers is vital to improving and advancing existing skills and practices and closing gaps in knowledge so that employees may continue practicing with ease [1,2]. By definition, upskilling is the process of refining existing skills or learning new skills [1]. Within the health care sector, upskilling is required to promote workforce flexibility, skill delegation, and adaptation during times of change, restructuring, or crisis [3-5]. Ultimately, this also ensures that health care delivery is safe, aligns with best practice, and is standardized across staff.

Traditional health care training consists of role modeling, shadowing, and the *see one, do one* method [6-9], along with learning through textbooks, e-learning, workshops, and seminars, as well as reading peer-reviewed journal articles. Simulation-based methods have also traditionally been used in upskilling, training, and engaging health and care providers in continued education, with the ultimate purpose of practical learning to improve patient safety [10]. These include part- or full-body manikins, synthetic latex–based simulation models, bench-top simulators, human actors, and live animal and cadaveric procedures. However, a lack of time, inaccessible resources, and a tendency to rely on experiential knowledge limit the ability to upskill [11,12]. Furthermore, training with traditional simulators is becoming difficult because limits are placed on work hours [13], and opportunities for learners to practice technical procedures on live animals and humans or cadavers are reduced because of ethical issues, commitment to patient safety, cost, and limited availability of resources [13-15].

Virtual reality (VR) and augmented reality (AR) training programs may help to overcome these barriers because they can be continuously available and used independently by learners, and they do not increase costs with use [16,17]. Akin to traditional simulation methods, VR and AR training programs enable repeated practice within safe environments away from patients and stress or time pressure [13,18,19]. VR and AR have already helped to upskill registered health care professionals on disaster response [20,21], technical and behavioral skills [7,17,22-24], and nontechnical cognitive skills [25-27].

VR is a computer-generated simulated environment in which users are immersed [28,29]. However, immersion levels can vary greatly. For example, in nonimmersive VR, environments can simply be projected onto computer screens, whereas in fully immersive VR, users wear a headset to feel as though they have been transported into a digital environment. In contrast, AR is the projection of computer-generated imagery (eg, objects) onto real-world environments [28-30], with mixed reality enabling the objects to be responsive, interactive, and spatially aware [28,29].

The effectiveness and success of VR and AR training programs is often nonlinear and complicated. This is because fidelity and perceptions of *immersion* depend on various dimensions. Fidelity refers to the extent to which an experience is close to reality [31]. Accordingly, the five dimensions that influence fidelity include physical (ie, a simulated environment), psychological (eg, stress and emotions), social, group culture, and open-mindedness of the user [32,33]. The extent to which a simulation is perceived as *good* or realistic also depends on a user's willingness to believe in it [34]. Ultimately, this may require detail such as object collision detection (and response) or haptic technology for physical force feedback and tactile sensation [34]. These tools can introduce an additional dimension to VR by enabling users to interact with systems or manipulate digital objects through touch.

Previous literature reviews have focused on the novelty, application, and effectiveness of VR and AR training programs for health professionals, including for surgical training [13,15,18,19,35-37], nontechnical skills training [25], urology [38], disaster training [21], and dementia care [39], as well as to assess their cost-effectiveness compared with traditional simulators [40]. The reviews suggest that VR and AR may be effective for training various health care providers in both technical and nontechnical skills. However, research has also found that VR and AR training programs do not *work* for all learners, such as those who already have experience in a skill [14,41]. VR and AR learning methods are also sometimes reported as equal to, but not better than, traditional learning methods when used by nursing students [42-44] and other tools used in phlebotomy training [45]. In addition, the literature on implementing VR and AR in training for practicing health professionals is limited.

This realist review explores why there is variation in the effectiveness of VR and AR training programs and what factors influence their implementation and maintenance. Realist reviews can help to understand how, for whom, and in which contexts and conditions interventions or programs (such as the use of AR or VR for training) work. They offer a theory-driven approach to producing causal explanations of how different mechanisms of action may be triggered, which then lead to intended and unintended outcomes [46,47]. Mechanisms are changes in reasoning or individual or collective reactions (eg, behaviors, perceptions of fidelity, or cybersickness) to an intervention's resources [46]. These mechanisms are triggered under certain circumstances, contexts, or conditions, which may

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relate to training scenarios, populations, or diverse AR and VR technologies.

Ultimately, a program theory developed in alignment with realist methods will result in a collection of context-mechanism-outcome (CMO) configurations that consider context, mechanisms, and outcomes. The program theory explains how an intervention may contribute to a chain of events (ie, mechanisms) that result in expected and desired or unexpected outcomes. The realist approach also considers how interventions may work differently within different contexts or conditions. CMO configurations are presented as follows:

Context + Mechanisms = Outcomes

Underlying the realist methodology is the expectation that the VR or AR intervention does not produce outcomes by itself but is instead influenced by underlying social entities, processes, or social structures (mechanisms) [46,48]. This means that it also uncovers how an intervention works in practice and results in a transferable program theory [48] that considers demi-regularities (semipredictable outcomes), which may result in varying outcomes but consistent CMO patterns [47].

Objectives

The aim of this realist review is to develop, test, and refine an evidence-informed program theory on how, for whom, and to what extent training using AR or VR *works* for upskilling health care workers and to understand what facilitates or constrains their implementation and maintenance.

The review addressed the following questions:

1. How, for whom, and to what extent does training using AR or VR for upskilling health care workers work?
2. What facilitates or constrains the implementation (and maintenance) of training using AR or VR in health and care settings?

Methods

Overview

This realist review adheres to the processes explained in the RAMESES (Realist and Meta-narrative Evidence Syntheses: Evolving Standards) training documents [48]. Our protocol describes the methods in more detail [2]. In addition, we report the review in accordance with the RAMESES publication standards for realist syntheses [49]. The review followed a 3-step process, consisting of theory elicitation, theory testing, and theory refinement.

Step 1. Elicit Theory

Search and Screening

The purpose of the first step was to elicit an initial program theory from candidate theories found within existing literature, which could then be refined and tested. Academic and practitioner theories were located by searching a range of databases and practitioner journals for literature on using AR or VR to upskill health professionals. The databases, search terms, and eligibility criteria are presented in Textbox 1. No constraints were imposed on the dates of publication. Learning and technology adoption theories were identified within this literature. The search was conducted between January 18 and January 25, 2021.

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Textbox 1. Search strategy and eligibility criteria.

Search locations

- Databases
  - MEDLINE
  - Scopus
  - CINAHL
  - Embase
  - Education Resource Information Centre
  - PsycINFO
  - Web of Science
- Journals
  - Academic Medicine
  - MedEdPORTAL
  - Medical Teacher
  - International Journal of Medical Education
  - Journal of Continuing Education in the Health Professions
  - GMS Journal for Medical Education
  - Focus on Health Professional Education
  - Medical Education
  - Journal of Nursing Education and Practice
  - Nurse Education Today
  - International Journal of Nursing Studies

Search strategy keywords

- Keywords with Boolean operators *AND* and *OR* (asterisk [*] indicates other variations that are covered (eg, *nurs** includes *nurses*, *nurse*, *nursing*)
  - *augmented reality* OR *virtual reality* AND *health** OR *care** OR *nurs** OR *doctor* OR *surgeon* AND *training* OR *upskilling* OR *skill* OR *education* AND *evaluation* OR *implementation* OR *feasibility* OR *effectiveness*
- Search example (Scopus)
  - *TITLE-ABS-KEY* (*augmented* AND *reality* OR *virtual* AND *reality*) AND *TITLE-ABS-KEY* (*health** OR *care** OR *nurs** OR *doctor* OR *surgeon*) AND *TITLE-ABS-KEY* (*training* OR *upskilling* OR *skill* OR *education*) AND *TITLE-ABS-KEY* (*evaluation* OR *implementation* OR *feasibility* OR *effectiveness*)

Eligibility criteria for papers identified in databases and journals

- Inclusion criteria
  - Using simulation technologies (any type of immersion)
  - Health workers, care workers, and postgraduate or registered learners
  - Any health, care, or university-based setting
  - Covers detail on what contexts, how, and for whom they *worked* or on implementation (or maintenance)
  - Published in English
- Exclusion criteria
  - Simulation technologies that do not use augmentation or virtual reality (eg, web-based e-learning interventions or manikins)
  - Undergraduate students
  - Published in languages other than English

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- Exceptions
  - Work including undergraduate learners or other simulation technologies can be included if the data for postgraduate or registered learners and augmented reality or virtual reality can be separated

In alignment with previous realist reviews (eg, the study by Wong et al [50]), we conducted a 2-stage screening process, with a second researcher independently screening a random subset of papers. First, an author (NG) screened the title and abstract of each paper against the inclusion and exclusion criteria (Textbox 1) and generated a shortlist of possibly eligible papers. The full texts of these papers were then screened in the second stage. A second author (DD) independently screened a random selection of 20.2% (39/193) of the abstracts and titles and 20% (18/90) of the full texts. The raw interrater agreement rates for the 2 screening rounds were 85% and 89%, respectively. Discussion helped to reach consensus, with a third author (SNvdV) acting as a moderator.

Data Extraction

Data were extracted by 2 authors (NG and DD) into a coding sheet on Excel (Microsoft Corporation). This included information on the study (eg, author, date, title, research design, and sample), the intervention, contexts, mechanisms, outcomes, learning or technology adoption theories mentioned, and barriers and facilitators to implementation (or maintenance; see Table S1 in Multimedia Appendix 1). One author extracted all the data, whereas the second author reviewed 20% (16/80) of the papers for consistency. When complete CMO configurations were not provided, fragments were recorded.

Analysis

A narrative synthesis was conducted to determine overlapping CMO configurations and the most common barriers and facilitators to implementation and maintenance. We aggregated authors' hypothesized mechanisms, regardless of whether they had been tested, to identify the common ways in which VR or AR affect and lead to the outcomes. The learning and technology adoption theories were also summarized and used to discuss and make meaning of the CMO configurations (in step 2).

Finally, the research team discussed the initial program theory and selected a number of CMO configurations to test, focusing on those that were expected to be most feasible, measurable, and likely to apply or transfer to future AR and VR interventions aimed at upskilling health care workers.

Step 2. Test Theory

Search and Screening

The purpose of step 2 was to test the initial program theory, using existing evidence. Empirical literature was identified in a 2-step process. First, empirical studies were identified from the first search by removing nonempirical and non–full-length papers. Second, the same search as in step 1 was repeated but with a time frame of 3-6 months to identify recently published work that may have been missed. This search was conducted on March 8, 2021. We used the same screening process as in step 1 to assess the relevance of newly identified articles. The first author (NG) screened the papers to identify a shortlist of possibly eligible papers. The second author (DD) then independently screened a random selection of these papers (abstracts and titles: 2/9, 20%; full texts: 1/2, 50%), with interrater agreement rates of 100%.

Data Extraction and Quality Appraisal

The same items as in step 1 were extracted, along with specific evidence for the mechanisms (where applicable) and the expected outcomes identified in the initial program theory. Studies that did not provide evidence relating to the outcomes were excluded. Studies were assessed for quality using the Mixed Methods Appraisal Tool (MMAT; version 2018) [51].

The MMAT consists of 2 screening questions and 5 study design–specific criteria that could be scored 1 (yes) or 0 (no) [51]. In keeping with the studies by Pluye et al [52], Mogharbel et al [53], and Vusio et al [54], we calculated quality scores for each article and classified them as low quality (≤40%, ie, meeting 1-2 criteria), moderate quality (60%-80%, ie, meeting 3-4 criteria), or high quality (100%, ie, meeting all 5 criteria).

The quality of all the studies was assessed by 1 author (NG), whereas a second author (DD) assessed the quality of 22% (10/46) of the studies. We calculated the Cohen κ using SPSS software (version 23; IBM Corp) to determine the interrater reliability between the 2 authors.

Step 3. Refine Theory

To refine the theory, evidential fragments (parts of studies, rather than entire studies, that provided evidence) from the second search were compared and matched to the initial program theory. We made revisions by identifying differences and presented the final theory as a narrative and diagrammatic summary. The most commonly identified learning or technology adoption theories were used to discuss the program theory.

We then assessed our confidence in each CMO configuration as high, moderate, low, or very low according to the criteria presented in Table 1. The confidence level was determined by the criterion with the lowest level. For example, if a CMO configuration had 7 supporting studies, with 4 (57%) of them contesting, and an average MMAT score of 90%, the CMO configuration was deemed *low* confidence.

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Table 1. Criteria used to determine confidence in each context-mechanism-outcome configuration.

Confidence	Number of supporting studies	Contesting studies (if applicable), %	MMAT[a] average score, %
High	≥8	0-20	76-100
Moderate	5-7	21-29	51-75
Low	4	30-74	26-50
Very low	≤3	75-100	0-25

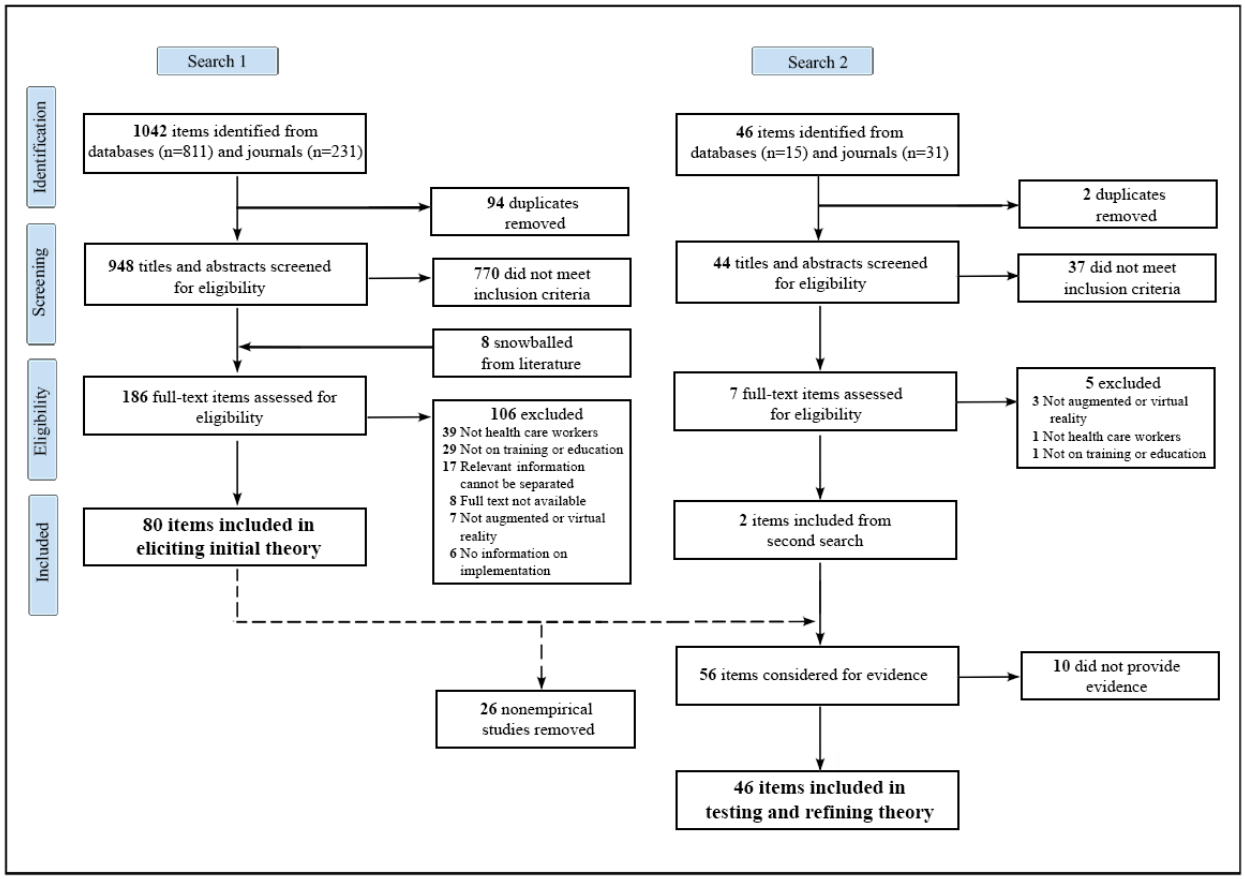
[a]MMAT: Mixed Methods Appraisal Tool.

Results

Search Outcome

The extended PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart [55] in Figure 1 shows the identification and screening process.

Figure 1. Extended PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart depicting the literature search and screening process.



Theory Elicitation

The initial search identified 1042 papers. After deduplication and abstract and title screening, 186 full texts, including 8 studies snowballed from the literature, were reviewed, of which we excluded 106 (56.9%), leaving 80 (43.01%) papers for inclusion for eliciting the initial theory. The most common reasons for exclusion were not including health care workers (39/106, 36.8%), not focusing on education and training (29/106, 27.4%), or relevant information not being separable (17/106, 16%).

Theory Testing

The second search identified 46 recently published empirical studies. After deduplication and abstract and title screening, 7 full texts were screened, of which 5 (71%) were excluded because they did not cover AR or VR (3/5, 60%), did not include health care workers (1/5, 20%), or did not focus on education or training (1/5, 20%). Of the 7 studies, the 2 (29%) that remained were combined with the empirical literature from the first search (n=54). Of these 56 studies, 46 (82%) were included in testing and refining the theory, after 10 (18%) were excluded for not providing evidence on the CMO configurations.

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Characteristics of the Included Articles

Theory Elicitation

The 80 papers identified in the first search consisted of empirical research (55/80, 69%), literature reviews (22/80, 28%), case reports (2/80, 3%), and cost-benefit analyses (1/80, 1%). Of these, 83% (66/80) focused on VR, 11% (9/80) on AR, and 6% (5/80) focused on both.

Theory Testing

Of the 46 empirical studies included in the second stage of the review, almost half (22/46, 48%) were quantitative descriptive studies [8,9,14,22,41,56-72], 11 (24%) were randomized controlled trials [6,7,17,20,23,73-78], 7 (15%) were quantitative nonrandomized studies [16,24,79-83], 5 (11%) were mixed methods studies [84-88], and 1 (2%) was a qualitative study [89]. They were published between 1999 [80] and 2021 [59,60,83]. Of the 46 studies, 21 (46%) were conducted in the United States [7,14,17,20,22,56,58,61,63-66,72,73,75,77,78,80-82,88], 4 (9%) in the United Kingdom [68,84-86], 3 (7%) each in China [24,67,70] and India [23,76,89], and 2 (4%) each in Germany [59,87], Taiwan [6,71], Italy [69,83], and France [57,79]. Of the 46 studies, 2 (4%) did not provide a location [8,62] and 1 (2%) study was conducted in each of the following countries: Spain [16], Canada [74], Malaysia [60], the Netherlands [9], and Australia [41].

A range of health care professionals participated, including surgeons, nurses, physicians, pharmacists, technicians, social workers, radiologists, community health workers, ophthalmologists, dentists, and respiratory therapists. Clinical experience ranged from <2 months [17] to 30 years [67]. Sample sizes ranged from 6 [24] to 109 [71] health care professionals and trainees, with an overall mean of 34.3 (SD 25.8) participants and a total of 1543 participants (of the 46 studies, 1, 2%, did not report a sample size). For those that provided a mean age, participants ranged in age from 19 years [71] to 43.7 years [87]. The characteristics of the included studies are presented in Table S2 in Multimedia Appendix 1.

The Initial Theory

In the initial program theory, a total of 12 contexts were identified. Table 2 presents all potential CMO configurations. Informed by the initial literature screening and discussion within the research team, two contexts (1 and 6) were combined because of considerable overlap in the mechanisms and outcomes. In all, 6 contexts were chosen to be tested with empirical evidence in the next step. We had low confidence that there would be evidence available to test the remaining CMO configurations.

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Table 2. The context-mechanism-outcome configurations identified in our initial program theory.

Context	Mechanisms	Outcomes[a]
1. Realistic (high-fidelity) simulations	• Perceptions of realistic haptics and imagery • Triggers interactive learning • Lack of perceived realism in haptics or tactile sensation	• Enhanced skills and proficiency • Learner satisfaction with realism • More effective learning • Preference for non-VR[b] learning, for example, laboratory dissection or physical reality
2. Artificial intelligence–enabled VR[c]	• Provides feedback and highlights deficiencies	—[d]
3. VR or AR[e] that immerses learners	• Engages or exposes learners in deep immersion • Provides a safe environment free from patient harm • Cybersickness	• Higher engagement and participation in training • Improved learning, knowledge, and comfort with knowledge • Improved skill performance
4. Comfortable devices[c]	• Cybersickness	• Poor learning experience
5. VR or AR that delivers standardized teaching	• Provides feedback to leaners • Enables repeated practice	• Improves skill or performance • Leads to better patient outcomes in the future
6. Visualization through VR or AR	• Interactive experience • Easier and more detailed visualization of patient anatomy • Perceived realism of the imagery	• Learner satisfaction with tool and realism • Increased understanding or learning of content • Improved performance or skill
7. Accounts for physical and mental workload[c]	• Psychological improvements (reduced stress and improved self-confidence)	• Decreased mental demand, effort, and physical workload scores
8. Team training delivered by AR or VR[c]	• Interaction between learners and environment, as well as real-time collaboration and communication	• Improves teamwork • Results in learner satisfaction
9. Knowledge or skill transfer	• Enhances skills • Practice in safe environment (with no risk to patients) • Deliberate practice	• Knowledge transfer to clinical practice • Skills transfer to cadaver, box trainer, and surgery and procedure • Better patient care in the future
10. Used with a teacher[c]	—	• Improved instruction
11. Embedded in curriculum[c]	—	—
12. Limited training opportunities	• Provides feedback on performance, skill or technique • Repeated practice • Access to experiential learning opportunities • Safe and stress-free learning environment	• Skill improvement, technical proficiency, and reduced incidence of complications or errors • Learner satisfaction • Improvements for learners with less experience
13. Novices	• Feedback and objective measurement of skills or knowledge • Independent or self-directed training • Safe, static, and risk-free environment without endangering patients • Repeated practice • Exposure to experience	• Technical proficiency and skill acquisition • Improved performance (including operative performance) • Learner satisfaction: VR was preferred • Novices (less experienced people) improved most

[a]Context + Mechanisms = Outcomes.

[b]VR: virtual reality.

[c]The context-mechanism-outcome configurations for which we had low confidence that there would be evidence available to test them.

[d]Not available.

[e]AR: augmented reality.

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Summary of the AR and VR Training Interventions

The interventions presented in the empirical literature aimed at improving technical, behavioral, or nontechnical skills. The technical skills included laparoscopic procedural skills and camera navigation [8,9,59-61,78], evacuation procedures [20], dental drilling techniques [70], and vesicourethral anastomosis during robot-assisted radical prostatectomy [24]. Nontechnical skills were less commonly focused on but included decision-making, communication, teamwork [56,85], and patient counseling and communication [89]. In keeping with the Kirkpatrick et al [90] criteria for evaluation outcomes, 78% (36/46) of the studies explored behavior or skill improvement, 67% (31/46) explored reaction to the simulators (eg, satisfaction, attitudes, opinions on user experience, or intention to use the simulator), 20% (9/46) explored knowledge or learning outcomes, and 7% (3/46) explored patient results (eg, vaccine refusal rates, patient pain, and medical errors).

Of the 46 studies, 22 (48%) used nonimmersive VR simulators, of which computer-based programs and the LapSim, AnthroSim, and MIST-VR simulators were the most commonly used [6,8,9,14,41,56,58-61,64,65,70,73,75,78,80,81,85-88]; 12 (26%) used fully immersive VR, with the most common headsets used being the Oculus Rift and HTC Vive [16,17,20,23,57,62,69,71,74,76,77,79]; and 2 (4%) used the stereographic CrystalEyes shutter glasses, which enabled 3D visualization when connected to an immersive workbench, for partially immersive VR [68,84]. Of the 46 studies, 6 (13%) used AR, with the Microsoft HoloLens glasses being the most commonly used device [7,22,66,82,83,89]. Other devices included smartphone apps, the ODG R-7 Smartglasses, and the Brother AiRScouter WD-200B headset. Of the 46 studies, 3 (7%) combined AR with VR [63,67,72]. For example, Luciano et al [63] used the ImmersiveTouch VR system in addition to high-resolution AR stereoscopic glasses. Qin et al [67] included nonimmersive VR, fully immersive VR, and AR in a comprehensive multimodal simulation training program. The study by Wang et al [24] did not clearly state the level of immersion.

Of the 46 studies, 24 (52%) used haptic technology for force feedback or tactile sensation [6,8,9,14,41,58-64,67-70,72,73,78-80,82,84,87]. Some used other tools such as manikins [22,69,82]. For example, Semeraro et al [69] connected the commercial Laerdal HeartSim 4000 manikin to a VR headset, tracking device, and sensor gloves. Robots were also used in some studies [24,62,85] to, for example, simulate operating with the da Vinci surgical robot. Finally, a training program also used human actors who were prompted by the simulator to provide patient feedback (eg, making groaning sounds to convey pain) during endoscopy training [86].

Quality of the Included Studies

There was substantial agreement for the MMAT appraisals between the 2 raters (NG and DD; 90%; κ=0.778, 95% CI 0.625-0.931; P<.001).

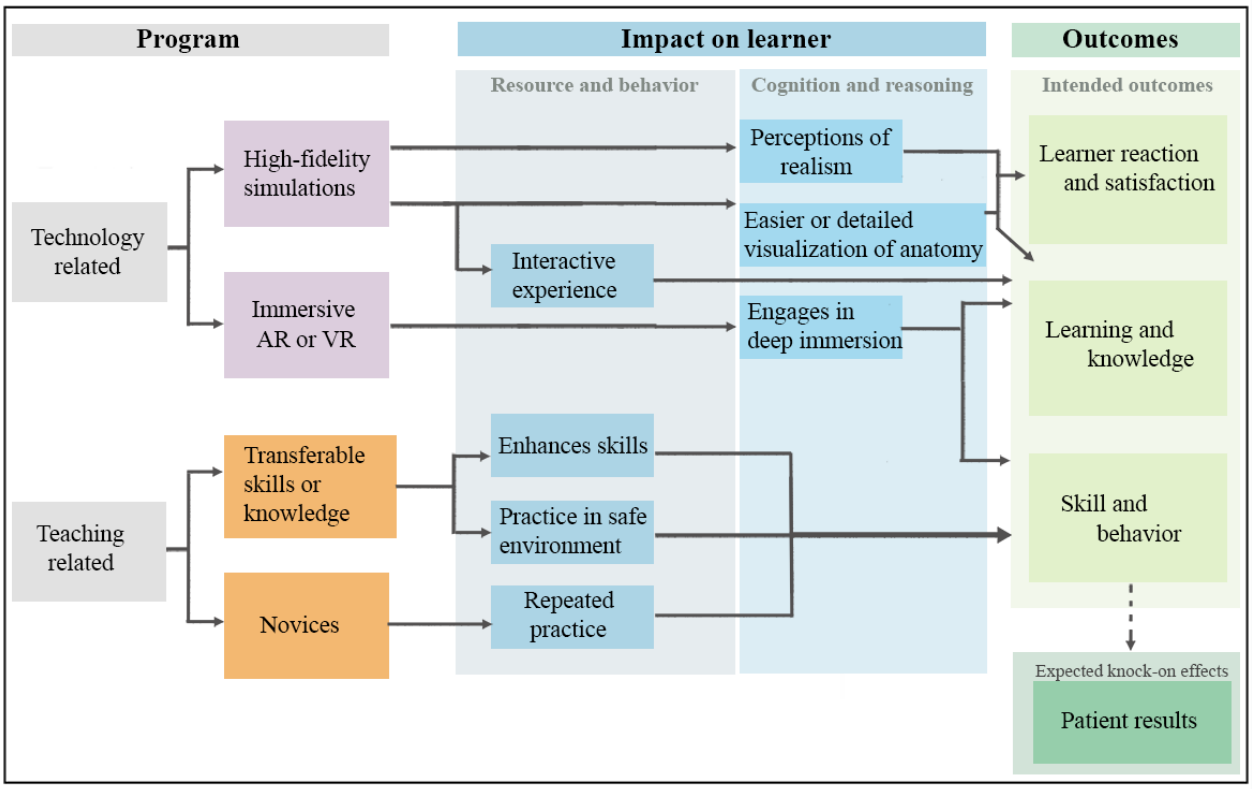
Overall, of the 46 studies, 13 (28%) were of high quality and 3 (7%) were of low quality, whereas the remaining 30 (65%) were of moderate quality. Of the 46 studies, 9 (20%) quantitative descriptive [8,56,58,61,63,64,66,68,70] and 4 (9%) quantitative nonrandomized studies did not include participants who were representative of the target population [24,80,82,83]; in addition, 9 (20%) quantitative descriptive studies did not clearly state their sampling strategy [41,56-58,60,62,66-68]; in 5 (11%) randomized controlled trials, randomization was not conducted properly [6,23,75-77]; in 6 (13%), blinding was either not possible or not conducted [6,7,17,20,23,76]; the qualitative approach was not reported for 2 (4%) mixed methods studies [84,85]; and the only qualitative study did not meet any of the criteria [89].

Final CMO Configurations

In all, 6 contexts were identified. We distinguished technology-related conditions (Table S3 in Multimedia Appendix 1) from training-related circumstances (Table S4 in Multimedia Appendix 1). Figure 2 provides a diagrammatic summary of the CMO configurations in which we had moderate or high confidence. These are discussed in detail next. The configurations in which we had very low or low confidence are presented in Tables S3 and S4 in Multimedia Appendix 1 but without further discussion in the text.

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Figure 2. Diagram of our program theory on AR and VR training for health care workers built from the context-mechanism-outcome configurations in which we had moderate or high confidence. AR: augmented reality; VR: virtual reality.



Realistic Simulations and Visualization (CMO 1)

The first condition relates to when VR (all levels of immersion, with and without haptics), AR, and a combination of VR and AR training programs portray realistic (high-fidelity) simulations or imagery (eg, on patient anatomy). This triggered perceptions of reality, enabled visualization of patient anatomy, and triggered an interactive experience [9,22,56,59,61,63-65,67-70,72,79,80,82-87]. Easier visualization was explained through the use of 3D imagery, which often helped to reduce cognitive load and limit extraneous data [68,83]. The interactive experience was characterized by users interacting with the imagery in real time or when engaging in multiuser team training [56].

Across the mechanisms, 2 expected outcomes included more effective learning (increased understanding and learning of content as well as enhanced skills, proficiency, and performance) and increased learner satisfaction. There was strong supporting evidence for more effective learning when perceptions of realism and easier visualization were triggered. For example, in the study by Balian et al [22], half of the 51 participants delivered more than 80% of the cardiopulmonary resuscitation compressions with complete chest recoil and reduced leaning on the chest. This was attributed to perceptions of a realistic simulation, whereby realistic feedback included auditory (heartbeat metronome) and visual cues (increase or decrease in blood flow to vital organs). We had moderate to high confidence that easier visualization, interaction, and perceptions of realism lead to more effective learning.

Increased learner satisfaction was contested within the evidence. Some studies identified that their haptic tools hindered perceptions of realism [59,80,87]. Burdea et al [80] stated that the learners in their study were not satisfied with the VR simulator because it was not perceived as realistic. In addition, the lack of perceived realism might be why their VR group performed worse than the control group (using a rubber simulator) in diagnosing prostate cancer (33% vs 92%, respectively). It was expected that a more realistic VR simulator would have improved performance and learner satisfaction. However, most of the studies provided evidence that learners were satisfied with the tools in general [9,22,56,59,61,63,67-70,72,79,82,84-87]. We had the lowest confidence that an interactive experience resulted in learner satisfaction but moderate to high confidence that easier visualization and perceptions of realism result in satisfaction with the realism and tools, respectively.

Immersion (CMO 2)

The second condition relates to when fully immersive VR (with and without haptics) or AR with a manikin immersed learners in the training environment [16,20,22,23,57,62,71,74,76,77,79]. This triggered perceptions of *deep immersion*, whereby learners were transported into their training environments and a safe learning environment, free from patient harm. Bhowmick et al [23] explained that isolation from the outside world and use of realistic scenarios (eg, environments, characters, and tasks) promoted feelings of deep immersion. This resulted in improved learning, knowledge, and comfort with knowledge and skill performance.

Improved learning, knowledge, and comfort with knowledge and skill performance were observed by 22% (10/46) of the studies [16,22,23,57,62,71,74,76,77,79]. For example, residents

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in the study by Luca et al [62] made significantly fewer major errors after the training on average (1.8 compared with 5.2). Barré et al [79] also reported decreased mental demand (thinking, deciding, and calculating) for those in the VR intervention group compared with increases in the control group. In the study by Bracq et al [57], the more users felt immersed in the environment, the more they perceived it to be useful for their learning. Increases in confidence were also observed over the training periods [23,74,76]. Given the strong evidence, lack of contrasting evidence, and the high MMAT score (78%), we had high confidence in this CMO configuration.

Knowledge or Skill Transfer (CMO 4)

In the training-related context of knowledge and skill transfer, AR, combined AR and VR, and VR (all levels of immersion, with and without haptics) were used. When teaching transferable skills, three mechanisms may be triggered: enhancement of existing skills, practice in a perceived safe environment (away from patient harm, time restraints, and stress), and deliberate practice [14,17,20,24,41,59,71-74,77,78,81,88,89]. This leads to transfer of knowledge and skills to clinical practice and other simulators.

Empirical evidence was found for transferable skills, especially enhancing skills. Enhanced skills through VR or AR training helped to transfer knowledge and skills to clinical settings [71,88,89], other simulators (eg, sheep) [41], and surgical or invasive procedures [24,73,81]. For example, the percentage of medical and nurse trainees who experienced >1 occupational needlestick injury in the first 2 months of clinical internship was 31%-35% compared with the percentage of past senior trainees (80%) [71]. In addition, in a study by Wang et al [24], the average time required for real-life anastomosis procedures was shortened from 40.0 (SD 12.4) minutes to 25.1 (SD 7.1) minutes. However, the VR and AR simulators were not always superior and sometimes presented similar outcomes to traditional training [73,81]. In the live procedures, some medical errors (leakages) were still found [24], showing that despite improvements, performance was not perfect. We had moderate confidence that skills are transferable to clinical practice.

Training Novices (CMO 6)

The last training-related context relates to when VR (nonimmersive and fully immersive, with and without haptics) or AR were used to train novices (learners with little or no experience). The programs were expected to trigger various resources and mechanisms, including feedback and objective measurement of skills or knowledge; independent and self-directed learning; a safe, static, and risk-free learning environment; repeated practice; and exposure to experience [6,8,9,14,17,41,58-62,65,70-72,76,79,81]. This may result in technical proficiency, skill acquisition and improved performance (including operative performance), learner satisfaction, and the most improvement in novices.

Evidence showed that repeated attempts and practice on VR or AR simulators significantly improved skills such as speed of decision-making [71], catheter-insertion depth [72], efficiency of endoscopies [58], 30° laparoscopic camera manipulation skills [60], and syringe aspiration time for central venous catheterization [65]. Given the strong supporting evidence, lack of contested evidence, and the high MMAT score (77.5%), we had high confidence that repeated practice results in technical proficiency, skill acquisition, and improved performance. Evidence for the remaining CMO configurations was very limited and often contested; thus, our confidence in them was very low or low (Table S4 in Multimedia Appendix 1).

Implementation and Maintenance of VR and AR Training Programs

Information regarding barriers and facilitating factors for implementing and maintaining VR or AR training programs for health care professionals was extracted from the studies included in creating (step 1) and refining (step 2) the program theory.

Cost

Some argued that high up-front expenses created barriers to implementation and maintenance, including purchasing simulators and headsets as well as software licenses, technology maintenance, staff training, and programming requirements [26,76,91-95]. Integrating VR or AR with manikins was reported to significantly increase costs further [22]. Others argued that these costs were justified because VR can be used repeatedly at no additional cost per learner [16,17,34,40]. VR can provide a complete training tool (unlike box trainers) [60], does not wear out quickly (like manikins), and can represent any anatomy or body type, making it more cost-effective [65]. VR can also reduce time related to clinical teaching [6] and travel for trainees and educators [88].

The cost of VR and AR was expected to decrease with commercialization and market competition in this area [17,40,77], facilitating implementation as cheaper options become available [27]. A *number-needed-to-train* metric may also encourage hospital trusts and universities to implement VR programs [13]. This considers how many clinical costs each hour of training can reduce. Lohre et al [74] exemplified this metric, whereby 1 hour of training on their VR simulator was equivalent to 48 minutes of real-world training time. The simulator was therefore deemed at least 34.1 times more cost-effective.

Attitudes and Experience

A lack of acceptance (ie, negative attitudes) of VR and AR [56,91] and negative experiences may reduce uptake and behavioral intention [57,91,94,96]. Symptoms of cybersickness and perceptuomotor aftereffects when using VR included nausea, eye fatigue, dizziness, vomiting, and ataxia [57,91,94,96]. Other negative experiences could include addiction to VR gaming [91] and increased cognitive load and stress during initial use [57].

It was expected that a cultural change toward acceptance will occur when VR gains traction [56], which may help to increase VR as a standard teaching tool [97] and ultimately improve acceptance. Researchers have already observed positive attitudes toward these novel training tools [9,77,94,95]. For example, Ryu et al [95] reported that 81% of the 45 program directors and residents in their study expressed that VR would be a useful training tool.

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Developmental and Logistical Considerations

Developmental and logistical considerations further create barriers because implementing and maintaining VR and AR programs requires imagination, resources, and planning [94]. From conception, the design and development of training resources can be a lengthy and complicated process, requiring specific programming and animation expertise [17,26,34,91]. Design needs to be multidisciplinary (to convey accurate content), attractive, and user centered [91]. Including external tools may further complicate development and implementation because haptic interaction systems and robotic arms may be cumbersome and limit use [61,84]. Logistical considerations also included storage space, maintenance, cleaning headsets between learners, and providing hazard-free and private learning spaces [27].

Access to Training

The studies highlighted access to training as a facilitator to uptake [18,27,34,40,58,62,77,98]. The mobility of AR and VR training can increase learning opportunities [18,34,62,77], which may fill educational gaps created by geographic or socioeconomic barriers [62]. Health professionals can also learn asynchronously, at their convenience [18,40], whereby self-guided training can be available to all shift workers [27,58]. These benefits also enable the potential scalability of VR and AR training [23,79,88].

Conversely, some studies reported that learners were not able to complete the training because of scheduling conflicts with patients and time constraints [27,60,95,99]. Stefanidis et al [100] clarified that initially, enthusiasm was high, but no one monitored training. Attendance only improved from 6% to 71% after a scheduling coordinator was hired.

Creating a Curriculum

The complexity involved in developing a standardized curriculum created barriers to implementation [8,34,37,57,91,93]. This required personnel to develop the program and schedule learners, validated training devices, and clearly defined objective criteria that aligned with existing curricula and could be used to evaluate learning outcomes [34,37,57,91,93]. Nationwide implementation was further challenged by locally established priorities, regional training budgets [93], and an unequal distribution of VR or AR resources between training centers and institutions [17,34,60].

According to the studies, leadership and collaboration are crucial to facilitate implementation [8,27,93,101]. At a local level, health professionals can develop credentialing committees [8], whereas at a higher level, national organizations and committees can help to ensure a standardized approach to training. With regard to localized training programs (eg, within hospitals), subspecialties could develop a shared training program [93,101]. Support from senior clinicians, boards of directors, and other organizational leaders is helpful to facilitate uptake [27,93,101].

Discussion

Principal Findings and Comparison With Prior Work

To our knowledge, this is the first realist review to explore AR and VR training programs for health care professionals. It contributes a transferable program theory that may be applicable to diverse health professionals and across AR and VR technologies with varying levels of fidelity and use of haptics or additional tools.

A total of 80 published papers were used to develop an initial program theory, and 46 empirical studies that reported on VR, AR, or mixed simulation training programs for health professionals then helped to refine and test the theory. A total of 41 individual CMO configurations were identified, across 6 contexts and conditions. Of the 41 CMO configurations, we had moderate to high confidence in 9 (22%) and low and very low confidence in 5 (11%) and 27 (59%), respectively. Our low confidence was often due to contesting studies as well as the outcomes (especially those on patient results) not being substantiated with sufficient empirical evidence.

We also identified barriers and facilitators to implementation and maintenance, which must be acknowledged for the CMO configurations to be operationalized. The most common barriers were up-front costs, poor acceptance, negative experiences (ie, cybersickness), logistics, and the complexity involved in developing a curriculum. Decreasing costs due to commercialization and the cost-effectiveness of training, a cultural shift toward acceptance, access to training opportunities, and leadership and collaboration facilitated implementation.

The CMO configurations can be explained by applying learning theories identified within some of the reviewed literature [57,83,84,87,96]. Constructivism assumes that learning is an active process, building on previous skills, knowledge and interaction with the physical and social environment [102]. Through active construction [103] and *learning by doing* [104], trainees interact with the environment to adapt and learn. In the same way, VR and AR can be used by health professionals who already have some previous experiences and acquired knowledge or skills in their clinical fields. VR and AR programs may enable upskilling through active learning by immersing health professionals within simulated *real-life* environments. This is reflected in the mechanism of immersing learners in deep immersion. The mechanisms of repeated practice, enhancing skills, and interactive experiences are also explained by constructivism because learners can interact with VR or AR environments to practice their skills.

Cognitive load theory (CLT) can also help to explain the mechanisms, especially in the context of realistic simulations and visualization. CLT assumes that people have a finite amount of working memory available [105,106]. However, we have an unlimited long-term memory, which holds cognitive schemas (experiential knowledge). Learning is then the process of constructing and automating these schemas so that it can be stored in long-term memory. Cognitive load is categorized into intrinsic load (task-specific cognitive effort), extraneous load

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(irrelevant cognitive effort), and germane load (residual working memory capacity).

Some of the CLT literature suggests that VR and AR may help to reduce extraneous load (ie, processes not related to learning) by providing cues and feedback in real time [68,83]. For example, AR glasses and 3D and realistic imagery can provide real-time visual clues to learning to reduce the cognitive effort of remembering this information. However, it is also possible that VR or AR learning tools may unintentionally increase task-specific or extraneous cognitive load because they may complicate learning processes. This is because learners may need to adapt to using VR or AR tools if they are not familiar with them. In some of the reviewed studies [23,57,79], health professionals reported discomfort with the VR headset because of either fatigue or cybersickness, which may also increase extraneous cognitive load because they focus on this discomfort and consequently impair their learning ability. Pretraining to gain familiarity is therefore crucial [57,107].

It was evident that the literature on implementation is premature, with little focus on implementation experiences [17,68,85,100,101]. Some of the considerations were context dependent, highlighting that when implementing VR and AR training programs, the contexts and conditions must be acknowledged. For example, novices (eg, residents and postgraduate medical and health students) may have already been exposed to VR or AR learning tools and may be more accepting of them as well as tolerant of cybersickness. This is because VR and AR is being implemented in new training curricula [77,100] and discomfort decreases with familiarity and use [79,108]. This consideration might be more relevant for those less familiar with the technologies.

Future Research

There was a clear absence of AR and VR training programs for allied health staff, care workers, and within care- and community-based settings. There was also less focus on simple behavioral skills such as disposing of hazardous medical waste or practicing hand hygiene, for which AR and VR smartphone apps have already been developed [109]. In addition, many of the VR and AR devices were used along with haptics, robotic arms, actors, or manikins, which may introduce confounding factors when exploring effectiveness. As also identified by Kyaw et al [110], the applicability of VR or AR training within care and community settings and use as a stand-alone training tool warrants further investigation.

As is common in realist reviews [111] and evident in the literature, most of the mechanisms were not measured, except for repeated practice where authors accounted for repetitions. Control groups were rarely used, and qualitative data on experiences were limited. Future work should use robust and hypothesis-driven methods to objectively measure the impact of the mechanisms. For example, the 14-item Igroup Presence Questionnaire [112] can measure spatial presence (deep immersion), involvement (interaction), and experienced realism, whereas the 16-item Simulator Sickness Questionnaire [113] can measure cybersickness and discomfort. These validated questionnaires should be used in addition to a control group, whereas qualitative data (eg, through interviews) may help to further understand why and when the mechanisms are (or are not) triggered.

More work is also needed to increase the confidence in some of the CMO configurations for which we had low or very low confidence and to understand context-dependent implementation outcomes, along with updating the barriers and facilitators to implementation. Cost and acceptance, for example, may not be a barrier in the future, given that commercialization and market demand will reduce up-front costs, whereas increasing use may create a cultural change that favors acceptance.

Strengths and Limitations

Unlike some realist reviews [111,114], we first used nonempirical literature to form our theory and then tested and refined it with empirical literature. This was crucial to helping us to refine the program theory; in addition, it helped to ensure that the program theory was evidence informed and more reliable. Unlike others [50], we also assessed the quality of the research used to test and refine the theory and ultimately determined our confidence in each CMO configuration. The criteria used to determine confidence were conservative and also considered contesting studies and quantity of evidence. This transparency is important because program theories developed through realist reviews are only as good as the quality and quantity of the evidence they include. To our knowledge, this is the first realist review to consider all these factors.

Limitations included not sense checking our CMO configurations with AR or VR training experts as well as not comprehensively searching for gray literature. This meant that some initial theories might have been missed. In addition, only 20% (9/46) of the included studies were assessed for quality by 2 researchers. As such, interpretation of our quality assessments may be subject to some caution. However, we did not exclude research because of low quality and amalgamated the quality of the studies to determine our confidence in the CMO configurations; therefore, we do not expect this to bias our results. Interrater reliability was also substantial.

Conclusions

This review explored the complex nature of AR and VR training programs for health care staff, highlighting how they may actually work in practice, for whom they are most likely to work, and in which contexts and circumstances or under which conditions they may work. We found evidence for improved skills, learning and knowledge, and learner satisfaction, but there was little evidence on patient results. We had moderate to high confidence that VR and AR training programs trigger perceptions of realism and deep immersion as well as enable easier visualization of patient anatomy, interactivity, enhanced skills, and repeated practice in a safe environment. Future testing of these mechanisms using hypothesis-driven approaches is required. More research is also required to explore implementation and maintenance considerations. Ultimately, our evidence-informed program theory can be used to support the development and implementation of AR and VR training programs for health care providers and as a starting point for further research.

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Acknowledgments

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Authors' Contributions

NG conceived and designed the review with support from DD, SNvdV, and PW. NG and DD identified and analyzed the literature and conducted the quality assessments. All authors contributed to developing the program theory. NG wrote the first draft of the manuscript. All authors revised and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Data extraction items, summary of the empirical articles (n=46), context-mechanism-outcome configurations, and our confidence in the configurations.
[DOCX File , 45 KB - games_v10i1e31644_app1.docx]

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Abbreviations

AR: augmented reality
CLT: cognitive load theory
CMO: context-mechanism-outcome
MMAT: Mixed Methods Appraisal Tool
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RAMESES: Realist and Meta-narrative Evidence Syntheses: Evolving Standards
VR: virtual reality

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Review

The Effectiveness of Serious Games in Alleviating Anxiety: Systematic Review and Meta-analysis

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Abstract

Background: Anxiety is a mental disorder characterized by apprehension, tension, uneasiness, and other related behavioral disturbances. One of the nonpharmacological treatments used for reducing anxiety is serious games, which are games that have a purpose other than entertainment. The effectiveness of serious games in alleviating anxiety has been investigated by several systematic reviews; however, they were limited by design and methodological weaknesses.

Objective: This study aims to assess the effectiveness of serious games in alleviating anxiety by summarizing the results of previous studies and providing an up-to-date review.

Methods: We conducted a systematic review of randomized controlled trials (RCTs). The following seven databases were searched: MEDLINE, CINAHL, PsycINFO, ACM Digital Library, IEEE Xplore, Scopus, and Google Scholar. We also conducted backward and forward reference list checking for the included studies and relevant reviews. Two reviewers independently carried out the study selection, data extraction, risk of bias assessment, and quality of evidence appraisal. We used a narrative and statistical approach, as appropriate, to synthesize the results of the included studies.

Results: Of the 935 citations retrieved, 33 studies were included in this review. Of these, 22 RCTs were eventually included in the meta-analysis. Very low–quality evidence from 9 RCTs and 5 RCTs showed no statistically significant effect of exergames (games entailing physical exercises) on anxiety levels when compared with conventional exercises (P=.70) and no intervention (P=.27), respectively. Although 6 RCTs demonstrated a statistically and clinically significant effect of computerized cognitive behavioral therapy games on anxiety levels when compared with no intervention (P=.01), the quality of the evidence reported was low. Similarly, low-quality evidence from 3 RCTs showed a statistically and clinically significant effect of biofeedback games on anxiety levels when compared with conventional video games (P=.03).

Conclusions: This review shows that exergames can be as effective as conventional exercises in alleviating anxiety; computerized cognitive behavioral therapy games and exergames can be more effective than no intervention, and biofeedback games can be more effective than conventional video games. However, our findings remain inconclusive, mainly because there was a high risk of bias in the individual studies included, the quality of meta-analyzed evidence was low, few studies were included in some meta-analyses, patients without anxiety were recruited in most studies, and purpose-shifted serious games were used in most studies. Therefore, serious games should be considered complementary to existing interventions. Researchers should use serious

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games that are designed specifically to alleviate depression, deliver other therapeutic modalities, and recruit a diverse population of patients with anxiety.

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KEYWORDS

serious games; exergames; anxiety; computerized cognitive behavioral therapy games; biofeedback games; systematic reviews; meta-analysis; mobile phone

Introduction

Background

Anxiety is a normal response to situations in human life. However, excessive anxiety may be indicative of anxiety disorders, which are mental disorders characterized by apprehension, tension, uneasiness, and other related behavioral disturbances. They are potentially coupled with other physiological symptoms, such as shortness of breath, headaches, nausea, and abdominal pain [1,2]. Anxiety disorders include separation anxiety disorder, phobia, social anxiety disorder, panic disorder, and substance- or medication-induced anxiety disorder [3]. Globally, the prevalence of anxiety disorders in the general population is estimated to be 26.9% [4]. Anxiety disorders affect all age groups, including children and adolescents [5], and can be debilitating in nature, causing significant impairment in one's social and professional functioning [6]. Evidence has revealed a strong association between anxiety and mortality rates among healthy individuals [7,8]. Anxiety contributes to a decrease in quality of life and other health-related problems [8]. Globally, over 45 million incidents are estimated to be attributed to anxiety disorders, which, in turn, are responsible for approximately 28.68 million disability-adjusted life years [9,10].

Despite the prevalence of anxiety disorders, they often go undetected and undertreated [11]. Anxiety requires treatment and management because of the stimulation of the sympathetic system, which can lead to adverse effects. Treatments for anxiety disorders can be divided into pharmacological treatments (eg, psychotropic medications) and nonpharmacological treatments (eg, cognitive behavioral therapy [CBT]) [12,13]. Although the use of pharmacological treatments can be effective for the treatment of anxiety disorders, they can cause many adverse events and would not be effective for everyone. Therefore, nonpharmacological treatments have been used to reduce anxiety levels [14,15].

One of the nonpharmacological treatments used for reducing anxiety is serious games, which are games that have a purpose other than entertainment [16-19]. In recent years, the popularity and adoption of serious games have been on the rise because of their ability to educate and influence change in one's experience or behaviors [20,21]. Evidence suggests that serious games can enable players to experience more meaningful, engaging, and challenging learning when compared with traditional interventions or other methods used to relieve anxiety [22].

Serious games come in a variety of types and formats, such as (1) exergames, or video games that entail physical exercises (eg, fitness and balance exercises) as part of the intended gameplay; (2) computerized CBT games, which are video games that provide CBT for the users; (3) biofeedback games, which are video games that use electrical sensors attached to the participant to receive information about the participant's body state (eg, electrocardiogram sensors) and seek to influence some of the player body's functions (eg, heart rate); (4) attention distraction games, which are video games that are used to direct a user's attention away from another focus or a given event; (5) brain training games, which are video games that aim to maintain or improve users' cognitive abilities (eg, working memory, executive function, processing speed, and attention), and (6) social skills training games that use computer-based games to improve social skills and mental health.

Research Gap and Aim

Various studies have assessed the effectiveness of serious games in alleviating anxiety. Examining and summarizing the evidence from these studies is critical to reach informed conclusions about the effectiveness of serious games in the treatment of anxiety disorders. Two published reviews summarized the evidence regarding the effectiveness of serious games on anxiety [16,17]. However, these reviews are undermined by certain shortcomings that limit the generalization of the findings. Specifically, these reviews (1) focused on only one type of serious games (ie, exergames) [16]; (2) included non-randomized controlled trials (RCTs) [16,17]; (3) focused on a specific age group (eg, adolescents) [17]; (4) did not search the main databases of the information technology and health care fields (eg, MEDLINE, PsycINFO, IEEE Xplore, and ACM Digital Library) [16,17], or (5) did not conduct meta-analyses [17]. To address the existing gaps in the literature, this review aims to assess the effectiveness of serious games in alleviating anxiety by summarizing the results of previous studies and providing an up-to-date review.

Methods

We conducted a systematic review and meta-analysis per the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Multimedia Appendix 1) [23]. The protocol for this review was registered at PROSPERO (International Prospective Register of Systematic Reviews; ID: CRD42021264126).

Search Strategy

Search Sources

We searched the following bibliographic databases to retrieve the relevant studies: MEDLINE (via Ovid), PsycINFO (via EBSCO), CINAHL (EBSCO), IEEE Xplore, ACM Digital

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Library, and Scopus. These databases were searched on June 29, 2021, by the first author (A Abd-alrazaq). We also set up automatic alerts, as needed, to retrieve weekly searches for 12 weeks (ending on August 28, 2021). Furthermore, we searched *Google Scholar* to identify gray literature. We considered only the first 10 pages (ie, 100 hits), as Google Scholar retrieves a vast number of studies, and it organizes them based on their relevance. Finally, we conducted backward and forward reference list checking (ie, screening the reference lists of the included studies and relevant reviews and screening the studies that cited the included studies).

Search Terms

Two experts in digital mental health were consulted before developing the search query for this review, and systematic reviews of relevance to this review were checked. The search terms were chosen based on the target intervention (eg, serious games and exergames), target outcome (eg, anxiety), and target study design (eg, RCT and clinical trial). Multimedia Appendix 2 summarizes the search query used for searching each of the 8 databases.

Study Eligibility Criteria

Only RCTs that assessed the effectiveness of serious games in alleviating anxiety levels were included in this study. Specifically, the target intervention in this review was serious games that were delivered on digital platforms such as computers, consoles (Xbox, PlayStation, etc), mobile phones, tablets, handheld devices, or any other computerized devices. Furthermore, gaming had to be an integral and primary component of the intervention. The serious games must have been used for therapeutic or preventive purposes. Nondigital games and those used for other purposes, such as monitoring, screening, and diagnosis, were excluded. RCTs on whether there were parallel RCTs, cluster RCTs, crossover RCTs, or factorial RCTs were all included, but we excluded quasi-experiments, observational studies, and reviews.

The outcome of interest in this review was *anxiety level*, regardless of the outcome measures. We included the outcome data measured immediately after the intervention rather than the follow-up data. Trials in the English language were eligible for inclusion in this review, and all other languages were excluded. Conference abstracts and posters, commentaries, preprints, proposals, and editorials were excluded. RCTs published as journal articles, conference proceedings, and dissertations were included. No restrictions related to the population, year of publication, country of publication, comparator, or study settings were applied.

Study Selection

We identified relevant studies in the following steps. First, we exported the retrieved studies into EndNote X8 software to identify and eliminate duplicate entries. In the second step, 2 reviewers (A Abd-alrazaq and MA) independently screened the titles and abstracts of all the retrieved studies. Finally, the full texts of the studies included in the previous step were screened independently by 2 reviewers. The 2 reviewers resolved any disagreements through discussion. The interrater agreement in steps 2 and 3 were Cohen κ=0.81 and Cohen κ=0.93, respectively, indicating a perfect level of interrater agreement [24].

Data Extraction

Two independent reviewers used Microsoft Excel to extract the data from the included studies. Multimedia Appendix 3 shows the data extraction form that was used by the 2 reviewers to extract the data precisely and systematically from the included studies. We pilot-tested the form using the 5 included studies before proceeding. Disagreements between the reviewers were resolved via discussion. We observed an interrater agreement of 0.86, indicating a perfect level of agreement [24]. Where outcome data such as mean, SD, and sample size were unavailable, we contacted the corresponding authors in an attempt to retrieve them. In this way, we managed to retrieve such information for an additional 5 studies.

Risk of Bias Appraisal

As recommended by the Cochrane Collaboration [25], the risk of bias was assessed by 2 independent reviewers using the Risk-of-Bias 2 (RoB 2) tool. This tool appraises the risk of bias in five domains in RCTs: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result [25]. The risk of bias judgments in these domains was used to determine the overall risk of bias for each included study. Disagreements in judgments between the 2 reviewers were resolved via discussion. Interrater agreement between the reviewers was perfect (Cohen κ=0.86) [24].

Data Synthesis

We used a narrative and statistical approach to synthesize the extracted data. Specifically, in our narrative synthesis, we describe the characteristics of the included studies, population, intervention, comparator, and outcome measures using texts and tables. The findings of the included studies were summarized and grouped according to the type of serious games (eg, exergames, computerized CBT games, and biofeedback games). We also conducted a meta-analysis, where at least 3 studies of the same type of serious games reported sufficient data (ie, mean, SD, and number of participants in each intervention group).

We used Review Manager (RevMan 5.4; The Cochrane Collaboration) to conduct the meta-analyses. The effect of each study and the overall effect was assessed using the standardized mean difference (SMD) because the type of data for the outcome of interest (anxiety level) was continuous, and the instruments used to evaluate the outcome were diverse among the included trials. We selected the random-effects model for the analysis because of the high clinical heterogeneity between the meta-analyzed studies in terms of serious game characteristics (eg, type, duration, frequency, and period), population characteristics (eg, sample size, mean age, and health condition), and outcome measures (eg, tools and follow-up period).

When the meta-analysis showed a statistically significant difference between the groups, we examined whether this difference was clinically important. We used the concept of *minimal clinically important difference* (MCID), which refers

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to the smallest change in a measured outcome that a patient would deem as worthwhile and substantial enough to warrant a change in a patient's therapy. MCID boundaries were calculated as −0.5 to +0.5 times the SMD of the meta-analyzed studies.

We calculated I^2 and a chi-square P value to examine the degree and statistical significance of heterogeneity, respectively, in the meta-analyzed studies. A chi-square P value of ≤.05 suggests heterogeneous meta-analyzed studies [26]. When I^2 ranged from 0% to 40%, 30% to 60%, 50% to 90%, and 75% to 100%, the degree of heterogeneity was judged as insignificant, moderate, substantial, or considerable, respectively [26].

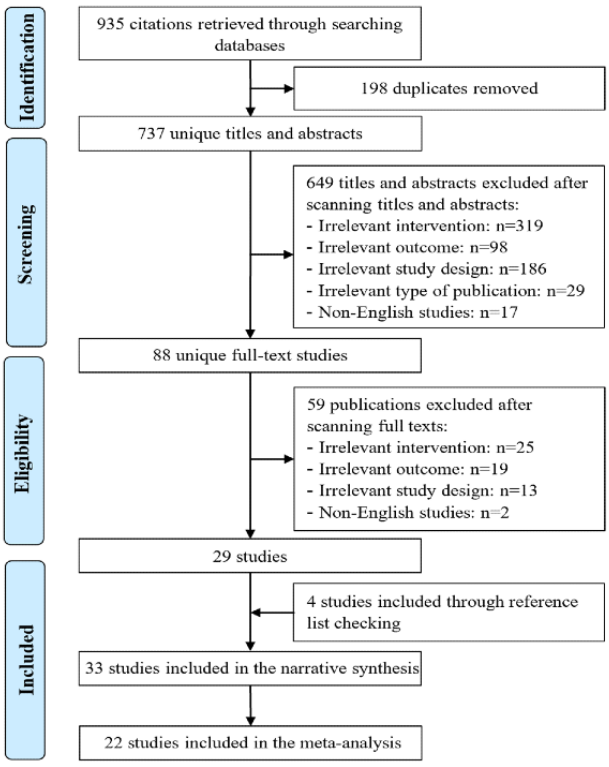
We used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to assess the overall quality of evidence resulting from meta-analyses [27]. The GRADE approach appraises the quality of evidence based on five domains: risk of bias, inconsistency (ie, heterogeneity), indirectness, imprecision, and publication bias [27]. The overall quality of the meta-analyzed evidence was appraised separately by 2 reviewers, and any differences in decisions were addressed by discussion. The reviewers' interrater agreement was deemed perfect (Cohen κ=0.96) [24].

Results

Search Results

As shown in Figure 1, we identified 935 records by searching 7 electronic databases. Of these records, we identified and removed 198 duplicates using EndNote software. The screening of the titles and abstracts of the remaining 737 records led to the exclusion of 649 citations because (1) they did not use serious games (n=319); (2) the anxiety level was not a measured outcome (n=98); (3) they were not RCTs (n=186); (4) they were not peer-reviewed articles, theses, or conference proceedings (n=29); and (5) they were published in languages other than English (n=17). Reading the full text of the remaining 88 publications led to the exclusion of 59 publications for the following reasons: (1) the intervention did not use serious games (n=25), (2) the anxiety level was not a measured outcome (n=19), (3) they were not RCTs (n=13), and (4) they were published in a language other than English (n=2). We identified 4 additional RCTs through backward and forward reference list checking. A total of 33 RCTs were included in this review [28-60]. We conducted a meta-analysis when at least 3 studies of the same type of serious games reported sufficient data (ie, mean, SD, and number of participants in each intervention group). Therefore, 22 of the included RCTs were included in the meta-analysis [28-46,49-51].

Figure 1. Flowchart of the study selection process.



Characteristics of Included Reviews

The included studies were published between 2012 and 2021 (Table 1). The year that witnessed the largest number of included studies was 2017 (n=8), followed by 2020 (n=6) and 2021 (n=6). The included studies were conducted in 16 different countries, as shown in Table 1. The country that published the largest number of included studies was the United States (n=6). All included studies were published in peer-reviewed journals, except for one that was a thesis. The trial type used in most of the included studies was parallel RCTs (n=31).

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Table 1. Characteristics of studies and populations.

Study	Year	Country	Publication type	RCT[a] type	Sample size, n	Age (years), mean	Sex (male), n (%)	Target group or condition	Setting
Adomaviciene et al [28]	2019	Lithuania	Journal article	Parallel	60	64.6	40 (66.7)	Stroke	Clinical
Carvalho et al [29]	2020	Brazil	Journal article	Parallel	35	51.3	0 (0)	Fibromyalgia	Educational
Meldrum et al [30]	2015	Ireland	Journal article	Parallel	71	54.1	27 (38)	Unilateral peripheral vestibular loss	Clinical
Schumacher et al [31]	2018	Germany	Journal article	Parallel	42	56.3	25 (59.5)	Hematopoietic stem cell transplantation recipients	Clinical
Ruivo et al [32]	2017	Ireland	Journal article	Parallel	32	59.9	26 (81.3)	Cardiovascular diseases	Clinical, community, and educational
Mazzoleni et al [33]	2014	Italy	Journal article	Parallel	40	71.2	NR[b]	Chronic respiratory diseases	Clinical
Polat et al [34]	2021	Turkey	Journal article	Parallel	40	44.8	0 (0)	Fibromyalgia	Clinical
Lin et al [35]	2020	Taiwan	Journal article	Parallel	80	57.0	39 (48.8)	Knee osteoarthritis	Clinical
Vieira et al [36]	2017	Portugal	Journal article	Parallel	46	57.7	NR	Cardiovascular diseases	Clinical
Thomas et al [37]	2017	United Kingdom	Journal article	Parallel	30	49.3	3 (10)	Multiple sclerosis	Clinical
Wagener et al [38]	2012	United States	Journal article	Parallel	41	14.0	14 (33.3)	Obese adolescents	Clinical
Jahouh et al [39]	2021	Spain	Journal article	Parallel	80	84.2	35 (44)	Older adults	Clinical
Collado-Mateo et al [40]	2017	Spain	Journal article	Parallel	83	52.5	0 (0)	Fibromyalgia	Clinical
Cooney et al [41]	2017	Ireland	Journal article	Parallel	52	40.6	20 (38.8)	Anxiety, depression, or intellectual disability	Clinical
Donker et al [42]	2019	Netherlands	Journal article	Parallel	193	41.3	64 (33.2)	Acrophobia	Community
Fish et al [43]	2014	United States	Journal article	Parallel	59	30.0	29 (49.2)	Depression	Clinical and educational
Fleming et al [44]	2012	New Zealand	Journal article	Crossover	32	14.9	18 (56)	Depression	Educational
Merry et al [45]	2012	New Zealand	Journal article	Parallel	187	15.6	64 (34.2)	Depression	Clinical and educational
Perry et al [46]	2017	Australia	Journal article	Cluster	540	16.7	199 (36.9)	Secondary students	Educational
Schoneveld et al [47]	2018	Netherlands	Journal article	Parallel	174	10.0	71 (40.8)	Anxiety	Educational
Tsui [48]	2016	Canada	Thesis	Parallel	143	13.6	52 (36.1)	Anxiety	Clinical and educational
Schoneveld et al [49]	2016	Netherlands	Journal article	Parallel	136	10.0	61 (45.2)	Anxiety	Educational
Wijnhoven et al [50]	2020	Netherlands	Journal article	Parallel	109	11.1	84 (77.1)	Anxiety and autism spectrum disorder	Clinical and educational
Scholten et al [51]	2016	Netherlands	Journal article	Parallel	138	13.3	48 (35)	Anxiety	Educational
Marechal et al [52]	2017	France	Journal article	Parallel	118	6.8	83 (70.4)	Children undergoing general anesthesia	Clinical
Sakızcı Uyar et al [53]	2021	Turkey	Journal article	Parallel	138	6.6	61 (44)	Adenoidectomy, adenotonsillectomy, or myringotomy	Clinical

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Study	Year	Country	Publication type	RCT[a] type	Sample size, n	Age (years), mean	Sex (male), n (%)	Target group or condition	Setting
Liu et al [54]	2020	United States	Journal article	Parallel	53	12.5	37 (69.8)	Otolaryngological conditions	Clinical
Butler et al [55]	2020	Germany	Journal article	Parallel	40	33.4	40 (100)	Posttraumatic stress disorder	Clinical
Bove et al [56]	2021	United States	Journal article	Parallel	44	51.1	9 (20.5)	Multiple sclerosis	Clinical
Sanchez et al [57]	2017	United States	Journal article	Parallel	69	NR	41 (59.4)	Social skills deficits	Community and educational
Beidel et al [58]	2021	United States	Journal article	Parallel	42	9.6	16 (38.1)	Social anxiety	Community
Haberkamp et al [59]	2021	Germany	Journal article	Parallel	68	22.8	9 (13)	Arachnophobia	Educational
Litvin et al [60]	2020	United Kingdom	Journal article	Parallel	709	NR	420 (59.3)	Generally healthy employees	Company

[a]RCT: randomized controlled trial.

[b]NR: not reported.

The sample size in the included studies ranged from 30 to 709, with an average of 112.8 (SD 93.2). The targeted participants were adults (aged >18 years) in 18 studies, adolescents (aged 12-18 years) in 5 studies, children (aged 5-11 years) in 5 studies, and both children and adolescents in 3 studies. Specifically, the mean age of participants reported in 31 studies ranged between 6.6 and 84.2 years, with an average of 34.7 (SD 22.4) years. The percentage of males reported in 31 studies ranged from 0% to 100%, with an average of 43.2% (SD 23.8%). The participants' health conditions varied between studies, and anxiety was the most common (n=7). The participants in most studies were recruited from clinical settings (n=22).

Only serious games were used as interventions in 28 of the included studies, whereas the remainder used serious games combined with other interventions (Table 2). Nintendo Wii Fit (n=5) was the most common game used in the included studies, followed by MindLight (n=4). We identified eight types of serious games based on the therapeutic modality that they deliver: exergames (n=13), computerized CBT games (n=6), biofeedback games (n=5), attention distraction games (n=3), brain training games (n=2), social skills training games (n=2), exposure therapy games (n=1), and psychoeducation games (n=1). In 20 studies, games were designed with a *serious* purpose from the beginning (designed serious games); however, in the remaining 13 studies, they were not designed as serious games from the start but rather were used for a serious purpose (purpose-shifted games). The most common platforms used for playing games were computers (n=17) and video game consoles (n=8). The duration of the games in the included studies ranged from 5 to 150 minutes, but it was ≤60 minutes in most studies (n=28). The frequency of playing the games varied between only one time throughout the study and once a day, but it ranged between once a week and 3 times a week in 24 studies. The intervention period ranged from 1 to 24 weeks, but it ranged from 1 to 10 weeks in 25 studies.

As shown in Table 3, the comparison groups received inactive interventions in 14 studies while they received active interventions in 21 studies (eg, conventional exercises, CBT programs, video games, medication, and psychotherapy). Note that the numbers do not add up because 2 studies delivered both active and inactive interventions as comparators. The duration of the active comparators ranged from 10 to 180 minutes. The frequency of the active comparators varied between only one time throughout the study and once a day, but it ranged between once a week and 3 times a week in about half of the studies (15/33, 45.5%. The period of active comparators varied between 1 week and 24 weeks. The outcome of interest (eg, anxiety level) was measured using 15 different tools, but the most common tools used by the included studies were the Spence Children's Anxiety Scale (SCAS; n=8) and the Hospital Anxiety and Depression Scale (n=7). The outcome of interest was measured immediately after the intervention in all included studies, and the most common follow-up period was 3 months (n=10). Participant attrition was reported in 32 studies, ranging from 0 to 335.

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Table 2. Characteristics of interventions.

Study	Intervention	Serious game name	Serious game type	Serious game genre	Platform	Duration (minute)	Frequency (time per week)	Period (week)
Adomaviciene et al [28]	Serious game	N/A[a]	Exergame	Designed	Computer, Kinect	45	Once a day	2
Carvalho et al [29]	Serious game	Wii Fit Plus	Exergame	Purpose-shifted	Wii console, balance board, Wii remote plus	60	3	7
Meldrum et al [30]	Serious game	Wii Fit Plus	Exergame	Purpose-shifted	Wii console, balance board, Frii Board	15	5	6
Schumacher et al [31]	Serious game	Wii Fit, Wii Sports	Exergame	Purpose-shifted	Wii console, balance board	30	5	2
Ruivo et al [32]	Serious game	Wii Sports	Exergame	Purpose-shifted	Wii console, Kinect	60	2	6
Mazzoleni et al [33]	Serious game + pulmonary rehabilitation program	Wii Fit Plus	Exergame	Purpose-shifted	Wii console, balance board, Wii remote plus	60	7	3
Polat et al [34]	Serious game + cycling activity	Kinect Sports (Beach Volleyball)	Exergame	Purpose-shifted	Computer, Kinect	35	3	4
Lin et al [35]	Serious game + hot packs + transcutaneous electrical nerve stimulation	Hot Plus	Exergame	Designed	Computer, sensing pad	20	3	4
Vieira et al [36]	Serious game	Kinect-Rehab-Play	Exergame	Designed	Computer, Kinect	70-85	3	24
Thomas et al [37]	Serious game	Wii Fit Plus, Wii Sports, Wii Sports Resort	Exergame	Purpose-shifted	Wii console, balance board, Wii remote controls	27	2	24
Wagener et al [38]	Serious game	Dance Dance Revolution	Exergame	Purpose-shifted	Computer, sensing pad	40-75	3	10
Jahouh et al [39]	Serious game	Step, Nodding	Exergame	Purpose-shifted	Wii console	40-45	2-3	8
Collado-Mateo et al [40]	Serious game	VirtualEx-FM	Exergame	Designed	Computer, Kinect	60	2	8
Cooney et al [41]	Serious game	Pesky Gnats: The Feel Good Island	CBT[b] game	Designed	Computer	60	1	7
Donker et al [42]	Serious game	ZeroPhobia	CBT game	Designed	Smartphone, wearables (VR[c] goggles)	5-40	2	3
Fish et al [43]	Serious game	Bejeweled II, Peggle, Bookworm Adventures	CBT game	Purpose-shifted	Computer	30	3	4
Fleming et al [44]	Serious game	SPARX	CBT game	Designed	Computer	30	1-2	5
Merry et al [45]	Serious game	SPARX	CBT game	Designed	Computer	20-40	1-2	4-7
Perry et al [46]	Serious game	SPARX-R	CBT game	Designed	Computer	20-30	1-2	5-7
Schoneveld et al [47]	Serious game	MindLight	Biofeedback game	Designed	Computer, wearables (EEG[d] headset)	60	1	6
Tsui [48]	Serious game	MindLight	Biofeedback game	Designed	Computer	60	2	3

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Study	Intervention	Serious game name	Serious game type	Serious game genre	Platform	Duration (minute)	Frequency (time per week)	Period (week)
Schoneveld et al [49]	Serious game	MindLight	Biofeedback game	Designed	Computer, wearables (EEG headset)	60	2	3
Wijnhoven et al [50]	Serious game	MindLight	Biofeedback game	Designed	Computer, wearable (headset)	60	1	6
Scholten et al [51]	Serious game	Dojo	Biofeedback game	Designed	Computer	60	2	3
Marechal et al [52]	Serious game	N/A	Attention distraction game	Purpose-shifted	Tablet	20	One time throughout the study	N/A
Sakızcı Uyar et al [53]	Serious game	Angry Birds, Subway Surfers, Snail Bob	Attention distraction game	Purpose-shifted	Tablet	20	One time throughout the study	N/A
Liu et al [54]	Serious game + topical analgesia	SpaceBurgers	Attention distraction game	Designed	Wearables (VR goggles), handheld controller	NR	One time throughout the study	N/A
Butler et al [55]	Serious game + eye movement desensitization and reprocessing (EMDR[e]) therapy	Tetris	Brain training game	Purpose-shifted	Nintendo DS XL console	120-150	Once a day (Tetris); 2 time a week (EMDR)	6
Bove et al [56]	Serious game	Band Togather	Brain training game	Designed	Tablet	25	5	6
Sanchez et al [57]	Serious game	Adventures	Social skills training game	Designed	Computer	25	1	9
Beidel et al [58]	Serious game	Pegasys-VR	Social skills training game (Social effectiveness therapy game)	Designed	Tablet	60-120	2	12
Haberkamp et al [59]	Serious game	Spider app	Exposure therapy game	Designed	Smartphone	12	2	1
Litvin et al [60]	Serious game	eQuoo	Psychoeducation game	Designed	Smartphone, tablet	10-15	1	5

[a]N/A: not applicable.

[b]CBT: cognitive behavioral therapy.

[c]VR: virtual reality.

[d]EEG: electroencephalography.

[e]EMDR: Eye Movement Desensitization and Reprocessing.

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Table 3. Characteristics of comparators and outcomes.

Study	Comparator	Duration (minute)	Frequency (time per week)	Period (week)	Outcome measures	Follow-up	Attrition
Adomaviciene et al [28]	Robot-assisted trainings	45	Once a day	2	HADS[a]	Postintervention	18
Carvalho et al [29]	Conventional exercises	60	3	7	Fibromyalgia Impact Questionnaire	Postintervention	14
Meldrum et al [30]	Conventional exercises	15	5	6	HADS	Postintervention	9
Schumacher et al [31]	Conventional exercises (physiotherapy)	30	5	2	HADS	Postintervention, 30- and 100-day follow-up	11
Ruivo et al [32]	Conventional exercises	60	2	6	HADS	Postintervention, 2-month follow-up	4
Mazzoleni et al [33]	Conventional exercises (pulmonary rehabilitation program)	60	7	3	STAI[b]	Postintervention	1
Polat et al [34]	Conventional exercises + cycling activity	35	3	4	HADS	Postintervention, 1-month follow-up	6
Lin et al [35]	Conventional exercises + hot packs + transcutaneous electrical nerve stimulation	20	3	4	HADS	Midintervention, postintervention, and 1 and 3-month follow-up	1
Vieira et al [36]	Conventional exercises, control	70-85	3	24	Depression Anxiety and Stress Scale 21	Midintervention, postintervention	13
Thomas et al [37]	Control	N/A[c]	N/A	N/A	HADS	Postintervention	2
Wagener et al [38]	Control	N/A	N/A	N/A	Behavior Assessment System for Children-2	Postintervention	1
Jahouh et al [39]	Control	N/A	N/A	N/A	Goldberg Anxiety and Depression Scale	Postintervention	N/A
Collado-Mateo et al [40]	Control	N/A	N/A	N/A	Fibromyalgia Impact Questionnaire	Postintervention	7
Cooney et al [41]	Control	N/A	N/A	N/A	Glasgow Anxiety Scale for people with an Intellectual Disability	Postintervention, 3-month follow-up	3
Donker et al [42]	Control	N/A	N/A	N/A	Beck Anxiety Inventory, Acrophobia Questionnaire	Postintervention, 3-month follow-up	59
Fish et al [43]	Educational website	30	3	4	State-Trait Anxiety Inventory	Postintervention	0
Fleming et al [44]	Control	N/A	N/A	N/A	SCAS[d]	Postintervention	5
Merry et al [45]	Control	N/A	N/A	N/A	SCAS	Postintervention, 3-month follow-up	17
Perry et al [46]	Control (interactive web-based program)	20-30	1-2	5-7	SCAS	Postintervention, 6- and 18-month follow-up	134
Schoneveld et al [47]	Conventional CBT[e]	60-90	1	8	SCAS	Postintervention, 3- and 6-month follow-up	36
Tsui [48]	Conventional CBT (web-based CBT)	60	2	3	SCAS, STAI	Postintervention, 3-month follow-up	19
Schoneveld et al [49]	Video game	60	2	3	SCAS	Postintervention, 3-month follow-up	21

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Study	Comparator	Duration (minute)	Frequency (time per week)	Period (week)	Outcome measures	Follow-up	Attrition
Wijnhoven et al [50]	Video game	60	1	6	SCAS	Postintervention, 3-month follow-up	33
Scholten et al [51]	Video game	60	2	3	SCAS	Postintervention, 3-month follow-up	9
Marechal et al [52]	Midazolam	N/A	N/A	N/A	Modified Yale Preoperative Anxiety Scale	Postintervention, 2-hour follow-up	3
Sakızcı Uyar et al [53]	Midazolam, watching an informative cartoon	N/A	One time throughout the study	N/A	Modified Yale Preoperative Anxiety Scale	Postintervention	4
Liu et al [54]	Control (topical analgesia)	N/A	N/A	N/A	Subjective Units of Distress	Postintervention	0
Butler et al [55]	Eye Movement Desensitization and Reprocessing therapy	60-90	2	6	STAI	Postintervention, 6-month follow-up	0
Bove et al [56]	Video game	25	5	6	STAI	Postintervention, 2-month follow-up	4
Sanchez et al [57]	Control	N/A	N/A	N/A	Social Anxiety Scale for Children-Revised	Postintervention	24
Beidel et al [58]	Social effectiveness therapy	60-180	2	12	SPAI-C[f]	Postintervention	4
Haberkamp et al [59]	Video game	12	2	1	Survey developed by the authors	Midintervention, Postintervention	6
Litvin et al [60]	Conventional CBT, control	10	1	5	Survey developed by the authors	Midintervention, Postintervention	355

[a]HADS: Hospital Anxiety and Depression Scale.

[b]STAI: State-Trait Anxiety Inventory.

[c]N/A: not applicable.

[d]SCAS: Spence Children's Anxiety Scale.

[e]CBT: cognitive behavioral therapy.

[f]SPAI-C: Social Phobia and Anxiety Inventory for Children.

Results of Risk of Bias Appraisal

Approximately 70% (23/33) of the included studies generated an appropriate random allocation sequence for the randomization process. The allocation sequence in 14 studies was concealed until the participants were assigned to the interventions. The groups were comparable at baseline in the 29 studies. On the basis of these judgments, the risk of bias because of the randomization process was rated as low in 12 studies (Figure 2).

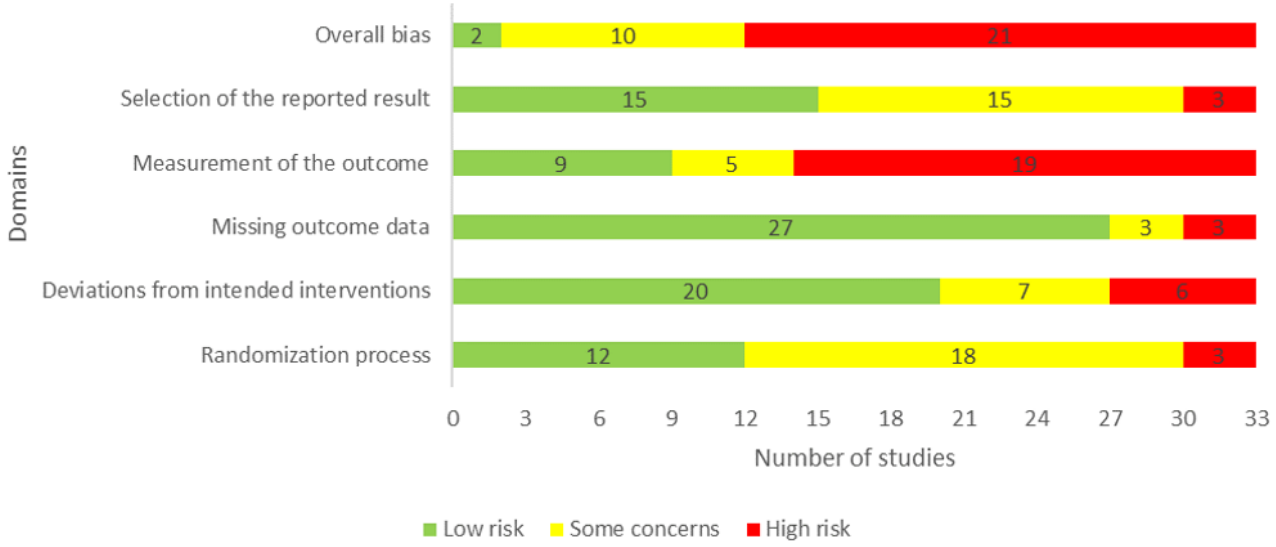
Participants and those who were delivering the interventions were blinded to the assigned interventions during the trial in 4 and 5 studies, respectively. In 2 studies, there was a deviation from the intended intervention, which occurred because of the experimental contexts. An appropriate analysis (eg, intention-to-treat or modified intention-to-treat analyses) was used in 26 studies to estimate the effect of the intervention. According to these judgments, the risk of bias because of deviations from the intended interventions was low in 20 studies (Figure 2).

Outcome data were available for more than 95% of the participants only in 12 studies. There was evidence that the findings were not biased by the missing outcome data in only 7 studies. In 8 studies, the missing outcome data resulted from reasons that were documented and not related to the outcome. Accordingly, 27 studies were judged as having a low risk of bias in the *missing outcome data* domain.

Four studies assessed the outcome of interest (ie, anxiety levels) using inappropriate measures. The measurement methods were comparable across the intervention groups in all included studies. The assessor of the outcome was aware of the assigned interventions in the 20 studies. Given that the outcome measure was subjective in all studies, the assessment of the outcome could have been affected by knowledge of the intervention received. Accordingly, only 9 studies were rated as having a low risk of bias in the *measuring the outcome* domain (Figure 2).

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Figure 2. Review authors' judgments about each risk of bias domain.



There was a prespecified analysis plan (ie, protocol) for the 15 studies. Only 3 studies reported outcome measurements that differed from those specified in the analysis plan. In all studies, there was no evidence that they selected their results from many results produced from multiple eligible analyses of the data. Accordingly, the risk of bias because of the selection of the reported results was considered low in 15 studies (Figure 2).

In the last domain, *overall bias*, the risk of bias was considered high in 21 studies as they were judged as having a high risk of bias in at least one domain. Ten studies were judged to raise some concerns in the domain of *overall bias*, as they had some concerns in at least one of the domains and were not at high risk for any domain. The 2 remaining studies were judged to be at low risk of bias for the domain of *overall bias*, given that it was rated as having a low risk of bias for all domains. Reviewers' judgments about each *risk of bias* domain for each included study are presented in Multimedia Appendix 4 [29-60].

Results of Studies

In this review, serious games were classified into eight types based on the therapeutic modality that they deliver: exergames [28-40], computerized CBT games [41-46], biofeedback games [47-51], attention distraction games [52-54], brain training games [55,56], social skills training games [57,58], exposure therapy games [59], and psychoeducation games [60]. The results of the included studies are shown in the following subsections based on the types of serious games.

Exergames

Exergames Versus Conventional Exercises

In total, 9 studies compared the effects of exergames with conventional exercises on the level of anxiety [28-36]. While 7 studies did not find a statistically significant difference in the anxiety levels between the groups [30-36], the 2 remaining studies showed a statistically significant difference in the anxiety level between the groups (one of them favored exergames over conventional exercises [29] while the other favored conventional exercises over exergames [28]).

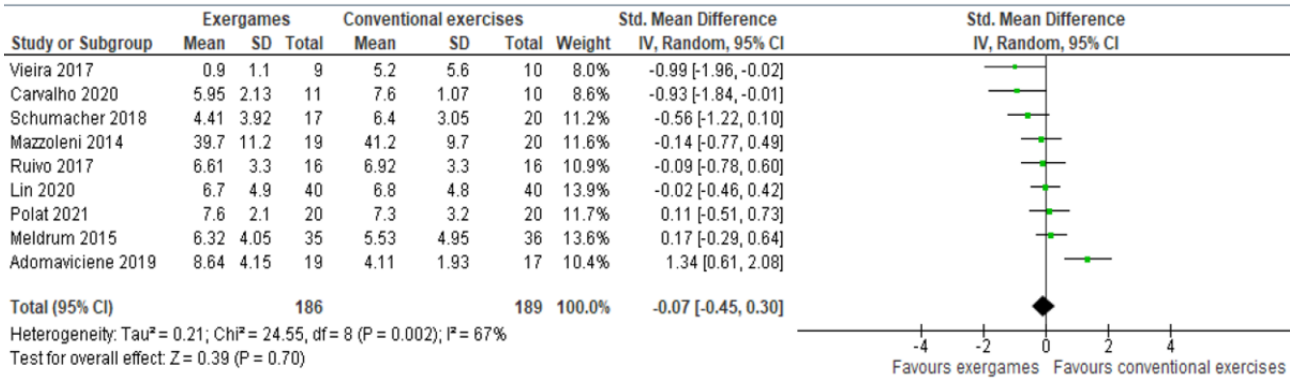
The results of the 9 studies were meta-analyzed as shown in Figure 3 [28-36]. No statistically significant difference (P=.70) in the anxiety levels was found between the exergame group and conventional exercise group (SMD −0.07, 95% CI −0.45 to 0.30). The degree of evidence heterogeneity was substantial (P=.002; I^2=67%). The quality of the evidence was very low, as it was downgraded by 6 levels because of a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

We ran a sensitivity analysis, given that some effect sizes seem to be outliers. Specifically, we removed the study conducted by Adomaviciene et al [28] for two reasons: (1) the anxiety level at baseline was statistically higher (P<.001) in the exergame group (mean 9.16, SD 4.59) than in the conventional exercise group (mean 5.52, SD 2.37) and (2) the comparator was conventional exercises guided by robotic devices, which is not the case in other studies. Although the degree of heterogeneity decreased significantly from 67% to 30% by excluding Adomaviciene et al [28], there was still no statistically significant difference (P=.18) in the anxiety levels between groups (SMD −0.18, 95% CI −0.45 to 0.08; Multimedia Appendix 6 [28-60]).

We also reran the meta-analysis after excluding another study [36] because the anxiety level at baseline was considerably higher in the conventional exercise group (mean 8.0, SD 9.1) than in the exergame group (mean 2.7, SD 2.0). Similar to the first sensitivity analysis, the degree of heterogeneity decreased significantly from 30% to 13% by excluding Vieira et al [36]; however, there was still no statistically significant difference (P=.38) in the anxiety levels between groups (SMD −0.11, 95% CI −0.35 to 0.13; Multimedia Appendix 6).

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Figure 3. Forest plot of 9 studies comparing the effect of exergames to that of conventional exercises on the anxiety level [28-36]. Std: standardized.

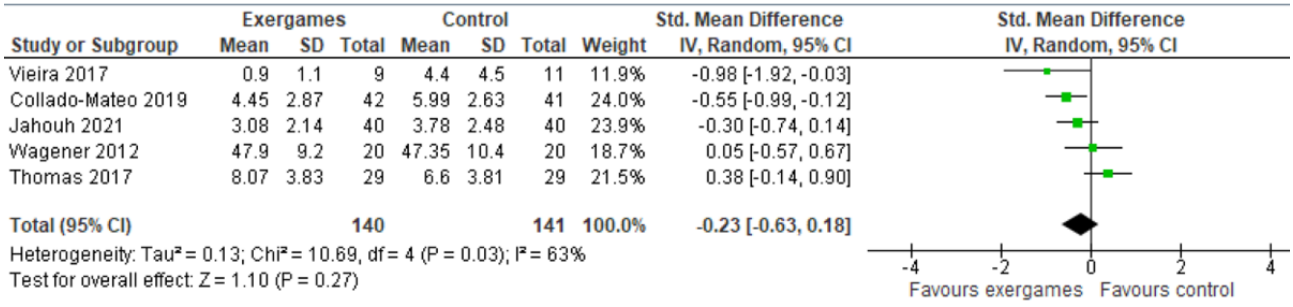


Exergames Versus No Intervention

Five studies compared the effect of exergames with no intervention or inactive intervention on anxiety levels [36-40]. Whereas 4 studies did not find a statistically significant difference in anxiety levels between the groups [36-39], the remaining study showed a statistically significant difference in the anxiety levels between the groups, favoring exergames over no intervention [40].

A meta-analysis of the results of the 5 studies showed no statistically significant difference (P=.27) in the anxiety levels between the exergame group and the no intervention group (SMD −0.23, 95% CI −0.63 to 0.18; Figure 4 [36-40]). The heterogeneity of the meta-analyzed evidence was substantial (P=.03; I^2=63%). The quality of the evidence was very low, as it was downgraded by 6 levels because of a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

Figure 4. Forest plot of 5 studies comparing the effect of exergames to that of no intervention on the anxiety level [36-40]. Std: standardized.



We ran a sensitivity analysis because some effect sizes seemed to be outliers. Specifically, we excluded a study conducted by Thomas et al [37], given that the anxiety level at baseline was statistically higher (P=.01) in the exergame group (mean 8.53, SD 3.62) than in the control group (mean 6.27, SD 3.28). The degree of heterogeneity decreased significantly from 63% to 28% when excluding the results in Thomas et al [37]. The difference in anxiety levels between the groups was statistically significant (P=.02; SMD −0.38, 95% CI −0.71 to −0.06), favoring exergames over no intervention (Multimedia Appendix 6). This difference was also clinically important as the overall effect was outside the MCID boundaries (−0.19 to +0.19) and its CI did not cross the *no-effect* line (zero effect). We also performed a sensitivity analysis after excluding another study [36] because anxiety levels at baseline were considerably higher in the control group (mean 6.9, SD 7.4) than in the exergame group (mean 2.7, SD 2.0). However, the degree of heterogeneity and total effect size did not change significantly (Multimedia Appendix 6).

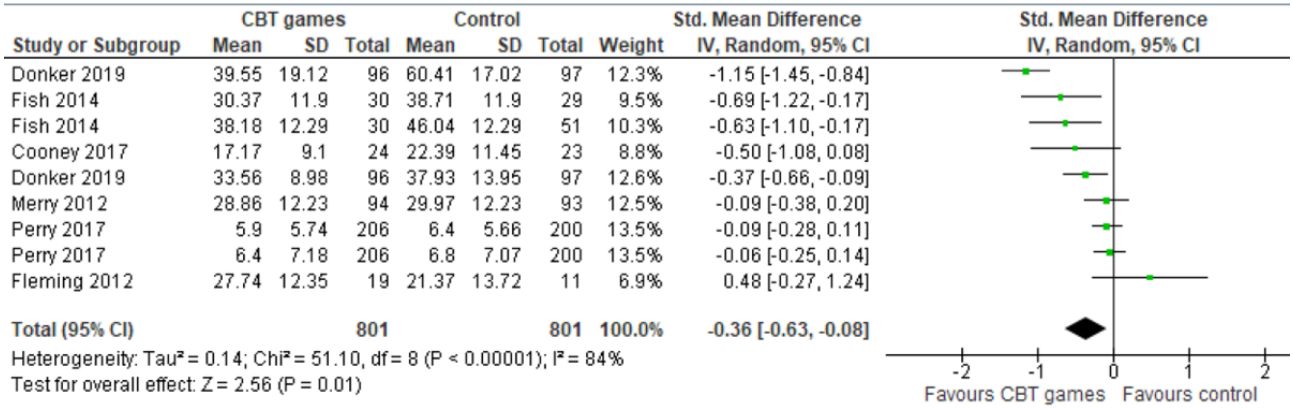
Computerized CBT Games

Six studies compared the effect of computerized CBT games with no intervention on anxiety levels [41-46]. While 3 studies did not find a statistically significant difference in anxiety levels between the groups [44-46], the 3 remaining studies showed a statistically significant difference in the anxiety levels between the groups, favoring computerized CBT games over no intervention [41-43].

The results of these 6 studies were included in the meta-analysis. Three of these studies assessed anxiety levels using 2 different measures (Acrophobia Questionnaire [AQ] and Beck Anxiety Inventory [BAI] [42], State-Trait Anxiety Inventory [STAI]–State and STAI-Trait [43], SCAS–Generalized Anxiety Disorder, and SCAS-Social Anxiety [46]). Therefore, we included the results of all these measures in the meta-analysis to form 9 comparisons (Figure 5 [41-46]). The meta-analysis showed a statistically significant difference in the anxiety levels (P=.01) between computerized CBT games and control groups, favoring computerized CBT games over no intervention (SMD −0.36, 95% CI −.63 to −0.08). This difference was also clinically important as the overall effect was outside the MCID boundaries (−0.18 to +0.18) and its CI neither crossed the *no-effect* line (zero effect) nor any of the 2 MCID boundaries. For this outcome, MCID boundaries were calculated as −0.5 to +0.5 times the SMD value (−0.36). The statistical heterogeneity of the evidence was considerable (P<.001; I^2=84%). The quality of the evidence was very low, as it was downgraded by 5 levels because of a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

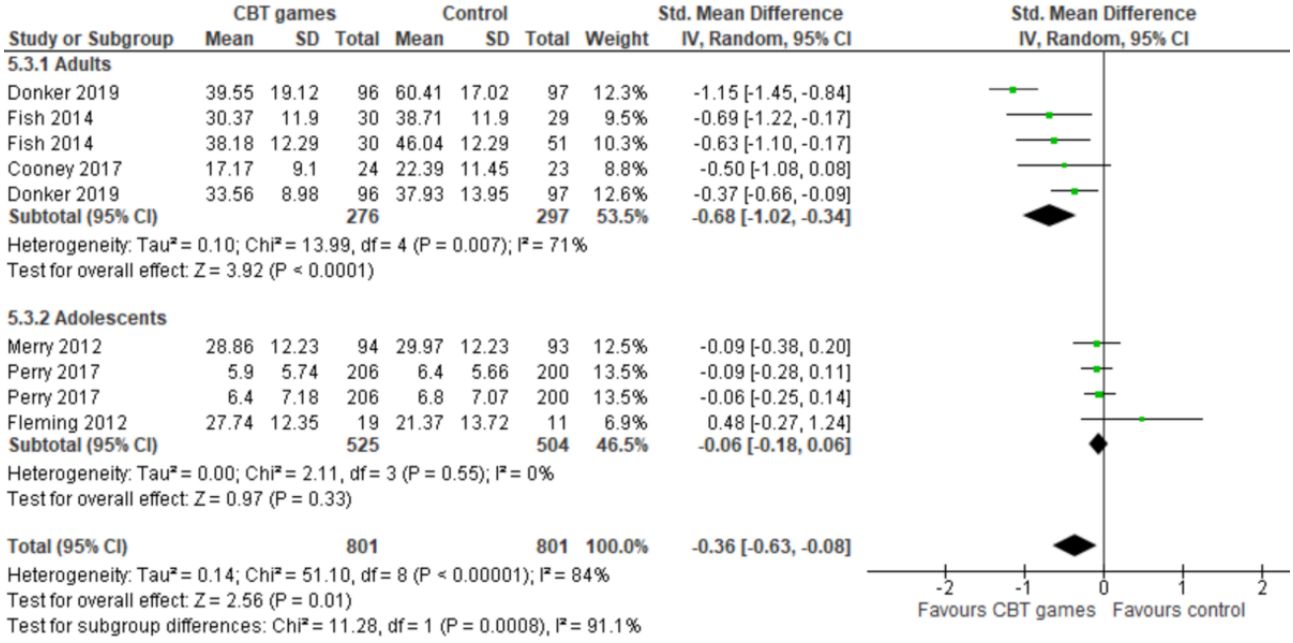
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Figure 5. Forest plot of 6 studies (9 comparisons) comparing the effect of CBT games to that of no intervention on the severity of depressive symptoms [41-46]. CBT: cognitive behavioral therapy; Std: standardized.



It is noteworthy that 3 of the 6 studies in the group targeted adults [41-43] while the reminders targeted adolescents [44-46]. Therefore, we conducted a subgroup analysis to assess whether the effect of computerized CBT differs between adults and adolescents. The subgroup analysis showed that the effect of computerized CBT on anxiety was statistically different (P<.001) between adults and adolescents (Figure 6 [41-46]). Specifically, while there was no statistically significant difference (P=.33) in the anxiety levels between the exergame group and the no intervention group among adolescents (SMD −0.06, 95% CI −0.18 to 0.06), there was a statistically significant difference in the anxiety levels (P<.001) between computerized CBT games and control groups among adults (favoring computerized CBT games over no intervention [SMD −0.68, 95% CI −1.02 to −0.34]). The statistically significant difference among adults was also clinically important as the overall effect was outside the MCID boundaries (−0.34 to +0.34) and its CI neither crossed the *no-effect* line (Zero effect) nor any of the 2 MCID boundaries. For this outcome, MCID boundaries were calculated as −0.5 to +0.5 times the SMD value (−0.68). The statistical heterogeneity of the evidence was substantial (P=.007; I^2=71%). The quality of the evidence was very low, as it was downgraded by 4 levels because of a high risk of bias and heterogeneity (Multimedia Appendix 5).

Figure 6. Forest plot of 6 studies (9 comparisons) comparing the effect of CBT games to that of no intervention on the anxiety level among adults and adolescents [41-46]. CBT: cognitive behavioral therapy; Std: standardized.



Donker et al [42] used two different questionnaires to assess anxiety levels: BAI and AQ-anxiety. The BAI is used to measure general anxiety symptoms while AQ-anxiety measures a specific type of anxiety, which is height-related anxiety [61]. We performed a sensitivity analysis by excluding the AQ-related results reported by Donker et al [61] because all studies in the meta-analysis assessed general anxiety symptoms. The sensitivity analysis showed a significant decrease in the degree of heterogeneity (from 84% to 56%), and the difference in anxiety levels between the groups remained statistically significant (P=.01; SMD −0.23, 95% CI −0.41 to −0.05), favoring computerized CBT games over no intervention (Multimedia Appendix 6). This difference remained clinically important as the overall effect was outside the MCID boundaries (−0.12 to +0.12) and its CI did not cross the *no-effect* line (zero effect). We also performed a sensitivity analysis after excluding

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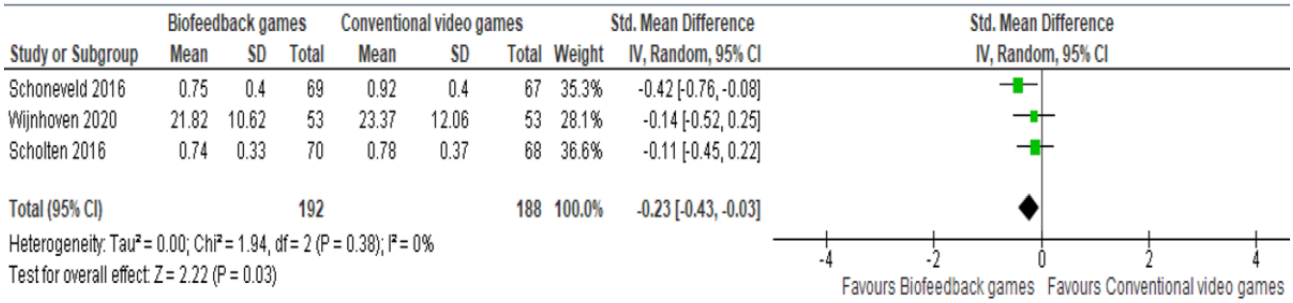
another study [44] because its sample size (n=30) was relatively small compared with other studies. However, the degree of heterogeneity and total effect size did not change significantly (Multimedia Appendix 6).

Biofeedback Games

Biofeedback games were used as interventions in 5 studies [47-51]. Two studies examined the effect of a biofeedback game (MindLight) and conventional CBT on anxiety levels (measured by the SCAS) among children with anxiety [47,48]. Both studies found no statistically significant difference in anxiety levels between the biofeedback game group and the conventional CBT group [47,48].

The 3 remaining studies examined the effect of biofeedback games and conventional video games on anxiety levels (measured by the SCAS) among children with anxiety [49-51]. While 2 studies did not find a statistically significant difference in anxiety levels between the groups [50,51], the remaining study showed a statistically significant difference in the anxiety level between the groups, favoring biofeedback games over conventional video games [49]. A meta-analysis of the results of these 3 studies demonstrated a statistically significant difference in the anxiety levels (P=.03) between the biofeedback game group and conventional CBT group, favoring biofeedback games over conventional video games (SMD −0.23, 95% CI −0.43 to −0.03; Figure 7 [49-51]). This difference was also clinically important as the overall effect was outside the MCID boundaries (−0.115 to +0.115) and its CI neither crossed the *no-effect* line (zero effect) nor any of the 2 MCID boundaries. For this outcome, MCID boundaries were calculated as −0.5 to +0.5 times the SMD value (−0.23). The heterogeneity of the evidence was considered insignificant (P=.38; I^2=0%). The quality of the evidence was low, as it was downgraded by 2 levels because of a high risk of bias and imprecision.

Figure 7. Forest plot of 3 studies comparing the effect of biofeedback games to that of conventional video games on the anxiety level [49-51]. Std: standardized.



Attention Distraction Games

Distraction games were used as interventions in 3 studies. Attention distraction games were interventions in 3 studies [52-54]. While 2 studies found a statistically significant effect of attention distraction games [53,54], the remaining study did not [52]. Specifically, Marechal et al [52] compared the effect of attention distraction games with medication (ie, midazolam) on anxiety levels (measured by the Modified Yale Preoperative Anxiety Scale) among children undergoing general anesthesia for minor surgical procedures. No statistically significant difference (P=.99) in anxiety levels was detected between the 2 groups [52]. The second study examined the effect of attention distraction games (Angry Birds, Subway Surfers, or Snail Bob), medication (midazolam), and watching an informative cartoon on the anxiety level (measured by the Modified Yale Preoperative Anxiety Scale) among children undergoing adenoidectomy, adenotonsillectomy, or myringotomy [53]. The study showed a statistically significant difference (P<.001) in the anxiety level between the groups, favoring the attention distraction games over medication (midazolam) and watching an informative cartoon. In the third study [54], the effect of an attention distraction game (SpaceBurgers) on anxiety levels (measured by Subjective Units of Distress) among children with otolaryngological issues was compared with topical analgesia. The study found a statistically significant difference (P<.001) in the anxiety levels between the groups, favoring attention distraction games over topical analgesia [54].

Brain Training Games

Brain training games were interventions in 2 studies [55,56]. The first study compared the effect of a brain training game (Tetris) to eye movement desensitization and reprocessing therapy on the levels of trait anxiety (measured by STAI) among patients with posttraumatic stress disorder [55]. The study did not detect any statistically significant difference (P=.81) in the level of trait anxiety postintervention [55]. The second study compared the effects of a brain training game (Band Together) and traditional video games on the level of anxiety (measured by STAI) in patients with multiple sclerosis [56]. No statistically significant difference in the levels of state anxiety (P=.95) and trait anxiety (P=.75) between the 2 groups was detected.

Social Skills Training Games

Social skills training games were an intervention in 2 studies [57,58]. The first study investigated the effect of a social skills training game (Adventures) on the anxiety level (measured by the Social Anxiety Scale for Children-Revised) among patients with social skills deficits in comparison with no intervention. The study showed no statistically significant difference (P=.10) in anxiety levels between the groups. In the second study, the effect of a social skills training game (Pegasys-Virtual Reality) and social effectiveness therapy on the anxiety level (measured by Social Phobia and Anxiety Inventory for Children) among children with social anxiety were examined. The study demonstrated no statistically significant difference (P=.23) in anxiety levels between the groups.

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Other Types of Serious Games

One study compared the effect of an exposure therapy game (Spider App) to an entertainment video game (Bubble Shooter) on anxiety levels among patients with arachnophobia [59]. No statistically significant difference in anxiety level was detected between the groups postintervention [59].

Litvin et al [60] examined the effect of a psychoeducation game (eQuoo), conventional CBT, and no intervention on anxiety levels among healthy employees. The study did not find any statistically significant difference (*P*=.95) in anxiety levels between the 3 groups [60].

Discussion

Principal Findings

This review examined the effectiveness of serious games on anxiety levels, as reported by RCTs. Of the 33 RCTs included in the current review, 20 were included in 4 main meta-analyses. The review found no statistically significant effect of exergames on anxiety levels, though it showed a statistically significant effect of computerized CBT games and biofeedback games on anxiety levels. Owing to the paucity of evidence, no statistical analysis was carried out for other types of serious games included in this review.

Very low–quality evidence from 9 RCTs showed no statistically significant effect of exergames on anxiety levels as compared with conventional exercises. This insignificant effect can be attributed to the fact that exergames are comparable with conventional exercises; therefore, it should not be surprising that comparing the effect of 2 very similar interventions did not produce a significant difference. This indicates that conventional exercises are at least as effective as conventional exercises. Our findings are similar to those of previous reviews [16,62]. Specifically, a meta-analysis of 5 RCTs showed no statistically significant difference (*P*=.81) in anxiety levels between the exergames group and the usual care group (ie, conventional exercises) [16]. Similarly, no statistically significant difference (*P*=.12) in *depression* levels between the exergames group and conventional exercises was found in another meta-analysis of 7 RCTs [62].

Very low–quality evidence from 5 RCTs showed no statistically significant effect when compared with the effects of exergames on anxiety levels as opposed to no intervention. However, a sensitivity analysis of 4 RCTs showed a statistically and clinically significant effect of exergames on anxiety level when compared with no intervention.

This finding is consistent with that of a previous review [16,62]. Specifically, a meta-analysis of 8 studies showed a statistically significant difference (*P*=.004) in *depression* levels between the exergames group and the control group. In contrast, exergames have a statistically and clinically significant effect on *depression* levels when compared with no intervention, according to a meta-analysis of 8 studies [62].

Very low–quality evidence from 6 RCTs demonstrated a statistically and clinically significant effect of computerized CBT games on anxiety levels when compared with no intervention. A subgroup analysis showed that the effect of computerized CBT on anxiety was significantly higher among adults than among adolescents. However, this finding may not be generalizable to older adults as participants in all the 6 studies were, on average, ≤41.3 years. To the best of our knowledge, no previous reviews have examined the effect of computerized CBT games on anxiety, although many reviews have assessed the effect of computerized CBT in general (ie, games are not part of the intervention) [63-66]. However, our findings are in line with a previous review focusing on depression, which found a statistically and clinically significant effect of computerized CBT games on depression level according to a meta-analysis of 6 RCTs.

Low-quality evidence from 3 RCTs showed a statistically and clinically significant effect of biofeedback games on anxiety levels when compared with conventional video games. It is worth mentioning that the studies used biofeedback games specifically for alleviating anxiety and recruited participants with anxiety. The generalizability of this finding may be limited because of the following reasons: (1) participants in the 3 studies were adolescents (10-13.3 years), (2) all studies were conducted in the Netherlands, and (3) there was a small number of studies included in the meta-analysis.

Meta-analyses were not conducted to assess the effect of other types of serious games because of the small number of studies. Individual studies found no statistically significant effect of brain training games, social skills training games, exposure therapy games, and psychoeducation games on anxiety levels. However, other studies have shown contradictory results regarding the effects of attention distraction games on anxiety levels.

Strengths and Limitations

Strengths

This review can be considered more comprehensive than the 2 previous reviews [16,17] because it was not restricted to a certain type of serious games, age group, or comparator, and it searched the main databases in health and information technology fields. This review was conducted according to highly recommended guidelines (ie, PRISMA) and included only RCTs. Therefore, it can be considered a robust and high-quality review.

The risk of publication bias is not a concern in this review because we sought to retrieve as many relevant studies as possible by searching the most popular databases in information technology, health fields, and gray literature databases, conducting backward and forward reference list checking, using a comprehensive search query, and not restricting our search to a certain country, year, setting, population, and comparator.

There is no concern about the risk of selection bias in this review, given that 2 reviewers independently performed the study selection, data extraction, risk of bias assessment, and quality of evidence evaluation with a perfect interrater agreement for all processes. The quality of the evidence was appraised using the GRADE approach to enable the reader to draw more accurate conclusions. When possible, we synthesized data statistically, which improved the power of the studies and

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increased the estimates of the likely size of the effect of serious games on anxiety.

Limitations

This review excluded studies that used serious games delivered on nondigital platforms and those used for other purposes (eg, screening or diagnosis). Therefore, this review cannot comment on the effectiveness of these types of serious games. This review focused on the effectiveness of serious games on anxiety only; thus, we cannot comment on the effectiveness of serious games on other diseases.

Numerous studies were excluded as they were quasi-experiments and written in languages other than English. Therefore, it is likely that we missed relevant studies. We excluded these studies because quasi-experiments have lower internal validity than RCTs [67] and, owing to practical constraints, it was not possible to translate all non-English studies. Participants in most studies did not have anxiety before the intervention; therefore, the effect of serious games could not be significant.

This review meta-analyzed postintervention data rather than follow-up data; thus, this review cannot comment on the long-term effects of serious games on anxiety. Postintervention outcome data were selected given that about half of the included studies (16/33, 48.5%) did not follow-up with participants to measure the outcome data, and the follow-up period in the other half of the studies (17/33, 51.5%) was not consistent between studies.

We used postintervention data for each group to assess the effect size for each meta-analyzed study rather than the pre–post intervention change for each group; therefore, it is likely that the effect size is overestimated or underestimated. We used postintervention outcome data because most studies did not report the SD for pre- or postintervention change for each group, and preintervention outcome data were significantly different between groups in only 2 studies [36,37].

Research and Practical Implications

Research Implications

Although anxiety was one of the measured outcomes in all the included studies, only 6 studies targeted the recruitment of people experiencing anxiety. This may lead to a severe underestimation of the effect of serious games on anxiety levels. This finding is consistent with a similar study that investigated the effects of depression [62]. Similarly, we recommend purposefully recruiting participants who have anxiety and establishing a baseline to objectively assess the effectiveness of serious games in reducing anxiety levels.

We would like to point out that several studies recruited very small samples, with a minimum of only 30 patients. Gaining statistically reliable insights from such small samples can be difficult and may be an additional reason why our meta-analyses provide no conclusive answer to the question of whether serious games can improve or augment traditional anxiety treatment. Thus, we encourage researchers to recruit a sample size that is sufficient to achieve a power of at least 80%.

Most of the included studies were conducted in a clinical setting. Although this could offer a controlled environment to run the studies, it could also introduce stress to the participants because of the nature of such a setting. Conducting more studies in the community and educational settings could present different findings as people usually play games outside of the traditional clinical setting.

The current literature focused mainly on exergames and computerized CBT games, while the effect of other types of serious games was investigated in only a few studies. There are opportunities to enrich the body of evidence on the effectiveness of serious games delivered through other therapeutic modalities such as psychoeducation games, biofeedback games, exposure therapy games, and brain training games.

Although serious games can be used for several purposes and many diseases, we focused on serious games that were used for therapeutic or prevention purposes and anxiety only. Researchers should conduct systematic reviews to assess the effectiveness of serious games used for other purposes (eg, monitoring, screening, and diagnosing) and for other diseases.

In only 2 studies, the overall risk of bias was low given that most studies had issues in the randomization process, measurement of the outcome, and selection of the reported result. Outcome data were missing from several studies; therefore, they were not included in the meta-analyses. Accordingly, researchers should avoid the abovementioned biases by conducting and reporting RCTs according to recommended guidelines or tools (eg, RoB 2 [25]).

Finally, most of the included studies were conducted in high-income countries, which, in turn, can limit the generalizability of our findings to low-income nations. There is a need to conduct more studies in low-income countries, especially given the varying nature of their cultures, socioeconomic conditions, and sources of stress and anxiety (eg, overpopulated cities, poor socioeconomic areas, and refugee camps). Furthermore, more studies are needed to determine any variance in the effectiveness of serious games that are designed specifically to reduce and alleviate anxiety levels intergenerationally.

Practical Implications

This review showed that exergames are as effective as conventional exercises in alleviating anxiety and that computerized CBT games and biofeedback games are more effective than no intervention and conventional video games, respectively. However, health professionals and decision-makers should be careful when interpreting these findings for the following reasons: the quality of meta-analyzed evidence ranged from very low to low, the overall risk of bias was high in most of the included studies, the heterogeneity of the evidence was high in the 3 meta-analyses, participants in most studies did not have anxiety, and many studies did not use serious games that were designed specifically to alleviate anxiety. Accordingly, psychologists and psychiatrists should consider offering serious games as complementary and not a substitute for existing interventions until further, more robust evidence is available.

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Although anxiety can be alleviated by many nonpharmacological interventions, there are no or few serious games that deliver nonpharmacological interventions other than exercises and CBT in this review. This may be attributed to the lack of such serious games in real life. Therefore, developers should consider developing serious games that deliver nonpharmacological interventions such as breathing techniques, mindfulness training, problem-solving, attention distraction, biofeedback, psychoeducation, relaxation-based exercises, and rational emotive behavioral therapy.

Only a handful (n=7) of studies used mobile devices (smartphones and tablets) as the platform for their intervention. Mobile devices are particularly appealing because they are cheaper than computers and more pervasive than gaming consoles. Moreover, mobile devices are more accessible than computers and gaming consoles; it is estimated that there are approximately 15 billion mobile devices and more than 7.1 mobile users worldwide in 2021 [68]. This could present a lucrative opportunity for app and game developers to develop serious games that target anxiety and can be played via mobile devices.

Few studies have been conducted in developing countries, and this may be attributed to the lack of serious games in these countries. Given that there is a greater shortage of mental health professionals in developing countries than in developed countries (0.1 per 1 million people [69] versus 90 per 1 million people [70]), it is likely that individuals in developing countries are more in need of serious games than those in developed countries. Therefore, more serious games should be developed to alleviate anxiety among people in developing countries.

We would like to point out that a significant portion of the studies (n=12) investigated intervention methods using now-discontinued platforms: Wii (n=8, end of life in 2017), Kinect (n=5, end of life in 2017), and Nintendo DS (n=1, end of life in 2014). Only in one case, other platforms will readily fill the gap in only one case (using Tetris [52]). For interventions using Microsoft's Kinect sensor, computer vision–based pose estimation on mobile phones or desktop PCs could fill the gap but will result in a different setup. Finally, some of the included studies using Wiimote (Wii Remote) and none of the more specialized Wii input devices could be recreated using newer Nintendo controllers. These considerations raise a few questions of practical importance: (1) How well can studies relying on legacy and specialized hardware be reproduced? (2) How useful are interventions that rely on platforms designed to undergo comparatively short life cycles? (3) Are off-the-shelf video games (purpose-shifted games) adequate intervention tools?

We believe that some of the included studies relying on legacy hardware could probably be salvaged, following the comments outlined above, but caution should be taken to fall victim to the novelty effect of emerging game controllers and proprietary input devices. The video game industry evolves quickly and is known to experiment with novel technology to spirit gamers away from competitors. Consequently, purpose-shifted games are not only very prone to depreciate quickly, but the same is true for the platforms they were designed for. We believe that researchers in this space should best assume the role of game designers, who focus on the game mechanics and purpose. In the second step, researchers are probably best advised to seek the help of a professional software development company to bring out the product in a timely fashion.

In addition, although we cannot rule out that off-the-shelf games that have undergone, first, a purpose-shift to become a serious game and yet another one to become part of a therapy (eg, Tetris) have a measurable effect, we also have little reason to assume that they do. It seems tempting to explain the effects of serious games on anxiety by their distractive nature, but studies do not agree with this question.

There is also an urgent need for an inclusive approach when developing these apps and games to include professionals from the gaming industry as well as mental health experts. Technologists and developers are usually very aware of the aforementioned concerns but need medical professionals to avoid falling prey to the temptation of purpose-shifting existing games or designing games for goals that are different from anxiety relief.

Conclusions

Evidence from this study suggests that serious games have the potential to reduce anxiety levels. Specifically, exergames can be as effective as conventional exercises in alleviating anxiety; computerized CBT games and exergames can be more effective than no intervention, and biofeedback games can be more effective than conventional video games. However, definitive conclusions regarding the effectiveness of serious games in reducing anxiety remain inconclusive, mainly because of the high risk of bias in the individual studies included, the low quality of meta-analyzed evidence, the low number of studies included in some meta-analyses, participants without anxiety in most studies, and using purpose-shifted serious games in most studies. Until further, more robust evidence is available, serious games should be deemed as complementary to existing interventions and not as a substitute for them. To obtain adequate and robust evidence, researchers should use serious games specifically designed to alleviate depression and deliver other therapeutic modalities, recruit patients with anxiety, and minimize the risk of bias by recommended guidelines for conducting and reporting RCTs (eg, RoB 2).

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.

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[DOCX File , 26 KB - games_v10i1e29137_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 24 KB - games_v10i1e29137_app2.docx]

Multimedia Appendix 3
Data extraction form.
[DOCX File , 19 KB - games_v10i1e29137_app3.docx]

Multimedia Appendix 4
Reviewers' judgments about each risk of bias domain for each included study.
[DOCX File , 47 KB - games_v10i1e29137_app4.docx]

Multimedia Appendix 5
Grading of Recommendations Assessment, Development, and Evaluation profile for the comparison of serious games to control or conventional exercises for anxiety.
[DOCX File , 17 KB - games_v10i1e29137_app5.docx]

Multimedia Appendix 6
Sensitivity analyses.
[DOCX File , 76 KB - games_v10i1e29137_app6.docx]

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Abbreviations

AQ: Acrophobia Questionnaire
BAI: Beck Anxiety Inventory
CBT: cognitive behavioral therapy
GRADE: Grading of Recommendations Assessment, Development, and Evaluation
MCID: minimal clinically important difference
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: International Prospective Register of Systematic Reviews
RCT: randomized controlled trial
RoB 2: Risk-of-Bias 2
SCAS: Spence Children's Anxiety Scale
SMD: standardized mean difference
STAI: State-Trait Anxiety Inventory

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Review

The Effectiveness of Virtual Reality–Based Interventions in Rehabilitation Management of Breast Cancer Survivors: Systematic Review and Meta-analysis

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Abstract

Background: Breast cancer survivors (BCSs) can present with various physical and psychological symptoms and functional deficits that impact their quality of life. Virtual reality (VR) technology is being used in breast cancer rehabilitation management to improve the emotional, cognitive, and physical well-being of BCSs.

Objective: This systematic review aimed to examine the effectiveness of VR-based interventions on health-related outcomes in BCSs. A meta-analysis was conducted to evaluate the effectiveness of VR-based interventions in the rehabilitation management of BCSs.

Methods: A systematic search was conducted on PubMed, Web of Science, EMBASE, CINAHL with Full Text, the Cochrane Central Register of Controlled Trials, CNKI, WanFang, VIP, and CBM, from inception to May 25, 2021. The inclusion criteria of the selected studies were as follows: (1) adults diagnosed with breast cancer; (2) any type of VR-based interventions (immersive and nonimmersive virtual environment); (3) comparison of traditional rehabilitation methods; (4) outcomes including pain, depression, anxiety, fatigue, cognitive function, shoulder range of motion (ROM), hand grip strength, lymphedema, cybersickness symptoms, fear of movement, bleeding, effusion, and flap necrosis, both during and after treatment; and (5) randomized controlled trials (RCTs), case-controlled trials, and quasi-experimental studies. The Cochrane Collaboration Tool was used to evaluate the risk of bias. Review Manager version 5.3 (Cochrane Collaboration) was used to conduct the meta-analysis. The mean difference (MD) and SDs with 95% CIs were used to calculate continuous variables.

Results: Twelve articles were included in this systematic review, of which 10 contributed information to the meta-analysis. A total of 604 participants were analyzed. The statistical analysis showed significant results for flexion (standard mean difference [SMD] 1.79; 95% CI 0.55 to 3.03; *P*=.005), extension (SMD 1.54; 95% CI 0.83 to 2.25; *P*<.001), abduction (MD 17.53; 95% CI 14.33 to 20.72; *P*<.001), adduction (MD 15.98; 95% CI 14.02 to 17.94; *P*<.001), internal rotation (MD 7.12; 95% CI 5.54 to 8.70; *P*<.001), external rotation (SMD 0.96; 95% CI 0.62 to 1.29; *P*<.001), anxiety (MD −6.47; 95% CI −7.21 to −5.73; *P*<.001), depression (MD −4.27; 95% CI −4.64 to −3.91; *P*<.001), pain (MD −1.32; 95% CI −2.56 to −0.09; *P*=.04), and cognitive function

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(MD 8.80; 95% CI 8.24 to 9.36; *P*<.001). The meta-analysis indicated little to no difference in hand grip strength (MD 1.96; 95% CI –0.93 to 4.85; *P*=.18).

Conclusions: Findings of this review noted a weak but consistent positive association between VR-based interventions and outcomes. However, these results must be interpreted with caution due to the limited number of controlled trials analyzed, small sample sizes, and poor methodological quality. Well - designed, large, high - quality trials may have a significant impact on our confidence in the results. Future studies should identify specific aspects that improve the clinical impact of VR-based interventions on major outcomes in BCSs in the clinical setting.

Trial Registration: PROSPERO International Prospective Register of Systematic Reviews CRD42021250727; https://tinyurl.com/2p89rmnk

(JMIR Serious Games 2022;10(1):e31395) doi:10.2196/31395

KEYWORDS

virtual reality; rehabilitation management; symptom; motor function; systematic review; meta-analysis

Introduction

Female breast cancer has surpassed lung cancer as the most commonly diagnosed cancer worldwide, with an estimated 2.3 million new cases in 2020 [1]. The 5-year relative survival rate for individuals with breast cancer is 82% [2]. An increasing number of patients with breast cancer have prolonged life following treatment; however, they can suffer from numerous physical and psychological symptoms (ie, pain, fatigue, depressive symptoms, anxiety, lymphedema), functional deficits (ie, cognitive impairment, reduced shoulder range of motion [ROM]), and complications (ie, bleeding, effusion, flap necrosis) during and after treatment, which can greatly affect their quality of life [3-5].

While chemotherapy improves the survival rate of patients with cancer, the potential adverse effects of chemotherapy limit the dose and treatment continuation. To some extent, adverse effects can aggravate patients' emotional distress. Emotional distress mainly includes fatigue, pain, anxiety, and depression, which is commonplace in cancer populations [6]. Distress was designated as the sixth vital sign in 2005 in Canada [7] associated with a reduction in overall quality of life among patients with cancer [8]. Cancer-related fatigue is also distressing, persistent, and related to a subjective sense of physical, emotional, or cognitive tiredness or exhaustion related to cancer or cancer treatment, which is not proportional to recent activity and interferes with general functioning [9]. The level of cancer-related fatigue peaks during breast cancer therapy, and the prevalence of chronic fatigue increases after treatment [10]. The prevalence rates of severe fatigue range from 7% to 52%, with a pooled prevalence of 26.9%. Risk factors of fatigue were higher disease stages, chemotherapy, and receiving the combination of surgery, radiotherapy, and chemotherapy, both with and without hormone therapy [11]. Patients with anemia are prone to fatigue owning to the reduced hemoglobin level after chemotherapy [12]. The prevalence of depression symptoms varies from 9.4% to 66.1%, whereas that of anxiety ranges from 17.9% to 33.3% [13]. Age, place of residence, marital status, educational level, religion, stage of cancer, and current activity burden of symptoms were found to be factors associated with the risk of anxiety and depression [8]. Anxiety did not show greater prevalence among women with early stage breast cancer in comparison to the general female population [13]. Breast cancer survivors (BCSs) have been shown to have an increased risk of depression 1 year after diagnosis, which decreases over the ensuing years [13]. Early interventions can improve treatment tolerance, which could be crucial to increase the chances of recovery [14]. Virtual reality (VR) is the use of computer technology to create an interactive 3D world by visual, audio, and touch simulation, where an individual has a sense of spatial presence. VR could be a promising strategy to improve chemotherapy tolerance by distraction. VR can include immersive or nonimmersive systems. With full immersive systems, the patient is enveloped in a computer-generated virtual world by using a head-mounted display and has opportunities to interact with and control the virtual environment (eg, relaxing landscapes, deep sea diving, the weather, plants/trees, or flowers) [15-17]. With nonimmersive systems, the patient is connected to the virtual world (eg, emotional parks and walk through nature) by an external monitor but can still communicate with the real world [18]. Nonimmersive system is intuitive and easy to use [18].

Pain related to cancer is a distressing experience, with sensory, emotional, cognitive, and social components [19,20]. The prevalence of persistent postsurgical pain in BCSs ranges from 2% to 78% [21]. Fear of movement further increases the risk of decline in upper limb function in BCSs [22]. However, avoiding movements that are likely to induce pain may aggravate upper limb dysfunction. VR exposure can target cognitive and affective pain pathways [23] and can decrease pain intensity, distress, and anxiety by altering how pain signals are processed in the central nervous system [23]. This is achieved by a series of mechanisms, including attentional distraction, conditioning of VR imagery, and reduced pain [23].

BCSs are at a lifelong risk for the development of breast cancer–related lymphedema (BCRL) [24], which has an incidence of 21.4% [25]. There is strong evidence that higher BMI, larger number of dissected nodes, certain chemotherapy agents (eg, taxane-based regimen), the extent of surgery (eg, total mastectomy), larger irradiation field, and sedentary lifestyles are associated with BCRL [25-27]. Disruption of the lymphatic system after surgery or radiation treatment results in the accumulation of lymph fluid causing BCRL [28]. BCRL is a chronic, potentially debilitating condition that involves progressive swelling, limited ROM, and feelings of pain and numbness, and requires lifelong symptom management [24].

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Resistance exercise ameliorates symptoms in patients with established lymphedema [29]. VR-based rehabilitation systems (eg, Xbox 360 Kinect games, the BrightArm Duo Rehabilitation System) have been identified to be effective for patients with weak arms and diminished grasping ability [22,30]. These systems use VR to engage the patient in upper body bimanual exercises. Moreover, the BrightArm Duo Rehabilitation System simultaneously provides cognitive training and affective relief via custom integrative rehabilitation games. Cancer-related cognitive impairment is characterized as deficits in areas of cognition, including memory, attention, information processing speed, and executive function [31,32]. Between 15% and 50% of individuals with breast cancer who receive chemotherapy experience persisting cognitive impairment [33], often referred to as "chemobrain" [34]. The duration of symptoms may extend for years after the completion of treatment [31]. The rapid development of VR promotes the combination of functional rehabilitation and cognitive exercises at a higher level, where patients can receive bimanual and cognitive exercises simultaneously.

However, it is unclear whether VR-based interventions could promote the rehabilitation management of BCSs. Additionally, until now, no systematic reviews or meta-analyses have investigated the association between VR and rehabilitation management of BCSs. Therefore, in this systematic review and meta-analysis, we will qualitatively and quantitatively examine the effects of VR-based interventions on BCSs.

Methods

Overview and Registration

This systematic review conforms to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [35] and was registered in advance in the international Prospective Register of Systematic Reviews (PROSPERO) database (registration number CRD42021250727).

Search Strategy

The literature search was conducted on PubMed, Web of Science, EMBASE, CINAHL with Full Text, the Cochrane Central Register of Controlled Trials, CNKI, WanFang, VIP, and CBM, from inception to May 25, 2021. The search terms were chosen to be inclusive of VR (eg, "virtual reality", "VR", "virtual environment") and breast cancer (eg, "breast neoplasm" OR "breast tumors"). Medical Subject Headings (MeSH) and Embase Subject Headings terms were used. See Multimedia Appendix 1 for the specific search strategy adapted for each database. Details of the search strings of the PubMed database are displayed in Table 1. Searches were limited to English and Chinese language sources.

Table 1. Search strategy in PubMed.

Strategy	Search string
1	"Virtual Reality"[Mesh] OR VR OR "virtual reality" OR "virtual environment" OR "head-mounted display" OR "virtual reality goggle"
2	"Breast Neoplasms"[Mesh] OR "breast neoplasms" OR "breast neoplasm" OR "breast tumors" OR "breast tumor" OR "breast cancer" OR "mammary cancer" OR "mammary cancers" OR "Breast Malignant Neoplasm" OR "Breast Malignant Neoplasms" OR "Malignant Tumor of Breast" OR "Breast Malignant Tumor" OR "Breast Malignant Tumors" OR "Cancer of Breast" OR "Cancer of the Breast" OR "Mammary Carcinoma" OR "Human Mammary Carcinomas" OR "Human Mammary Carcinoma" OR "Mammary Neoplasms" OR "Human Mammary Neoplasm" OR "Human Mammary Neoplasms" OR "Mammary Neoplasm" OR "Breast Carcinoma" OR "Breast Carcinomas"
3	#1 AND #2

Selection Criteria

The Population, Intervention, Comparison, Outcomes, and Study design (PICOS) model was used to establish the article inclusion criteria:

- *Population:* adults diagnosed with breast cancer;
- *Intervention:* any type of VR-based interventions (immersive and nonimmersive virtual environment);
- *Comparison:* traditional rehabilitation methods (including interventions under the guidance of medical staff or watching videos) or nonintervention;
- *Outcomes:* outcomes specifically related to rehabilitation management, such as pain, depression, anxiety, fatigue, cognitive function, shoulder ROM, hand grip strength, lymphedema, cybersickness symptoms, fear of movement, bleeding, effusion, and flap necrosis after surgery; and
- *Study design:* randomized controlled trials (RCTs), case-controlled trials, and quasi-experimental studies.

Studies were excluded if they (1) did not specify the type of cancer; (2) described the technologies only; (3) were conference papers, workshop papers, literature reviews, posters, comments, letters, study protocols, or proceedings papers.

Selection Process

Records from searches were imported into an EndNote library (EndNote X9.1) and duplicate studies were removed. The remaining records were transferred into an Excel spreadsheet (Microsoft). Screening was conducted by 2 independent reviewers (XB and WX) who assessed the article titles, abstracts, and full texts. Articles that did not meet the established inclusion criteria were excluded. Any disagreements between the 2 reviewers were resolved by discussion or in consultation with other investigators (QC, AC, and XL).

Data Extraction

Data extraction was performed independently by 2 reviewers (XB and WX) using a predesigned standardized form in Word (Microsoft). Any discrepancies between the 2 reviewers were resolved by discussion with other reviewers (QC, AC, and XL), who acted as arbiters where necessary. We removed duplicate data published in different manuscripts. Additionally, the authors of the included trials were contacted to obtain any unclear or

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missing data. Data extraction included study characteristics (the first author, study design, and study region), participant characteristics (sample size, age), intervention details (characteristics of interventions, duration), patient-important outcomes, measuring instrument, and main results.

Risk of Bias Assessment

Two reviewers (XB and WX) independently assessed the methodological quality of all included trials. The Cochrane risk-of-bias tool was used to assess the quality of included RCTs [36]. The Cochrane risk-of-bias tool includes 6 domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. After assessing the risk of bias of each study, the studies were categorized as "low risk," "high risk," or "unclear risk." The Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) was used to assess the quality of the included non-RCTs, covering 7 distinct domains: bias due to confounding, selection bias, bias in measurement classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in the measurement of outcomes, and bias in the selection of the reported result [37]. The ROBINS-I is a new tool for evaluating the risk of bias in estimates of the comparative effectiveness (harm or benefit) of interventions from studies that do not use randomization to allocate units (individuals or clusters of individuals) to comparison groups [37]. After assessing the risk of bias of each study, the studies were categorized as "low risk of bias," "moderate risk of bias," "serious risk of bias," "critical risk of bias," or "no information." In case of doubt, the final decision was determined through discussion or consultation with other reviewers (QC, AC, and XL).

Meta-analysis

The meta-analysis compared VR interventions with other interventions or nonintervention. The studies were divided into subgroups based on the measuring instrument that was used in the study. If more than 1 instrument was used in the same study, we included the study in more than 1 subgroup. The differences in the effect size between the groups were analyzed in terms of the standardized mean difference (SMD). Review Manager version 5.3 (Cochrane Collaboration) was used to conduct a meta-analysis. The mean difference (MD) and SDs with 95% CIs were used to calculate continuous variables. Initially, a fixed-effect model was used in the data analysis. An I^2 value over 0.5 was considered to represent substantial heterogeneity and a random-effect model was used [38]. Subgroup analyses were not possible due to the lack of patient-level data. All *P* values were 2 sided.

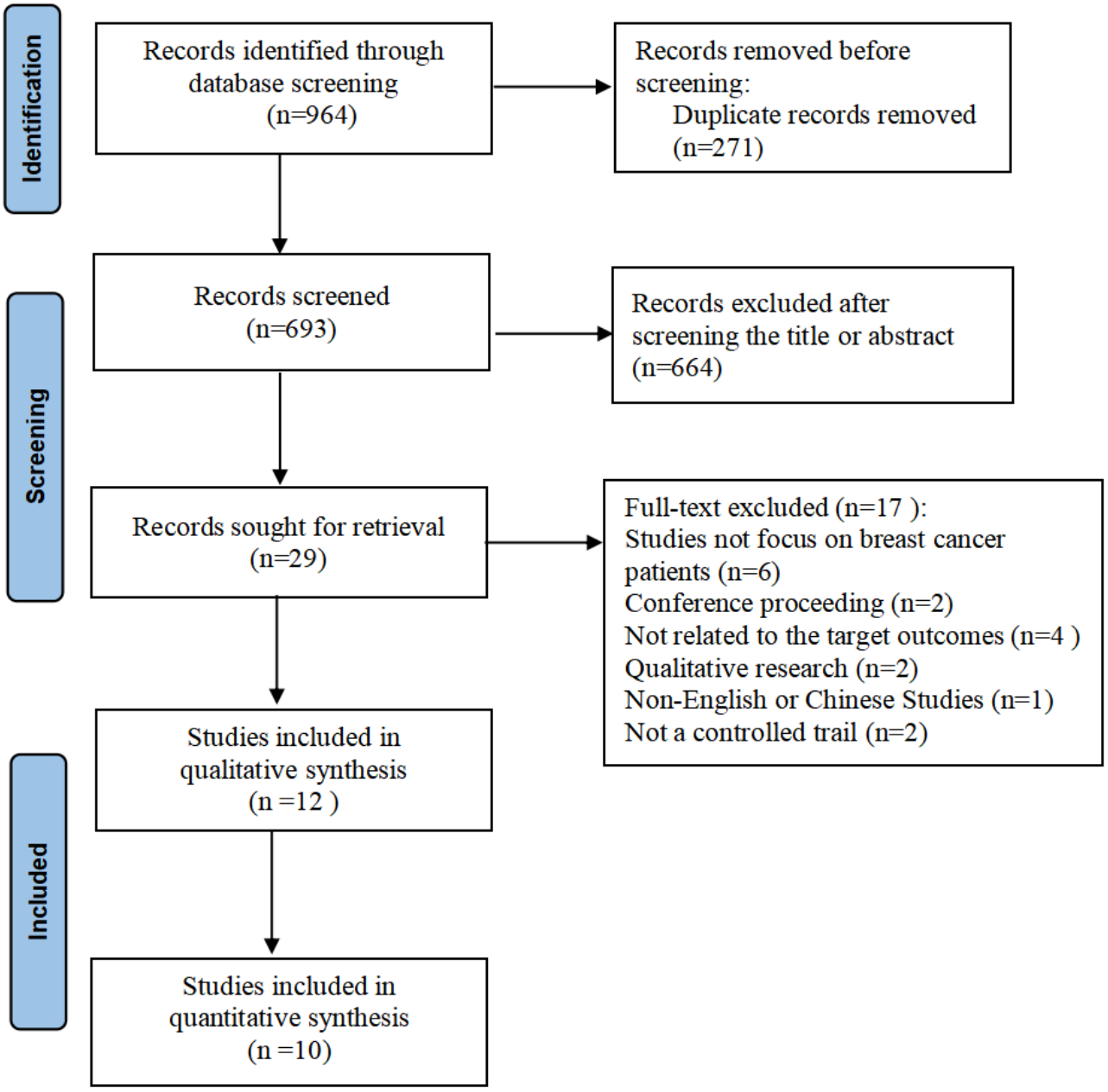
Results

Search Output

A total of 964 potentially relevant articles were initially identified from the 9 databases; 271 articles were removed due to duplication, and the remaining 693 studies were screened. We excluded 664 articles due to insufficient relevance based on the title and abstract. The characteristics of the excluded studies are shown in the PRISMA diagram (Figure 1). Twelve studies were included in the systematic review, 10 of which were further included in the meta-analysis.

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Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



Characteristics of the Included Studies

The characteristics of the 12 studies are shown in Table 2. Three studies were from the United States, 3 from China, and 1 each from Turkey, Italy, Egypt, France, Australia, and Jordan. The included studies were published between 2003 and 2021 [14-17,23,30,39-44]. Of the 12 studies, 6 were RCTs [15,16,23,41-43], 2 were quasi-experimental design studies [39,40], 1 was an externally controlled trial [14], and 3 [17,30,44] were pre–posttest study designs with a single arm. The number of participants ranged from 6 to 80. All participants were adult patients with breast cancer or BCSs. VR-based interventions included both immersive and nonimmersive formats. The intervention duration varied from 15 minutes to 10 months. All studies examined the effects of VR-based interventions on health-related outcomes, including shoulder ROM, hand grip strength, anxiety, depression, pain reduction, cognitive function, fatigue, incidence of complications, cybersickness symptoms, and fear of movement.

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Table 2. Characteristics of the 12 studies.

Author [reference], country	Study design	Study sample	Intervention methods	Intervention duration	Outcome/instrument	Main results
Feyzioğlu et al [22], Turkey	RCT[a]	Forty women with breast cancer were randomly assigned to the experimental group (use of Xbox 360 Kinect–based VR[b] training) and the control group (standardized physical therapy group).	Xbox 360 Kinect–based VR training: using Kinect Sports I (darts, bowling, boxing, beach volleyball, table tennis) and Fruit Ninja.	A total of 6 weeks of exercising with the Kinect (duration of 35 minutes/day for 2 days per week).	VAS[c], ROM[d], arm strength, DASH[e] questionnaire, TKS[f]	Significant changes in pain, ROM, muscle strength, grip strength, functionality, and TKS scores after the treatment (P<.05).
Chirico et al [14], Italy	Externally controlled trial	Patients were randomly assigned to the VR or music group (MT) and were compared with a nonconcurrently recruited control group. Thirty patients were included in the VR intervention group, 30 patients in the MT intervention group, and 34 patients constituted the control group.	Vuzix Wrap 1200VR head-mounted glasses with the Second Life platform was used to explore an island, walk through a forest, observe different animals, climb a mountain, and swim in the sea.	Patients used the equipment for 20 minutes during chemotherapy.	SAI[g], SV-POMS[h], VRSQ[i]	VR and MT are useful interventions for alleviating anxiety and for improving mood states in patients with breast cancer during chemotherapy (P<.05). VR seems more effective than MT in relieving anxiety, depression, and fatigue.
Atef et al [39], Egypt	Quasi-randomized clinical trial	Fifteen participants were assigned to the experimental group (use of Nintendo Wii) and 15 to the control group (proprioceptive neuromuscular facilitation).	Nintendo Wii game: tennis, triceps extension, and rhythmic boxing.	The duration of the VR-based therapy sessions included 30 minutes of training over a period of 4 weeks, with 2 sessions every week.	Circumferential measurements, excess arm volume, QuickDASH-9 scale	VR is beneficial in reducing postmastectomy lymphedema (P<.05) and can be used as an exercise-based technique in those who have undergone modified radical mastectomy with axillary lymph node dissection as it motivates and provides visual feedback to patients.
Buche et al [17], France	Pre–posttest	In a physiotherapy center, each of the 46 patients participated in 4 experimental conditions in a random order: 2 sessions used virtual immersion (ie, 1 participatory and 1 contemplative), 1 session proposed musical listening, and the fourth was a standard session care.	The Greener Gamer's Nature Treks VR relaxation application has 9 relaxing visual environments with relaxing sounds, including 2 immersive modes: contemplative mode and participatory mode.	The sessions were performed over a period of 10 months in a physiotherapy center. Each session lasted an average 30 minutes.	ITC–SOPI[j], feeling of elapsed time, SAI, QC[k]	An increase in positive emotions (ie, joy and happiness) and a decrease in anxiety regardless of which support methods were offered (P<.05). Participatory VR created a more intense feeling of spatial presence.
Jimenez et al [40], Australia	Quasi-experimental design study	Patients with breast cancer (n=18) in the control group received the standard pre-RT[l] education package at a targeted cancer therapy center. Patients with breast cancer (n=19) in the experimental group attended a VERT[m]-based education session detailing RT immobilization, planning, and treatment.	The VERT education program incorporated low-level technical information about RT, patient anatomy, and radiation dose. Aspects of immobilization, simulation, planning, and treatment pertinent to patients with breast cancer were explored.	Each patient attended 1 session, with each session lasting 1 hour.	Radiation therapy knowledge and experience, STAI[n]	VERT breast cancer–targeted education programs are of high value, which can improve patients' RT knowledge (P<.05) and decrease their anxiety (P>.05).

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Author [reference], country	Study design	Study sample	Intervention methods	Intervention duration	Outcome/instrument	Main results
Bani et al [16], Jordan	RCT	Female patients with breast cancer (n=80) were randomly assigned to the intervention and comparison groups.	The intervention group chose 2 scenarios: deep sea diving "Ocean Rift" or sitting on the beach with the "Happy Place" track.	The VR exposure session was ended at the peak time of painkiller efficacy.	VAS, SAI, MMSE[o]	One session of immersive VR plus morphine resulted in a significant reduction in pain and anxiety self-reported scores, compared with morphine alone, in patients with breast cancer (P<.05).
House et al [30], USA	Pre–posttest	Community-dwelling women (n=6) with postsurgical breast cancer pain in the upper arm.	The BrightArm Duo Rehabilitation System consists of a low-friction robotic rehabilitation table, computerized forearm supports, a display, a laptop for the therapist station, a remote clinical server, and a library of custom integrative rehabilitation games.	The duration of the VR-based therapy sessions progressed from 20 to 50 minutes, twice a week for 8 weeks.	BDI-II[p], BVMT-R[q], TMT-A[r], TMT-B[s], NAB[t], NPRS[u], HVLT-R[v], and PHQ-9[w]	Pain intensity showed a 20% downward trend. Outcomes indicate improvement in cognition, shoulder range, strength, function, and depression.
Schneider et al [15], USA	RCT: crossover design	A crossover design was used to examine the effects of a VR distraction intervention on chemotherapy-related symptom distress levels in 16 women aged ≥50 years.	Participants chose from 3 CD-ROM–based scenarios: Oceans Below, A World of Art, or Titanic: Adventure Out of Time.	Participants wore the head-mounted device during their intravenous chemotherapy treatment. Each scenario could last up to several hours.	MMSE, PFS[x], SAI, SDS[y]	A significant decrease in the SAI (P=.10) scores was observed immediately following chemotherapy treatments when participants used VR. No significant changes were found in SDS or PFS values. There was a consistent trend toward improved symptoms on all measures 48 hours following completion of chemotherapy.
Schneider et al [41], USA	RCT: crossover design	A crossover design was used to examine the effects of a VR distraction intervention on chemotherapy-related symptom distress levels in 20 women aged 18-55 years.	Participants chose from 3 CD-ROM–based scenarios: deep sea diving, walking through an art museum, or solving a mystery.	During the chemotherapy infusions, participants received the VR distraction intervention for 45-90 minutes.	SDS, STAI, PFS, evaluation of VR intervention	The major findings of this study demonstrated that symptom distress and fatigue were significantly lower following chemotherapy treatment during which the VR intervention was implemented.
Jin et al [42], China	RCT	Patients with breast cancer (n=38) assigned to the experience group received VR-based training, and the other 38 patients with breast cancer in the control group received standard physical training.	A rehabilitation VR system including a video learning module, an action acquisition module, and an action scoring module.	A total of 3 months, 15–30 minutes per session, twice per day.	Adherence, ROM, the climbing height of finger, degree of edema.	The VR system with auxiliary game treatment was able to substantially improve limb function recovery, compliance, and subjective initiative in rehabilitation training, and reduce the edema of affected limbs (P<.05).

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Author [reference], country	Study design	Study sample	Intervention methods	Intervention duration	Outcome/instrument	Main results
Zhu et al [43], China	RCT	Patients with breast cancer (n=80) who were randomly assigned to the experience group received VR-based training, while the control group received standard physical training.	Patients received VR-based shoulder and hand rehabilitation exercises.	A total of 3 months, 15–30 minutes per session, twice per day.	Adherence, ROM, the climbing height of finger, incidence of lymphedema	The VR rehabilitation system improved limb function recovery, compliance, and reduced the incidence of lymphedema (P<.05).
Chen et al [44], China	Pre–posttest	Patients with breast cancer (n=80) with cognitive impairment after chemotherapy.	The 80 patients received virtual cognitive intervention training.	An 8-week intervention	MoCA[z], activities of daily living	The scores of the Montreal Cognitive Assessment Scale increased significantly and the scores of ADL were lower than those before the intervention (P<.05).

[a]RCT: randomized controlled trial.
[b]VR: virtual reality.
[c]VAS: visual analog scale.
[d]ROM: range of motion.
[e]DASH: disability of the arm, shoulder, and hand.
[f]TKS: Tampa Scale of Kinesiophobia.
[g]SAI: State Anxiety Inventory.
[h]SV-POMS: short version of Profile of Mood States.
[i]VRSQ: Virtual Reality Symptom Questionnaire.
[j]ITC–SOPI: Independent Television Commission–Sense of Presence Inventory.
[k]QC: a questionnaire on cybersickness.
[l]RT: radiation therapy.
[m]VERT: Virtual Environment for Radiotherapy Training.
[n]STAI: State-Trait Anxiety Inventory.
[o]MMSE: Mini-Mental State Examination.
[p]BDI-II: Beck Depression Inventory, Second Edition.
[q]BVMT-R: Brief Visuospatial Memory Test, Revised.
[r]TMT-A: Trail Making Test A.
[s]TMT-B: Trail Making Test B.
[t]NAB: Neuropsychological Assessment Battery.
[u]NPRS: Numeric Pain Rating Scale.
[v]HVLT-R: Hopkins Verbal Learning Test, Revised.
[w]PHQ-9: Patient Health Questionnaire.
[x]PFS: Piper Fatigue Scale.
[y]SDS: Symptom Distress Scale.
[z]MoCA: Montreal Cognitive Assessment.

Assessment of the Risk of Bias of the Studies Included in the Review

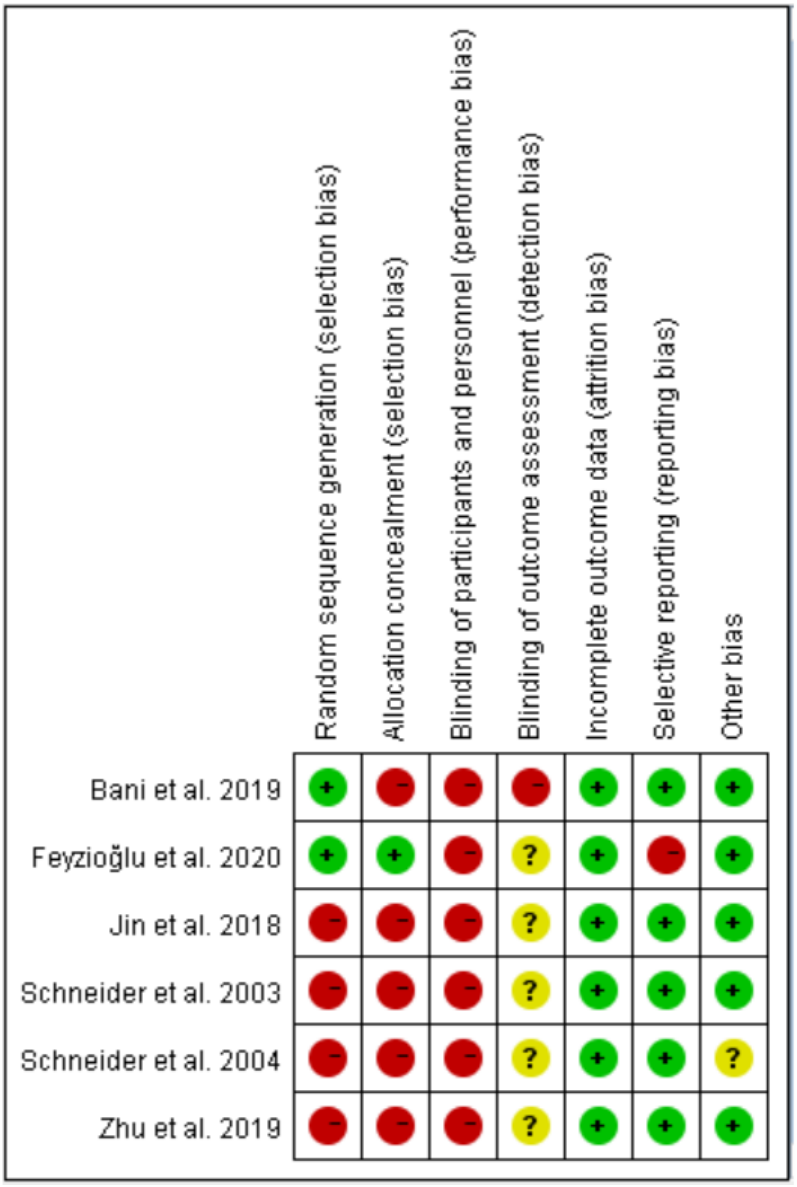
The results of the assessment of risk of bias are presented in Figures 2 and 3 and Table 3. The Cochrane risk of bias tool was used to assess the quality of the included RCTs. For RCTs, allocation concealment and blinding will not seriously influence the selection of patients and the measurement of outcomes. Two of the 6 RCTs reported randomized methods in detail [16,22], while the remaining 4 trials did not provide the methods of sequence generation, nor demonstrated that the participants were recruited randomly. None of the trials provided concealment methods, except 1 trial that reported the use of anonymization by placing numbers into opaque, sealed envelopes to conceal the allocation sequence [22]. In all trials, no blind method was used on participants due to the particularity of the intervention methods. None of the trials reported employing blinding of assessors, except for 1 trial that reported the person who collected the data [16]. Only 3 studies performed power calculations and reported adequate statistical power [16,22,41], while the other studies did not perform power calculations and were without dropouts [15,42,43].

ROBINS-I was used to assess the risk of non-RCTs. Four studies [14,17,40,44] had a moderate risk of bias, with confounding,

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outcome measurement, and selective reporting being the primary sources. Two studies [30,39] had a critical risk of bias due to missing data. The risk of selection bias was judged to be low for all studies. A detailed list of the risk of bias assessments is provided in Table 3.

Figure 2. Risk of bias analysis of included randomized controlled trials.



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Figure 3. Overall risk of bias analysis of randomized controlled trials.

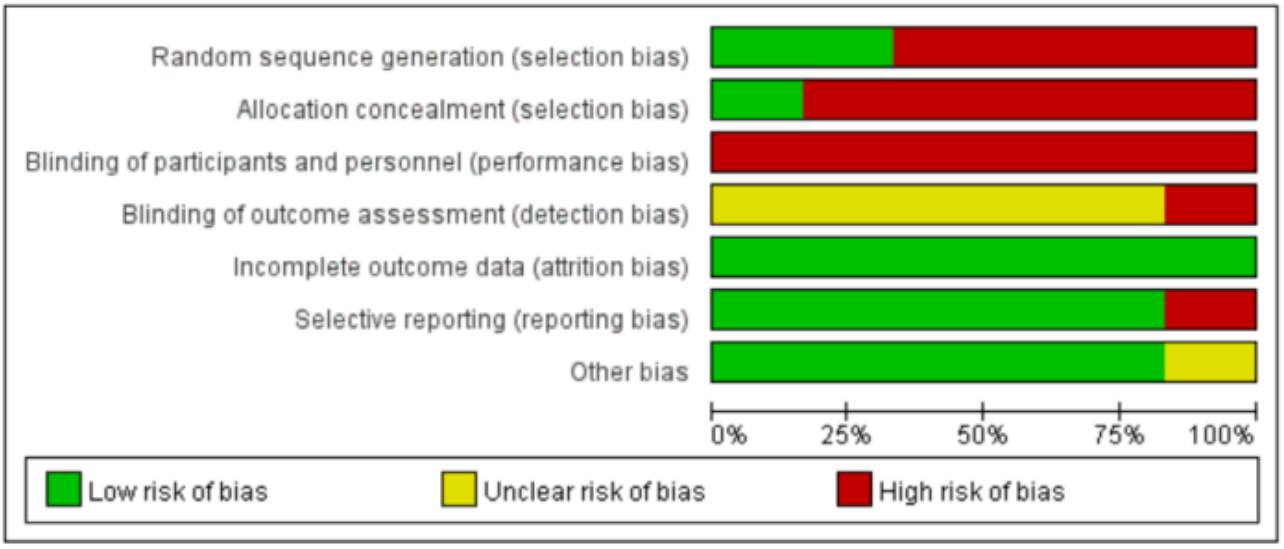


Table 3. Overall risk of bias analysis of the nonrandomized controlled trials.

Study	Bias due to confounding	Selection bias	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall bias
Chirico et al [14]	Moderate	Low	Low	Low	Low	Moderate	Moderate	Moderate
Atef et al [39]	Moderate	Low	Low	Moderate	Critical	Low	Low	Critical
Buche et al [17]	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate	Moderate
Jimenez et al [40]	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate	Moderate
House et al [30]	Moderate	Low	Low	Serious	Critical	Moderate	Moderate	Critical
Chen et al [44]	Moderate	Low	Low	Low	Low	Moderate	Moderate	Moderate

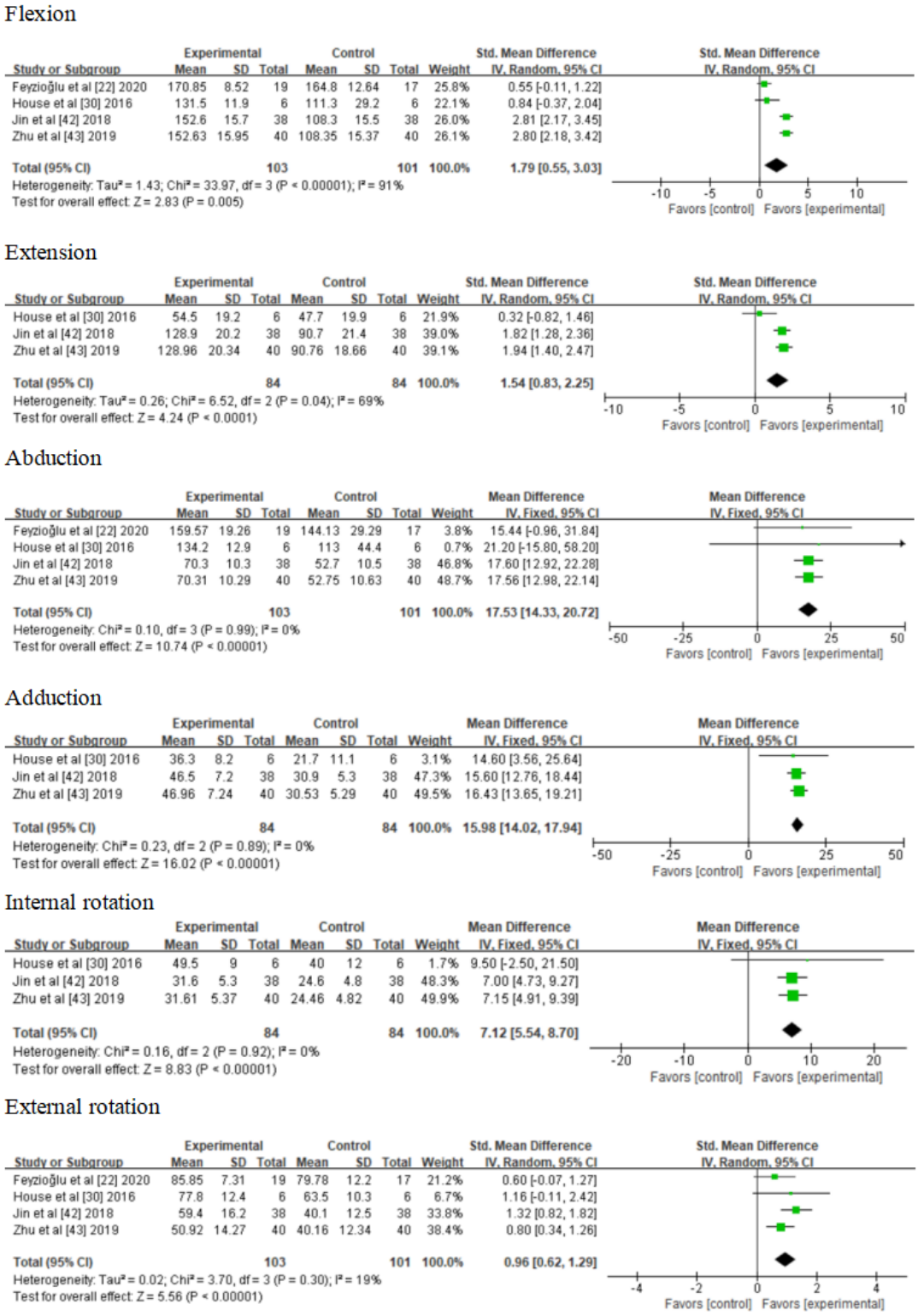
Effects of Interventions

Shoulder Range of Motion

A meta-analysis of 4 studies [22,30,42,43] suggested statistically significant results for VR-based interventions for upper shoulder ROM. ROM was measured in degrees using a digital goniometer. We observed that VR-based interventions were more effective than standard training, as shown in Figure 4. The statistical analysis showed significant results for flexion (standard mean difference [SMD] 1.79; 95% CI 0.55 to 3.03; P=.005), extension (SMD 1.54; 95% CI 0.83 to 2.25; P<.001), abduction (MD 17.53; 95% CI 14.33 to 20.72; P<.001), adduction (MD 15.98; 95% CI 14.02 to 17.94; P<.001), internal rotation (MD 7.12; 95% CI 5.54 to 8.70; P<.001), and external rotation (SMD 0.96; 95% CI 0.62 to 1.29; P<.001).

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Figure 4. Forest plot assessing the effectiveness of using virtual reality-based interventions on shoulder range of motion.

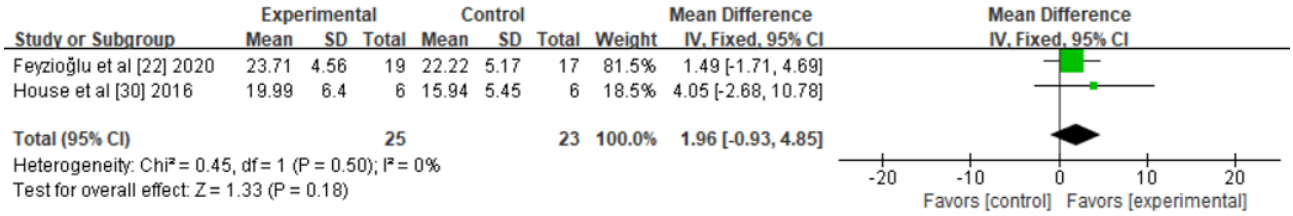


Hand Grip Strength

Two studies [22,30] measured grip strength. The Saehan hydraulic hand dynamometer was used to measure grip strength. According to the I^2 statistic, 0% of variation across studies was due to heterogeneity. This homogeneity was confirmed by the chi-square test (P=.50). A fixed-effect model was fitted. The study by House et al [30] reported better results than that by Feyzioğlu et al [22]. We observed that VR-based interventions were more effective than standard training. However, the overall result of this meta-analysis was not conclusive, as shown in Figure 5.

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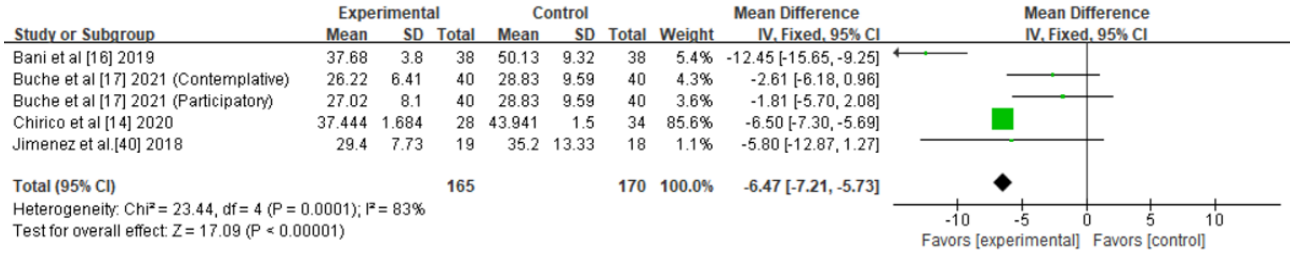
Figure 5. Forest plot assessing the effectiveness of using virtual reality-based interventions on hand grip strength.



Anxiety

Of the 10 studies, 4 assessed the influence of VR-based interventions on the severity of anxiety [14,16,17,40]. The severity of anxiety was measured using the State Anxiety Inventory [14,16,17] and the State-Trait Anxiety Inventory [40]. A meta-analysis of anxiety symptoms from 4 studies produced similar positive results favoring VR-based interventions over standard education, pharmacological interventions, or noninterventions. There was substantial heterogeneity (P<.0001; I^2=83%), likely due to different duration, schedule, intensity, and type of interventions and methodological factors. Figure 6 shows the meta-analysis of the anxiety symptoms.

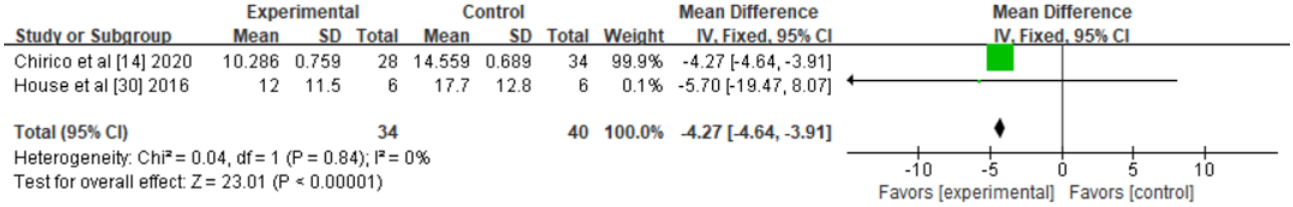
Figure 6. Forest plot assessing the effectiveness of using virtual reality-based interventions on anxiety.



Depression

Of the 10 studies, 2 assessed the influence of VR-based interventions on the severity of depression [14,30]. The severity of depression was measured using the short version of Profile of Mood States and Beck Depression Inventory, Second Edition. A meta-analysis of depression from 2 studies produced similar positive results favoring VR-based interventions (MD −4.27; 95% CI −4.64 to −3.91; P<.001). Figure 7 shows the meta-analysis of the depression symptoms.

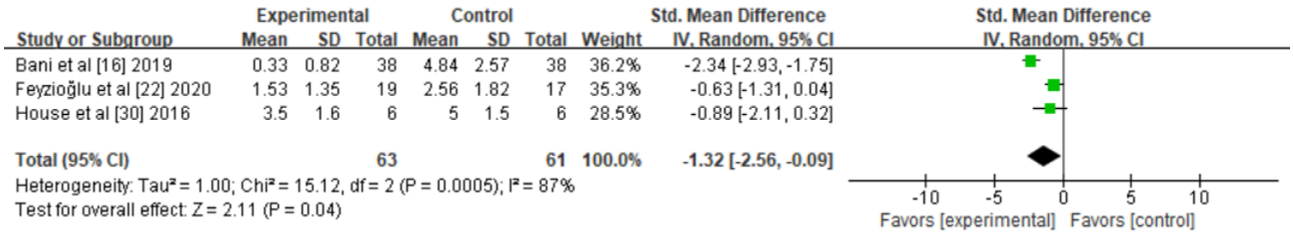
Figure 7. Forest plot assessing the effect of using virtual reality-based interventions on depression.



Pain

Of the 10 studies, 3 assessed the influence of VR-based interventions on the severity of pain [16,22,30]. The severity of pain was measured using the visual analog scale. A meta-analysis of pain from 3 studies produced similar positive results favoring VR-based interventions over standard education, pharmacological interventions, or noninterventions. There was substantial heterogeneity (P<.001; I^2=87%), likely due to different duration, schedule, intensity, and type of interventions and methodological factors. Figure 8 presents the meta-analysis of the pain symptoms.

Figure 8. Forest plot assessing the effectiveness of using virtual reality-based interventions on pain.



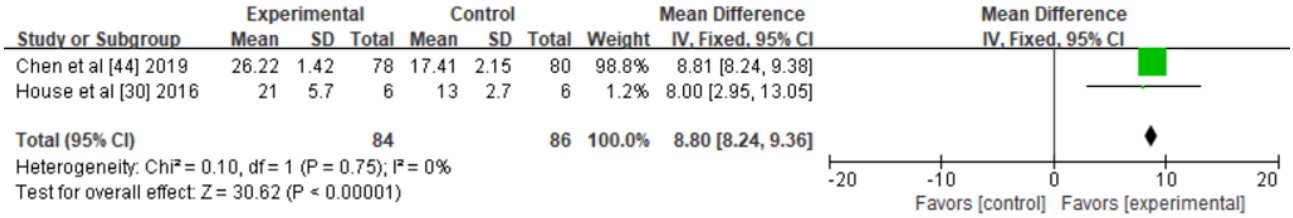
Cognitive Function

Of the 10 studies, 2 assessed the influence of VR-based interventions on cognition function [30,44]. Cognition function was measured using the Montreal Cognitive Assessment Scale and Brief Visuospatial Memory Test, Revised. A meta-analysis of cognitive function from 2 studies [30,44] produced similar positive results favoring VR-based interventions (MD 8.80;

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95% CI 8.24 to 9.36; *P*<.001). Figure 9 presents the meta-analysis of the pain symptoms.

Figure 9. Forest plot assessing the effect of using virtual reality-based interventions on cognitive function (ie, verbal memory).



Fatigue

Chirico et al [14] reported significant changes in fatigue using the short version of the Profile of Mood States and revealed a significant difference between the 2 study groups (13.50 [SD 0.58] vs 15.03 [SD 0.53]; *P*<.001). Further studies are needed to explore the efficacy of VR-based rehabilitation interventions in reducing the level of fatigue.

Incidence of Complications

Of the 10 studies, 2 [42,43] focused on the incidence of complications after surgery. Jin et al [42] reported significant differences in lymphedema incidence between their 2 study groups (10.53% vs 42.11%; *P*<.05). Zhu et al [43] reported the incidence of total complications, such as lymphedema, bleeding, effusion, and flap necrosis, between their 2 study groups (12.50% vs 32.50%; *P*<.05).

Cybersickness Symptoms

Of the 10 studies, 4 [14,15,17,41] focused on cybersickness symptoms. Chirico et al [14**]** analyzed possible VR-associated cybersickness symptoms using the Virtual Reality Symptom Questionnaire. The findings showed that with the exception of a slight difficulty in concentrating, all symptoms (eg, headache, dizziness, nausea, eyestrain, drowsiness) occurred with a frequency less than 20%. Buche et al [17] used a questionnaire on cybersickness to evaluate the possible side effects (nausea, headache, and dizziness, etc.) of VR. The findings showed that 4 out of 46 patients (8.70%) experienced mild physical discomfort following VR. None of the patients in the other 2 studies [15,41] reported any unusual symptoms, such as dizziness, increased nausea, or visual disturbances.

Fear of Movement

Feyzioğlu et al [22] reported significant changes in fear of movement using the Tampa Kinesiophobia Scale and revealed a significant difference between the study 2 groups (29.47 [SD 5.31] vs 37.35 [SD 4.51]; *P*<.001). Further studies are needed to explore the efficacy of VR-based rehabilitation interventions in reducing the level of kinesiophobia.

Discussion

Principal Findings

This research aimed to use qualitative and quantitative methods to evaluate the effectiveness of VR-based interventions in the rehabilitation management of patients with breast cancer. Twelve studies were included in the systematic review, 10 of which were included in the meta-analysis. A total of 604 participants were involved in different studies. In view of our results, we can conclude that VR-based interventions are more effective in improving the emotional, cognitive, and physical well-being of BCSs. For other outcomes (and comparators), the evidence was less compelling in improving learners' skills, attitudes, satisfaction, and patient-related outcomes.

Quality of the Evidence

For RCTs, due to the nature of the intervention, we judged the majority of studies to be at a high risk of bias for nonblinding of participants and study personnel and nonblinding of outcome assessment. Although blinding of outcome measurement would not seriously influence the results, nonblinding of participants might bias the effect [45]. For non-RCTs, most of the studies had a moderate risk of bias in confounding, outcome measurement, and selective reporting. Some studies had a serious or critical risk of bias, most frequently due to the outcome measurement, missing data, and choice of analyses, which did not allow controlling for missing data.

Moreover, the lack of randomization and power analysis to calculate the appropriate sample size, as well as different duration, schedule, intensity, and type of interventions, and different scales of measurements all contributed to the heterogeneity of the included studies. Additionally, some outcomes could not be analyzed quantitatively due to data format (eg, incidence of complications, cybersickness symptoms) or the fact that the data were only reported in 1 study (eg, fatigue, fear of movement). Furthermore, we could not assess the risk of publication bias because funnel plot–based methods are not accurate for less than 10 included studies per outcome.

Overall Completeness and Applicability of the Evidence

We identified 12 studies; however, most of them were limited by small sample sizes. Therefore, additional studies are needed to confirm our findings. We are encouraged that a number of larger RCTs are currently underway [46-52], which are likely to inform the field further.

Our findings must be viewed with caution owing to the limited number of trials with low quality. Moreover, as we only included a small number of trials, it was not feasible to conduct subanalyses regarding VR-based interventions or study design. A more empirical study is needed to determine the applicability of VR-based interventions in BCSs according to intense physical and psychological symptoms, function defects, and adverse effects. Additionally, further study is needed to standardize the contents of VR-based interventions, especially for upper limb recovery. Moreover, to successfully implement VR-based

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rehabilitation exercises into daily practice, it is better to provide detailed information on training frequency, duration of the intervention, and targeted motor skills [53].

Potential Biases in the Review Process

Although we performed extensive searches of the literature, there is a possibility that we did not identify all relevant studies. Two review authors independently completed data screening, extraction, evaluation of risk of bias, and certainty of evidence rating. Any discrepancies between the reviewers were resolved by discussion or in consultation with other reviewers in the event that disagreement persisted. Even though we contacted all relevant study authors for additional information, we did not always receive a response. Low study quality, inadequate methodological details, and significant inconsistencies across trials decrease the overall quality of the evidence. Moreover, the variability in VR-based interventions, as well as the timing, regimens, and definitions of outcome measurements all have the potential to contribute to inaccuracies in the assessment of the intervention effects.

Agreement With Other Studies or Reviews

The findings of this systematic review and meta-analysis indicated that VR-based interventions have a positive effect on physical and psychological symptom management and ROM. Our findings are a valuable extension of recently published systematic reviews and meta-analyses. Previous similar studies mainly focused on the effect of immersive or nonimmersive VR-based interventions in cancer survivors or stroke survivors; however, the results of the studies were inconsistent.

Ahmad et al [54] and Chow et al [55] reported that VR-based interventions may be more effective in the management of pain and anxiety in patients with cancer, whereas a nonsignificant difference in pain and anxiety was reported by Zeng et al [56]. By contrast, Ioannou et al [57] reported that VR-based interventions demonstrated a trend toward improvement in pain. One possible explanation for this difference is that the intervention effects of immersive and nonimmersive systems differ and that these reviews focused on cancer survivors. Moreover, different cancer survivors may have various physical and psychological symptoms that lead to variability within the findings. Therefore, it is necessary to conduct controlled trials between different interventions and populations. In addition, although no significant improvement was observed in most studies, we cannot ignore the potential health-promoting effects of VR-based interventions. In agreement with our review, Aminov et al [58] found evidence of a significant effect in improving upper limb function using VR-based rehabilitation interventions and suggest VR as an adjunct for stroke rehabilitation.

Overall, previous reviews have presented similar conclusions to those of our review, suggesting that although the evidence is limited, it does exist. However, the results of this review should be interpreted with caution due to the limited number of controlled trials analyzed, the small sample sizes, and low methodological quality. The majority of previous reviews/meta-analyses indicate that more high certainty of evidence is needed before VR-based interventions can be considered as potential strategies for rehabilitation management in BCSs consistently.

Implications for Research and Practice

The examination of VR-based interventions is recommended to ascertain whether there is a role for technology‐based exercise in improving the late and long-term side effects of breast cancer treatment. Furthermore, empirical evidence is required to provide well‐substantiated recommendations regarding the frequency, duration, and content of the VR intervention. Finally, future studies on VR-based interventions could utilize more consistent reference standards, such as standardizing the frequency, duration, and content of the VR interventions. Such standardization minimizes bias and heterogeneity between studies. Future studies could focus on (1) the late and long-term side effects of breast cancer management; (2) the mechanism of symptom management; and (3) combination of VR with artificial intelligence, physiological indexes, and electroencephalogram.

Conclusions

The late and long-term side effects resulting from breast cancer treatment are persistent and prominent. The findings from this review suggest that VR has the potential to facilitate immediate and longer-term improvements in symptom management and the performance of upper extremity function following a surgery for BCSs. Although the use of VR-based interventions has expanded in the rehabilitation management of BCSs, the current evidence for using VR-based interventions for both immediate and long-term improvements among BCSs remains limited. Future trials would benefit from using multicenter data, with larger sample sizes, longer follow-up periods, and high methodological quality.

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Authors' Contributions

XB conceived the idea for the review. XB, PHFN, QC, and XL wrote the first draft of the manuscript. XB, WX, QC, ASKC, and XL were involved in the study selection, quality assessment, and data extraction. XL, PHFN, and QC conducted the statistical

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analysis. All authors reviewed the manuscript, contributed to critical changes, and approved the final version of the manuscript for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search Strategy.
[DOC File , 43 KB - games_v10i1e31395_app1.doc]

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Abbreviations

BCRL: breast cancer–related lymphedema
BCS: breast cancer survivor
MD: mean difference

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PICOS: Population, Intervention, Comparison, Outcomes and Study
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: Prospective Register of Systematic Reviews
RCT: randomized controlled trial
ROBINS-I: Risk Of Bias In Non-randomized Studies of Interventions
ROM: range of motion
SMD: standard mean difference
VR: virtual reality

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Review

Benefits of Virtual Reality Balance Training for Patients With Parkinson Disease: Systematic Review, Meta-analysis, and Meta-Regression of a Randomized Controlled Trial

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Abstract

Background: Virtual reality (VR) balance training is increasingly being pursued in biomedical research, specifically with respect to investigating balance ability with VR. However, existing systematic reviews have found inconsistent conclusions about the efficacy of VR in improving balance in Parkinson disease (PD) patients.

Objective: The goal of the research was to evaluate the impact of VR balance training on the balance ability of patients with PD.

Methods: All major databases, including Web of Science, PubMed, Scopus, China National Knowledge Infrastructure, and Wanfang, were searched to identify all relevant studies published in English or Chinese since September 15, 2010. Two researchers independently conducted document retrieval, study selection, data extraction, and methodological quality evaluation.

Results: A total of 16 randomized controlled trials were analyzed (n=583 patients with PD), with the methodological quality evaluation score ranging from 5 to 8 points. A random effects model was selected to combine effect sizes. Meta-analysis showed that the balance ability of PD was significantly improved after VR training compared with the control group (standardized mean difference [SMD] 2.127, 95% CI 1.202 to 3.052, P<.001, I^2=95.1, df=15). It is worth noting that the intervention platform may be the main reason for heterogeneity. Meta regression analysis showed that no training program could predict the impact of VR training (P=.57 to .94) on PD balance ability. Subgroup result showed that a single training time of 0 to 20 minutes (SMD 6.446), 4 to 6 times per week (SMD 4.067), training for 3 to 5 weeks (SMD 62.478), training course reached more than 30 times (SMD 4.405), and 201 to 300 minutes per week (SMD 4.059) maybe have more benefit.

Conclusions: A systematic review and meta-analysis confirmed that VR balance training is a highly effective means to improve balance performance with large effects in PD. In addition, we preliminarily extracted dose-effect relationships for training volume, informing clinicians and practitioners to design effective VR balance training for balance ability. Further research is needed to reveal optimal dose-response relationships following VR balance training.

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KEYWORDS

virtual reality; Parkinson disease; balance; systematic review; meta-analysis; meta-regression; serious games; VR; rehabilitation; VR training

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Introduction

Background

Parkinson disease (PD) is the most common neurodegenerative movement disorder and is the result of impaired dopamine-producing nerve cells in the ventral midbrain accompanied by progressive neuronal loss [1,2]. These impairments lead to the maladjustment of motor performance and symptoms such as tremors, stiffness, and reduced limb coordination [3]. Such symptoms can reduce the ability to balance, which often further increases the risk of falling, limits mobility, and reduces the quality of daily life [4-6]. PD has a higher incidence rate among people older than 50 years, with a prevalence rate as high as 4% [4-6]. It is also the fastest growing neurodegenerative condition, impacting 17.5 million individuals globally by 2040. [7,8]. At present, PD is mainly treated by slowing down the course of the disease and improving its core symptoms. The most common clinical scheme for the current treatment of PD is dopamine and deep brain electrical stimulation; however, these have limited and unstable effects in improving posture control and balance [9,10]. In addition, rehabilitation therapy is crucial in the treatment of PD. Exercise has been used as a common rehabilitation therapy, including stretching exercises, strength training, and aerobic exercises to help restore motor function in PD patients [11]. Overall, research shows that rehabilitation therapy based on exercise and cognitive reeducation can effectively improve balance and motor function of PD patients in daily life [12].

As a relatively new intervention measure, virtual reality (VR) technology has become an important auxiliary means in the treatment of various diseases. VR technology involves human-computer interaction technology based on perception (visual, tactile, kinesthetic) and can provide patients with multisensory stimulation and rich virtual scenes, increase the sense of immersion, and realize real-time feedback on physical actions. The main potential mechanisms of VR therapy include the repeatability of virtual tasks, positive feedback from virtual devices, and concrete simulation of a virtual environment. Studies have found that task-oriented repetitive training can enhance the synaptic strength in the brain, continuously affect nerve transmission, and maintain the enhanced functional circuit, thereby accelerating neuroplasticity in patients with neurodegenerative diseases [13]. Therefore, VR technology may be an effective means of treating neurodegenerative diseases such as PD. Under VR conditions, individuals experience multiple sources of sensory stimulation and complete multiple forms of repetitive tasks in a comfortable, safe, and immersive virtual environment, thereby promoting individual functional learning and the transfer of learning function. The potential advantage of VR is that training in VR environments can realize the maintenance and transfer of individual motor skills, which is an important feature of motor skill learning and the basis of real-world behavior [14]. Therefore, VR therapy is considered a supplement to traditional rehabilitation therapy and has been proven to be feasible and effective for treating a variety of neurological diseases [15,16].

At present, optimizing and strengthening the brain compensation mechanism is an important treatment method for PD and other movement disorders [17]. The virtual environment created by VR technology can promote the illusion of bodily movement, increase immersion to enhance the activation of motor brain regions, mobilize the changes of brain neural plasticity, reconstruct the synapses of nervous system cells, and directly train the central nervous system [18,19], resulting in significant benefits to the reorganization and recovery of nerve structure in PD and other neurodegenerative diseases [20]. Existing systematic reviews have found inconsistent conclusions about the efficacy of VR in improving balance in PD patients. One such review found that VR training can effectively improve balance in PD patients compared to other positive interventions [20,21]; however, other studies did not find these effects [22], a discrepancy that may be due to publication bias and diversity of interventions [20]. In addition, sample sizes of randomized controlled trials (RCTs) are currently insufficient to explore the dose effect of VR technology training on improving PD balance [20].

Objectives

In view of the current state of research consensus, the primary objective of this study was to review and analyze the existing RCT studies to verify whether VR training can improve balance in PD patients. Positive findings would prompt further investigation of an optimal dose of VR training to improve the balance of PD patients with the eventual goal of providing clinical workers with stronger theoretical support for VR training in the treatment of PD.

Methods

This study was conducted in accordance with the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-analyses [20].

Research Retrieval

We searched 5 databases: Web of Science, PubMed, Scopus, China National Knowledge Infrastructure, and Wanfang. The last retrieval date was September 15, 2020. We conducted a literature retrieval using three sets of keywords: (1) virtual reality, VR, Kinect, Wii, Xbox; (2) Parkinson, parkinsonian disorders, Parkinson, parkinsonism, Parkinson disease, PD; and (3) balance, equilibrium, dynamic postural control; the three groups of keywords were retrieved using the AND combination in the database. The Chinese database used the Chinese translation of the above keywords. Finally, the references of all included studies and relevant systematic reviews [20,21,23-27] were manually searched to further identify relevant studies.

Inclusion Criteria

Research Type

The studies were either RCTs or nonrandomized controlled trials, where nonrandomized trials generated by pseudorandom or nonrandom sequences were defined as nonrandomized controlled trials. Those that did not involve a comparison group or did not report intergroup comparisons were excluded. In the case of cross-sectional designs, a set of postmortem and

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qualitative analyses were also excluded. We further excluded reviews, conference summaries, and book chapters and restricted our research to articles written in the English or Chinese language.

Participant Type

The subjects of the study were PD patients aged 18 years or older who had been formally diagnosed by the hospital or by internationally recognized diagnostic criteria. There were no restrictions on sex, course of disease, or severity of the disease.

Intervention Type

The VR training immersion included a variety of modes, such as nonimmersive, semi-immersive, and fully immersive. The control group consisted of a wait group, routine physical therapy, or other types of treatment such as drug therapy.

Types of Outcome Indicators

In order to improve the quality of research, it was necessary to use effective and reliable tools to measure balance ability. Due to the high task specificity of balance ability, we selected the Berg Balance Scale (BBS), which is widely used to assess overall balance ability of patients with movement disorders [28]. The full assessment includes 14 balance-related activities, in which higher scores indicate better balance ability. The maximum possible score is 56 points, and a score below 40 indicates a risk of declining balance ability.

Study Selection and Data Extraction

We conducted independent screening of studies based on the title, abstract, and full text, and two researchers discussed the results before reaching a consensus. In the event of no consensus, a third researcher made the final decision.

Descriptive data were extracted after reading the full text. The extracted content comprised 3 categories: literature characteristics, participant characteristics, and intervention plan. Literature characteristics included first author, number of years of publication, country, and language. Participant characteristics included diagnostic criteria (diagnostic tools), number of participants (number and sex ratio of the experimental group and control group), and age. In order to determine the dose-response relationship of VR training to improve balance in PD patients, the balance training scheme was coded as follows: training group (experimental group and control group), single training duration, training frequency, total number of training sessions, weekly training duration and total training duration, and VR training platform [27,29]. We extracted the quantitative balance data in the experimental and control group in each eligible RCT study (ie, BBS scores before and after intervention were extracted), and the results must be quantitative data that can be used for effect size calculation. If there were multiple control groups in the study, only the control group with active intervention measures was extracted.

Quality Assessment

We used the Physiotherapy Evidence Database (PEDro) Scale to assess the methodological quality of clinical trials in physiotherapy and rehabilitation [30]. The quality evaluation was carried out using the PEDro quality assessment sheet to evaluate the treatment included in the study. The evaluation criteria were as follows: eligibility criteria, randomization, concealed allocation, baseline equivalence, blinding of participants, blinding of instructors, blinding of assessors, retention rate of 85%, missing data management (intent-to-treat analysis), between-group analysis, and measures of variability. One point was awarded if the information was explicitly presented, with a maximum of 9 points per study. If the above information was clear in the study, 1 point was awarded; if not, 0 points were awarded, while the maximum score for each study was 11 points. According to the scores, the quality of these studies can be divided into 4 grades: excellent (>9 points), good (6 to 8 points), fair (4 to 5 points), and poor (<4 points) quality. For studies that did not provide enough information to complete the assessment, the authors requested relevant information via email; a lack of author response resulted in a designation of ambiguous information.

Data Analysis

In order to explore the benefits of VR training on PD balance, we combined extracted BBS scale data with effect size using the statistical software STATA (version 15.1, StataCorp LLC), resulting in a random effect model for further analysis calculation. The standardized mean difference (SMD) was selected as the index of effect scale for statistics. The effect size indicated the degree of impact of VR training on PD balance ability, where SMD <0.20 indicated a negligible effect, 0.20 to <0.50 indicated a small effect, 0.50 to <0.80 indicated a large effect, and an SMD >0.80 indicated a larger effect [31].

We used the statistic I^2 to evaluate the heterogeneity of the selected studies, in which a larger I^2 statistic indicates greater heterogeneity [31]. In addition, we used funnel plots and Egger tests to evaluate publication bias [32]. Subgroup analyses were used to estimate the impact of publication bias on the interpretation of results [33]. We further used meta-regression models to analyze the effect of the VR training program according to length and frequency of training courses, total time of weekly training courses, total number, and time of training courses. Therefore, this meta-regression part was not analyzed in this study due to its failure in quantifying the intensity of treatment. For studies that did not provide the above data, the author was contacted by email to obtain the data, so as to improve the quality of this research.

Results

Study Selection

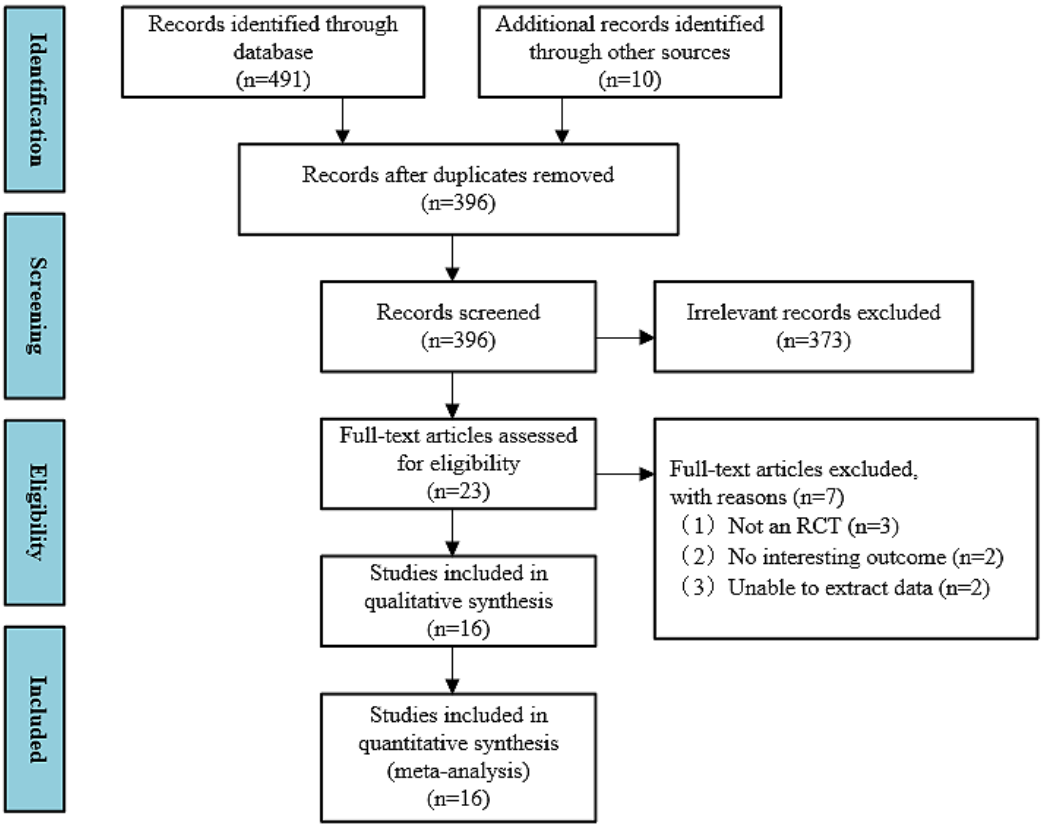
We retrieved a total of 491 records through electronic databases: 200 records were retrieved by Web of Science, 84 records were retrieved by PubMed, 144 records were retrieved by Scopus, 53 records were retrieved by China National Knowledge Infrastructure, and 10 records were retrieved by Wanfang. In addition, 10 records were added manually.

We then excluded 105 duplicate records. The remaining 393 records were further screened by titles and abstracts, and 373 records that did not meet the study criteria were deleted. We then evaluated 23 studies for full-text qualification, and 7 studies were found not to meet the predetermined inclusion criteria.

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Finally, a total of 16 studies were identified for meta-analysis. The flow chart of literature retrieval and study selection is shown in Figure 1.

Figure 1. The flow of literature search and study selection. RCT: randomized controlled trial.



Research Characteristics

Table 1 lists the characteristics and descriptions of the 16 studies published from 2012 to 2020, involving 583 PD (experimental group: 291; control group: 292) participants aged 55 to 75 years in the included study. All the included PDs were tested using diagnostic tools such as the Movement Disorder Society Clinical Diagnostic Criteria for Parkinson disease (MDS-PD), the United Kingdom Parkinson Disease Society Brain Bank criteria (UK-PDSBB), and the Chinese Parkinson Diagnostic Criteria, or patients who had been clinically diagnosed as PD by doctors, of which six [33] studies were conducted in China, two [34,35] studies were conducted in the United Kingdom, two [34,35] studies were conducted in Brazil, and two [36,37] studies were conducted in Taiwan, including one study each in South Korea [38], Italy [39], the United States [40], and Istanbul [41]. All of the included studies were comparative studies between the VR group and conventional rehabilitation.

The VR training program has a single duration between 30 and 60 minutes, with frequency varying from 2 to 5 times per week and duration ranging from 4 to 12 weeks. All of the 16 studies were nonimmersive VR devices, including Xbox (Microsoft) and Wii Fit (Nintendo Co Ltd). Among them, four studies [35,36,41,42] used Xbox Kinect equipment and five studies [38-40,43,44] used Wii Fit equipment. Additionally, two studies [45,46] used Silverfit 3D motion capture analysis system, three studies [37,47,48] were personalized development VR rehabilitation systems, and one study [34] only reported device components and game types, among which one study [49] did not report the name of VR device. The outcome indicators of interest in this study were all BBG scales, thereby having no separate description in the study characteristics.

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Table 1. Study characteristics.

Reference			Participant characteristics			Intervention protocol		
Authors	Country, Language	Diagnostic criteria	Hoehn-Yahr classification	N, male/female	Age	Method	Session duration/frequency/period/# sessions/duration of VR[a] treatment per week	Platform
Chen et al [33]	China, Chinese	Chinese Parkinson Diagnostic Criteria	EG[b]: 2.52 (SD 0.51); CG[c]: 2.57 (SD 0.50)	EG: 23, 14/9; CG: 23, 12/11	EG: 62.09 (SD 6.11); CG: 64.65 (SD 5.06)	EG: VR training; CG: routine rehabilitation training	50 min/5 times per wk/6 wk/30/250 min	BioFlex-FP posture control evaluation and training system
Cheng et al [47]	China, Chinese	MDS-PD[d]	EG: 3.1 (SD 0.6); CG: 3.0 (SD 0.6)	EG: 20, 9/11; CG: 20, 8/12	EG: 59.2 (SD 7.3); CG: 58.6 (SD 7.5)	EG: VR training+ routine rehabilitation training (40 min); CG: routine rehabilitation training	20 min/2 times per wk/8 wk/16/40 min	Silverfit 3D motion capture analysis system
Sun et al [46]	China, Chinese	Clinical diagnosis	Total: 1-4	EG: 30, 19/11; CG: 30, 21/9	EG: 61.43 (SD 7.34); CG: 62.54 (SD 6.98)	EG: VR training + strengthen muscle strength training (20 min); CG: routine rehabilitation training + medication	20 min/5 times per wk/4 wk/20/100 min	Silverfit 3D motion capture analysis system
Lin et al [48]	China, Chinese	Chinese Parkinson Diagnostic Criteria	Total: 2.5-4	EG: 18, 12/6; CG: 15, 10/5	EG: 61.4 (SD 8.2); CG: 62.1 (SD 6.3)	EG: VR training + medication; CG: routine rehabilitation training + medication	30 min/5 times per wk/4 wk/20/150 min	Xbox (Microsoft Corp)
Liu et al [45]	China, Chinese	Chinese Parkinson diagnostic criteria	Total: 3	EG: 21, 11/10; CG: 21, 12/9	EG: 60.9 (SD 7.20); CG: 63.9 (SD 5.82)	EG: VR training; CG: routine rehabilitation training	20 min/5 times per wk/4 wk/20/150 min	Computer-assisted rehabilitation environment (CAREN)
Pompeu et al [35]	Brazil, English	Clinical diagnosis	Total: 1-2	Total: 32, 17/15	Total: 67.4 (SD 8.1)	EG: VR training; CG: routine rehabilitation training	30 min/2 times per wk/7 wk/14/60 min	Wii Fit (Nintendo Co Ltd)
Van et al [34]	UK, English	UK-PDSBB[e]	Total: 2-3	EG: 17, 12/5; CG: 16, 8/8	EG: 66.3 (SD 6.39); CG: 68.8 (SD 9.68)	EG: VR training; CG: routine rehabilitation training	60 min/2 times per wk/5 wk/10/120 min	Workstations consisted of a flat-panel LCD monitor connected to a PC containing a total of 6 commercially available, interactive dynamic balance exercises (Motek Medical)
Lee et al [37]	Korea, English	Clinical diagnosis	NR[f]	EG: 10, 5/5; CG: 10, 5/5	EG: 68.4 (SD 2.9); CG: 70.1 (SD 3.3)	EG: VR training + neurodevelopmental therapy (NR) + functional electrical stimulation therapy (NR); CG: routine rehabilitation training	30 min/5 times per wk/6 wk/30/150 min	k-pop dance festival (Nintendo Inc) game for the Wii (Nintendo Inc) video game system
Shih et al [41]	Taiwan, English	UK-PDSBB	EG: 1.6 (SD 0.84) ; CG: 1.4 (SD 0.52)	EG: 10, 9/1; CG: 10, 7/3	EG: 67.5 (SD 9.96); CG: 68.8 (SD 9.67)	EG: VR training; CG: routine rehabilitation training	50 min/2 times per wk/8 wk/16/100 min	Kinect sensor (Microsoft Corp)

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Reference			Participant characteristics			Intervention protocol		
Authors	Country, Language	Diagnostic criteria	Hoehn-Yahr classification	N, male/female	Age	Method	Session duration/frequency/period/# sessions/duration of VR[a] treatment per week	Platform
Yang et al [36]	Taiwan, English	UK-PDSBB	Total: 2-3	EG: 11, 7/4; CG: 12, 7/5	EG: 75.4 (SD 6.3); CG: 72.5 (SD 8.4)	EG: VR training; CG: routine rehabilitation training	50 min/2 times per wk/6 wk/12/100 min	VR balance training system included a 22-inch all-in-one touchscreen computer (Micro-Star International Co Ltd) and a wireless balance board
Ozgonenel et al [40]	Istanbul, English	Clinical diagnosis	Total: 1-3	EG: 15, 10/5; CG: 18, 12/6	EG: 64; CG: 65	EG: VR training + routine rehabilitation training (NR); CG: balance rehabilitation training	20 min/3 times per wk/5 wk/15/60 min	Xbox (Microsoft Corp)
Gandolfi et al [38]	Italy, English	UK-PDSBB	Total: 1-3	EG: 38, 23/15; CG: 38, 28/10	EG: 67.45 (SD 7.18); CG: 69.84 (SD 9.41)	EG: VR training + balance rehabilitation training (NR); CG: sensory integration balance rehabilitation training	50 min/3 times per wk/7 wk/21/150 min	Wii Fit gaming system and balance board (Nintendo Co Ltd)
Ribas et al [43]	Brazil, English	UK-PDSBB	Total: 2-3	EG: 10, 4/6; CG: 10, 4/6	EG: 61.7. (SD 6.83); CG: 60.20 (SD 11.29)	EG: VR training; CG: routine rehabilitation training	30 min/2 times per wk/12 wk/24/60 min	Wii Fit gaming system, and balance board (Nintendo Co Ltd)
Santos et al [39]	US, English	UK-PDSBB	EG: 1.4 (SD 0.6); CG: 1.3 (SD 0.3)	EG: 13; CG: 14	EG: 61.7 (SD 7.3); CG: 64.5 (SD 9.8)	EG: VR training; CG: routine rehabilitation training	50 min/2 times per wk/8 wk/16/100 min	Wii Fit gaming system and balance board (Nintendo Co Ltd)
Feng et al [42]	China, English	UK-PDSBB	EG: 3.03 (SD 0.55); CG: 2.97 (SD 2.66)	EG: 14, 8/7; CG: 14, 9/6	EG: 67.47 (SD 4.79); CG: 66.93 (SD 4.64)	EG: VR training + medication; CG: routine rehabilitation training + medication	45 min/5 times per wk/12 wk/60/225 min	NR
Tollár et al [49]	UK, English	UK-PDSBB	EG: 2.3 (SD 0.48); CG: 2.4 (SD 0.51)	EG: 25, 12/13; CG: 25, 11/14	EG: 70.0 (SD 4.69); CG: 70.6 (SD 4.10)	EG: VR training + medication; CG: routine rehabilitation training + medication	60 min/5 times per wk/5 wk/25/300 min	EXE[g] used the following 3 visual feedback modules of the Xbox 360 core system (Kinect Adventures, Microsoft Corp)

[a]VR: virtual reality.

[b]EG: experiment group.

[c]CG: control group.

[d]MDS-PD: Movement Disorder Society clinical diagnostic criteria for Parkinson disease.

[e]UK-PDSBB: United Kingdom Parkinson Disease Society Brain Bank criteria.

[f]NR: no report.

[g]EXE: exergame.

Methodological Quality

The results of methodological assessment are shown in Table 2, with scores ranging from 5 to 8 and an average score of 6.56. Specifically, the most common methodological flaw in these studies was that there was no allocation concealment. Due to the difficulty in conducting blind training in VR training and routine rehabilitation training, most of the included studies did not implement subject blindness, therapist blindness, or evaluator blindness.

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Table 2. Study quality assessment of eligible studies.

Author	Eligibility criteria	Randomization	Concealed allocation	Similar baseline	Blinding of participants	Blinding of instructors	Blinding of assessors	Retention >85%	Intent-to-treat analysis	Between-group comparison	Point measure and measures of variability	Sum score
Chen et al [33]	1[a]	1	0[b]	1	0	0	0	1	0	1	1	6
Cheng et al [47]	1	1	0	1	0	0	0	0	0	1	1	5
Sun et al [46]	1	1	0	1	0	0	0	1	0	1	1	6
Lin et al [48]	1	1	0	1	0	0	1	1	0	1	1	7
Liu et al [45]	1	1	0	1	0	0	0	1	0	1	1	6
Pompeu et al [35]	1	1	0	1	0	0	1	1	0	1	1	7
Van et al [34]	1	1	1	1	0	0	1	0	0	1	1	7
Lee et al [37]	1	1	0	0	0	0	1	0	0	1	1	5
Shih et al [41]	1	1	1	1	1	0	0	1	0	1	1	8
Yang et al [36]	1	1	1	0	0	0	1	1	1	1	1	8
Ozgonenel et al [40]	1	1	0	1	1	0	0	0	0	1	1	6
Gandolfi et al [38]	1	1	0	1	0	0	1	1	0	1	1	7
Ribas et al [43]	1	1	0	1	0	0	0	1	0	1	1	6
Santos et al [39]	1	1	1	1	0	0	0	1	0	1	1	7
Feng et al [42]	1	1	0	1	0	0	0	1	0	1	1	6
Tollár et al [49]	1	1	1	1	1	0	0	1	0	1	1	8

[a]Explicitly described and present in details.

[b]Absent, inadequately described, or unclear.

Effect Of VR Training on Improving PD Balance Ability

A total of 16 studies investigated the effects of VR training on improving PD balance ability. These data were analyzed for random effects to combine the results. Figures 2 and 3 illustrate the effects of VR balance training on balance. The meta-analysis results showed that SMD 2.13, 95% CI 1.20 to 3.05, $P<.001$ (see Figure 2). This indicates the balance ability of PD was significantly improved after VR training compared with the control group. The Egger test results found no significant publication bias (Egger regression intercept 10.69691, $P<.001$, $df=15$). However, results of funnel plots showed that three studies [49] exhibited asymmetry. That is, the included studies may have publication bias (see Figure 3). It is worth noting that the interstudy heterogeneity was very high, the value of I^2 with over 75% ($I^2=95.1$, $P<.001$).

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Figure 2. Forest plot for balance. SMD: standardized mean difference.

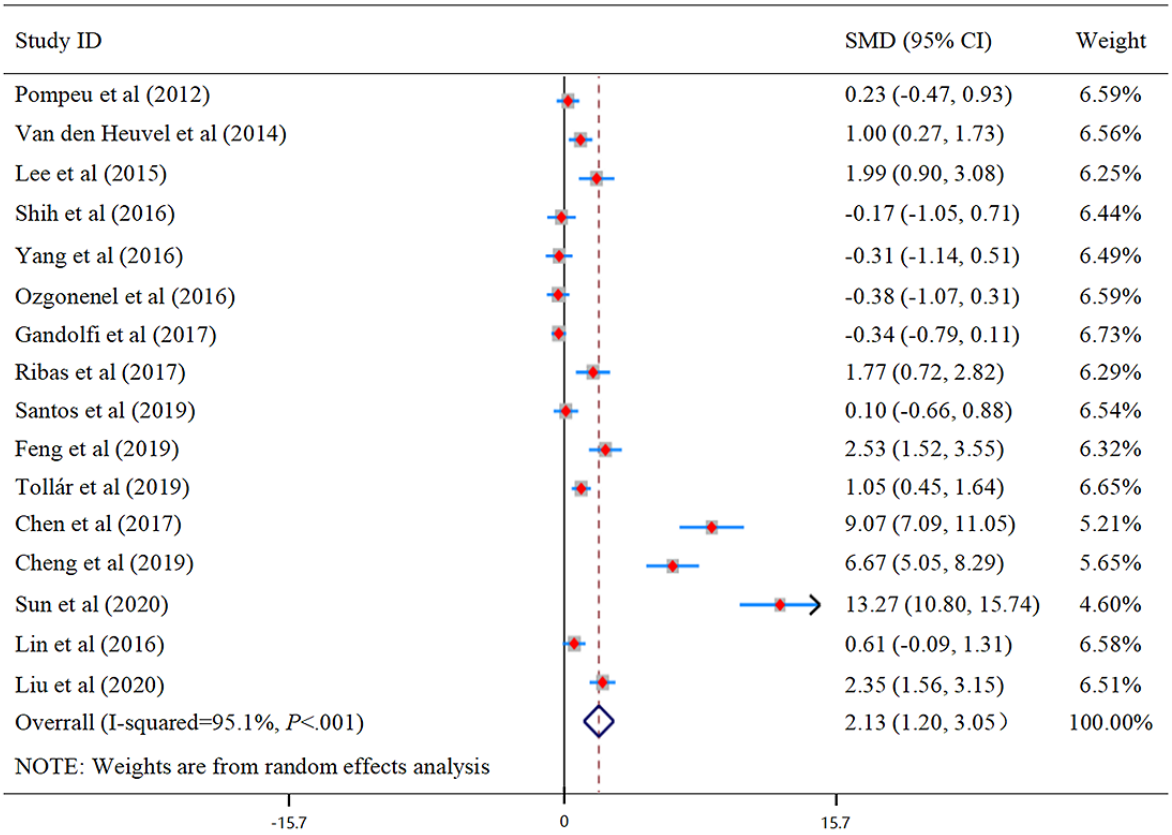
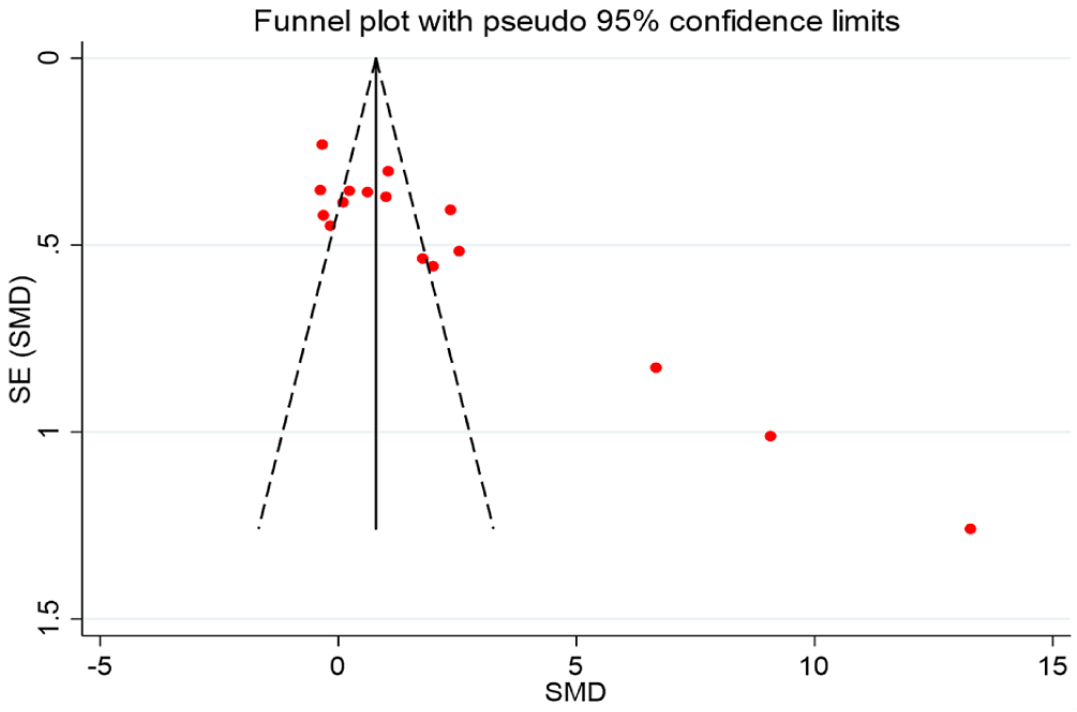


Figure 3. Funnel plot for balance. SMD: standardized mean difference.



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Moderating Variable Analysis: Impact of Premode and Intervention Platform

We conducted subgroup analysis on intervention modes and intervention platforms (excluding one study [49] that did not report VR equipment) to clarify the regulatory effect of these 2 variables on PD balance ability. Subgroup analysis showed that training methods had great influence on balance ability. It is worth noting that intervention platform may be the main reason for heterogeneity, as subgroup analysis of the VR rehabilitation and commercial game VR platforms found that the heterogeneity of VR rehabilitation platforms (I^2=96.8%) was very large, while that of commercial game VR reality platforms was relatively small; however, there was no significant difference in the improvement of PD balance ability of commercial game VR platforms (SMD 0.447, 95% CI 0.03 to 0.898), which may be the reason for the different conclusions in the previous review. Nevertheless, due to the lack of research on VR rehabilitation platforms, this result should be treated with caution (Table 3).

Table 3. Results of the overall balance subgroup analyses on the influence of intervention method and intervention platform on virtual reality training in Parkinson disease.

Independent training modality	SMD[a]	95% CI	*z* value (*P* value)	I^{2b} (%)	*df*	*P* value between groups
Intervention method						
Virtual reality mixed physical rehabilitation methods	2.64	0.699 to 4.588	2.66	96.8	5	<.001
Virtual reality	1.83	0.795 to 2.872	3.46	93.5	9	<.001
Intervention platform						
Virtual rehabilitation platform	7.75	3.134 to 12.365	3.29	97.1	3	<.001
Commercial gaming virtual reality platform	0.45	–0.0.3 to 0.898	1.95	76.2	10	<.001

[a]SMD: standardized mean difference.

[b]I^2: heterogeneity between studies.

Impact of VR Balance Training and the Dose-Effect Relationship

In order to explore the optimal training variables, this study first conducted a meta-regression to explore the effect of a training program on the effectiveness of PD balance. In addition to meta-regression (Table 3), subgroup analysis was conducted to preliminarily analyze the effect size of each training program subgroup and presented for the preliminary analysis of dose response relationships (Table 4).

Table 4. Results for the subgroup analyses on the effects of different categories of respective training volume on balance ability.

Training volume	Coefficient	SE	95% CI	*z* value	2-sided *P* value
Training period	–0.0558	0.2075	–0.4626 to 0.3509	–0.27	.79
Training frequency	1.9711	3.4458	–4.7826 to 8.7248	0.57	.57
Number of sessions	0.4613	1.3035	–2.0935 to 3.0162	0.35	.72
Single session duration	–0.1145	0.3182	–0.7381 to 0.5091	0.36	.72
Total duration per week	–2.1933	0.0572	–0.1167 to 0.1077	–0.08	.94

Meta-Regression Analysis of Volume of VR Balance Training

Due to the low number of studies, we performed meta-regression only for the subcategory training volume. The regression analysis revealed that no variable within the training volume subcategory (single training duration, training frequency, total number of training sessions, weekly training duration, total training duration) produced significant effects (*P*=.57 to .94) on the ability of improving balance level. That is, in the included studies, we could not use time or number of training sessions to predict the ability of improving balance level (see Table 4).

Dose-Effect Relationship of VR Balance Ability

Single Training Time

A total of 13 studies were included in this subanalysis, and the time range of single training from 0 to 20 minutes produced large effects on balance, with SMD of 6.446 (95% CI –1.098 to 13.990; *z*=1.67; I^2=98%; *df*=2; see Table 5).

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Table 5. Results for the subgroup analyses on the effects of different categories of respective training volume on overall balance.

Independent training modality	SMD[a]	95% CI	*z* value (*P* value)	I^{2b} (%)	*df*	*P* value between groups
Single training time						
0-20 min	6.446	–1.098 to 13.990	1.67 (.094)	98.7	2	<.001
21-40 min	1.050	0.122 to 1.979	2.22 (.027)	89.4	5	<.001
41-60 min	1.644	0.378 to 2.910	2.54 (.011)	93.6	6	<.001
Training frequency						
1-3 sessions per week	0.770	–0.060 to 1.600	1.82 (.069)	90.6	8	<.001
4-6 sessions per week	4.067	2.223 to 5.911	4.32 (<.001)	96.1	6	<.001
Training period						
3-5 weeks	2.478	0.893 to 4.063	3.06 (.002)	95.9	5	<.001
6-8 weeks	1.917	0.515 to 3.320	2.68 (.007)	95.5	7	<.001
9-12 weeks	2.166	1.417 to 2.914	5.67 (.001)	5.30	1	<.001
Total number of training sessions						
10-20 sessions	0.844	–0.210 to 1.898	1.57 (.117)	91.4	6	<.001
21-30 sessions	2.638	1.003 to 4.272	3.16 (.002)	96.5	5	<.001
＞30 sessions	4.405	1.102 to 7.707	2.61 (.009)	95.0	2	<.001
Total duration of VR[c] training per week						
0-100 min	2.313	0.671 to 3.955	2.76 (.006)	96.1	7	<.001
101-200 min	1.079	0.046 to 2.112	2.05 (.041)	90.6	4	<.001
201-300 min	4.059	0.738 to 7.379	2.40 (.017)	96.7	2	<.001

[a]SMD: standardized mean difference.

[b]I^2: heterogeneity between studies.

[c]VR: virtual reality.

Training Frequency

The training frequency was 1 to 6 sessions per week in the 14 studies, and the result showed the SMD for 4 to 6 sessions per week was 4.067 (95% CI 2.223 to 5.911; z=4.32 ; I^2=96.1%; *df*=7), indicative of large effects (see Table 5).

Training Period

In 13 studies, during the training period, a time under training of 3 to 5 weeks with SMD of 2.478 appears most effective compared other training period (95% CI 0.893 to 4.063; z=3.03; I^2=95.9%; *df*=5) in this subanalysis (see Table 5).

Total Number of Training Sessions

Based on data from 13 studies, we computed the effect of total number of training sessions (range: 10 to 20 sessions, 21 to 30 sessions, ＞30 sessions) of VR training for balance ability. Above 30 sessions in total, with SMD of 4.405 is the most effective for balance ability (95% CI 1.102 to 7.707; z=2.61; I^2=95.0%; *df*=2; see Table 5).

Total Duration of VR Training per Week

In 14 studies, we also computed the effect of total duration of VR training per week (range 0 to 100 minutes, 101 to 200 minutes, 201 to 300 minutes). The largest effect was shown for 201 to 300 minutes of training per week (SMD 4.059; 95% CI 0.738 to 7.379; z=2.40; I^2=96.7%; *df*=2; see Table 5).

Discussion

Summary

In this study, we examined the effect of VR technology on improving PD balance ability. Data analysis of 16 RCTs showed that (1) VR technology has a significant impact on the improvement of PD balance ability, (2) different VR platforms may have different effects on PD balance and the effect of rehabilitation platforms is superior to commercial platforms, and (3) variability in training methods cannot predict the effect of VR training on PD balance ability.

Impact of VR on PD Balance Ability

VR can provide visual and auditory feedback to PD patients, thereby minimizing the lack of movement caused by internal prompts due to reduced dopamine consumption [49]. In addition, the real-time feedback provided by VR platforms may also facilitate the movement process [50]. PD, by contrast, shows insufficient interaction between vestibular and proprioceptive systems, leading to changes in human biomechanics that affect balance. The visual and auditory input provided by VR can therefore effectively integrate the feedback of vestibular

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receptors and proprioceptive receptors in PD patients, improving PD balance ability [51]. VR training has been shown to stimulate the integration of PD-related cognitive functions such as attention and executive ability, as well as stimulate the reward mechanism of the brain. Moreover, success in alleviating PD symptoms using VR training requires attention, sensory integration, and treatment of stimuli in VR environments and may be more effective than traditional rehabilitation programs [52,53]. A functional near-infrared spectroscopy study found that VR training increases the blood oxygen concentration in the prefrontal cortex of the brain, indicating that prefrontal cortex is involved in VR balance task and degree of activation is modulated by VR task difficulty [54].

Long-term physical therapy is also beneficial for PD. Due to the incentive stimulation of VR technology, it can maintain motivation during the long-term rehabilitation process and improve compliance so as to reduce the negative impacts during the rehabilitation process [55]. In addition, studies have indicated that VR balance training and traditional interventions can increase the muscle strength and balance ability of patients with anterior cruciate ligament injury [56], as well as improve coordination and reflex conduction [57]. However, due to the fact that the measurement methods are not often very precise, it is difficult to find optimal balance points between the two.

Moderating Effect

Our subgroup analyses of intervention methods and intervention platforms found no statistically significant difference between intervention methods, nor did heterogeneity decrease significantly. However, we found VR rehabilitation platforms to be significantly heterogeneous, and the commercial game VR platform's I^2 reduced to 71.2%, which may be the main source of heterogeneity in this study. It should also be noted that we found no statistically significant effect of VR platform training of commercial games; that is, the effects of VR training and traditional rehabilitation training on PD balance ability were similar, which is consistent with previous research results [22]. We therefore conclude that the VR platform itself may be one of the reasons for the inconsistency of previous results, although a small sample size means that this result should also be treated with caution.

Although commercial systems such as Wii are now included in the neurorehabilitation program [58], such commercial games are not personalized and do not allow precise interactions between individuals and VR environments [58]. Furthermore, the overall safety and clinical nature of sports-based computer games have not been fully confirmed [52]. In addition, VR device design may not be optimized for PD, which may damage the experience and safety of PD patients [52].

Impact of VR Training and the Dose-Effect Relationship

As discussed previously, VR balance training is of great benefit to PD patients. Our results showed that no particular training method could predict the effect of VR balance training on PD balance performance. With the exception of meta-regression, subgroup analysis was conducted for each training program to explore the magnitude of the effect of a specific subgroup.

In addition to meta-regression, subgroup analysis was conducted for each training program to explore the magnitude of the effect of a specific subgroup and explain the effect of the amount of certain subgroups. The most successful VR training program to enhance PD balance was a single training duration of 0 to 20 minutes, 4 to 6 times a week, training for 3 to 5 weeks, training course reached more than 30 times, 201 to 300 minutes per week. However, this study only provides a preliminary analysis of the dose-response relationship through subgroup analysis and should be more widely explored in future research.

Limitations

The biggest limitation of this study is that there was considerable heterogeneity across studies (ie, I^2=95.1%). Even if subgroup analysis was performed to observe the underlying causes of heterogeneity, the results should be treated with caution. Another limitation is that due to the limited number of available studies, there were data from only 16 RCTs, and the intervention plans included in the study varied widely, making it difficult for subgroup analyses to provide a clear picture of the dose-response relationship. Moreover, due to the fact that the BBS scale is assessed manually, there may be a degree of error in the balance ability data.

Conclusion

The systematic review and meta-analysis confirmed that VR balance training is a highly effective means to improve balance performance with large effects in PD. In addition, we preliminarily extracted dose-effect relationships for training volume, informing clinicians and practitioners to design effective VR balance training for balance ability. Future studies should particularly focus on the detailed description of training variables, so as to further analyze the dose-effect relationship of VR balance training in PD.

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Authors' Contributions

JW, H Zhang, and ZR contributed to the conception and design of the review. JW, RF, and HY applied the search strategy. JW, H Zhang, and ZC applied the selection criteria. JW and ZR completed assessment of risk of bias. JW and H Zhang analyzed and interpreted the data. JW wrote the manuscript. RF and H Zeng edited this manuscript. ZR is responsible for the overall project.

Conflicts of Interest

None declared.

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Abbreviations

BBS: Berg Balance Scale
MDS-PD: Movement Disorder Society Clinical Diagnostic Criteria for Parkinson disease
PD: Parkinson disease
PEDro scale: Physiotherapy Evidence Database
RCT: randomized controlled trial
SMD: standardized mean difference
UK-PDSBB: United Kingdom Parkinson Disease Society Brain Bank
VR: virtual reality

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Review

The Effectiveness and Safety of Serious Games for Improving Cognitive Abilities Among Elderly People With Cognitive Impairment: Systematic Review and Meta-Analysis

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Abstract

Background: Cognitive impairment is a mental disorder that commonly affects elderly people. Serious games, which are games that have a purpose other than entertainment, have been used as a nonpharmacological intervention for improving cognitive abilities. The effectiveness and safety of serious games for improving cognitive abilities have been investigated by several systematic reviews; however, they are limited by design and methodological weaknesses.

Objective: This study aims to assess the effectiveness and safety of serious games for improving cognitive abilities among elderly people with cognitive impairment.

Methods: A systematic review of randomized controlled trials (RCTs) was conducted. The following 8 electronic databases were searched: MEDLINE, Embase, CINAHL, PsycINFO, ACM Digital Library, IEEE Xplore, Scopus, and Google Scholar. We also screened reference lists of the included studies and relevant reviews, as well as checked studies citing our included studies. Two reviewers independently carried out the study selection, data extraction, risk of bias assessment, and quality of evidence appraisal. We used a narrative and statistical approach, as appropriate, to synthesize the results of the included studies.

Results: Fifteen studies met the eligibility criteria among 466 citations retrieved. Of those, 14 RCTs were eventually included in the meta-analysis. We found that, regardless of their type, serious games were more effective than no intervention (P=.04) and conventional exercises (P=.002) for improving global cognition among elderly people with cognitive impairment. Further, a subgroup analysis showed that cognitive training games were more effective than no intervention (P=.05) and conventional exercises (P<.001) for improving global cognition among elderly people with cognitive impairment. Another subgroup analysis demonstrated that exergames (a category of serious games that includes physical exercises) are as effective as no intervention and conventional exercises (P=.38) for improving global cognition among elderly people with cognitive impairment. Although some studies found adverse events from using serious games, the number of adverse events (ie, falls and exacerbations of pre-existing arthritis symptoms) was comparable between the serious game and control groups.

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Conclusions: Serious games and specifically cognitive training games have the potential to improve global cognition among elderly people with cognitive impairment. However, our findings remain inconclusive because the quality of evidence in all meta-analyses was very low, mainly due to the risk of bias raised in the majority of the included studies, high heterogeneity of the evidence, and imprecision of total effect sizes. Therefore, psychologists, psychiatrists, and patients should consider offering serious games as a complement and not a substitute to existing interventions until further more robust evidence is available. Further studies are needed to assess the effect of exergames, the safety of serious games, and their long-term effects.

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KEYWORDS

serious games; cognitive training; exergames; mild cognitive impairment; Alzheimer disease; dementia; global cognition; systematic review; meta-analysis

Introduction

Background

Societies globally are rapidly aging at unprecedented rates. The United Nations projects that by 2050, 1 in 6 people in the world will be over the age of 65 years [1]. The aging population requires special care and attention due to the emergence of several progressive complex health issues, including hearing loss, vision impairments, physical ailments, noncommunicable diseases (diabetes), and mental and cognitive disorders [2]. With the growing size of the geriatric population, the World Health Organization has recommended the prevention of cognitive decline to be ranked as a global mental health priority [3].

Unfortunately, declining mental and cognitive abilities not only affect people and their relatives but also burden health care systems. Among the top chronic diseases causing the progressive decline and deterioration of cognitive abilities are mild cognitive impairment (MCI), Alzheimer disease (AD), and dementia. Globally, it is estimated that the number of prevalent dementia cases more than doubled (117%) between 1990 and 2016 [4]. Moreover, globally, it has been estimated that there are about 40 million people aged over 65 years who have dementia, and AD affects about 70% of them [5]. Therefore, preventing and managing age-related cognitive abilities and functions are important public health issues.

Research suggests that cognitive symptoms experienced by people with declining or deteriorating cognitive abilities are often associated or even preceded by behavioral symptoms. Therefore, treatments for improving cognitive functions and abilities often cannot be separated from behavioral treatments [6], and the treatments include pharmacological and nonpharmacological interventions. If implemented effectively, nonpharmacological interventions, such as lifestyle, good nutrition, exercise, and serious games, can delay the onset of dementia and cognitive decline [7-10]. Serious games are defined as games that have a purpose other than entertainment, such as education, prevention, screening, diagnosing, and therapeutic rehabilitation [11-13]. With the ubiquity and accessibility of technology and handheld devices, these serious games have been integrated into personal computers, game consoles (eg, Xbox), and, more recently, smartphones and tablets [3]. This review focused on digital serious games that are used as a therapeutic rehabilitation. Serious games exist in a variety of formats based on the therapeutic modality, including (1) cognitive training games that aim to maintain or improve users' cognitive functions, such as working memory and attention; (2) exergames, or video games that entail physical exercises (eg, balance exercises) as part of the intended gameplay; (3) computerized cognitive behavioral therapy (CBT) games, which are video games that provide CBT for the users; and (4) biofeedback games, which are video games that utilize electrical sensors attached to the participant to receive information about the participant's body state (eg, electrocardiogram sensors) and seek to influence some of the player body's functions (eg, heart rate). Previous systematic reviews have shown that serious games have the potential to prevent or alleviate mental disorders such as depression [14] and anxiety [15]. Further, the literature suggests that serious games can be a good mental stimulant and improve brain health through the use of memory, visualization, and motor skills [16].

Research Gap and Aim

Numerous prior studies have investigated the effectiveness of serious games for improving cognitive abilities. Aggregating and summarizing the findings from these studies is crucial for drawing conclusions about the effectiveness of serious games for improving cognitive abilities. Several systematic reviews have aggregated evidence from these studies; however, they are undermined by certain shortcomings that limit the generalization of the findings. Specifically, these reviews (1) focused on older adults who did not have cognitive impairment [3,17,18]; (2) included pilot randomized controlled trials (RCTs) and/or quasiexperiments [18-20]; (3) conducted the search a long time ago (5 years ago) [18,19]; (4) did not assess the quality of evidence [3,18-20]; (5) did not assess the safety of serious games [17-20]; or (6) only focused on specific types of serious games, such as cognitive training games [3,19] and exergames [18,20]. To address the existing gaps in the literature, this review aims to assess the effectiveness and safety of serious games for improving cognitive abilities among elderly people with cognitive impairment.

Methods

Overview

We conducted a systematic review and meta-analysis following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Multimedia Appendix 1) [21]. The protocol for this review is registered at PROSPERO (ID: CRD42021272757).

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Search Strategy

Search Sources

The following 8 bibliographic databases were searched in order to retrieve studies that were relevant to this review: MEDLINE (via Ovid), PsycInfo (via Ovid), Embase (via Ovid), CINAHL (via EBSCO), IEEE Xplore, ACM Digital Library, Scopus, and Google Scholar. The search was conducted on August 6, 2021, by the first author (A Abd-alrazaq). In order to retrieve studies that were added to the databases after that date, an automatic alert was set up, and it ran its course for 12 weeks (ending on November 5, 2021). Due to the large number of studies retrieved on Google Scholar, only the first 10 pages (ie, 100 hits) were considered, as they are automatically ordered based on their relevance [22]. We applied backward reference list checking, which involves the screening of reference lists of the included studies and relevant reviews. Further, the studies that cited the included studies were screened (forward reference list checking).

Search Terms

For developing the search query for this review, we consulted 2 experts in digital mental health and checked the search query used in other systematic reviews within this field. The chosen search terms related to the target population (eg, cognitive impairment), target intervention (eg, serious games and exergames), and target study design (eg, RCT and clinical trial). Multimedia Appendix 2 summarizes the search query that was used for searching each of the 8 databases.

Study Eligibility Criteria

Only RCTs that assessed the effectiveness of serious games for improving cognitive abilities among elderly people with cognitive impairment were included in this study. For the purpose of this review, the target intervention was serious games that are available on digital platforms, such as computers, consoles (Xbox, PlayStation, etc), mobile phones, tablets, handheld devices, Nintendo, and other computerized devices. Further, gaming had to be an integral and primary component of the intervention and used solely for the purpose of therapy. Studies combining serious games with other interventions were eligible if the control group received the same adjacent intervention. Nondigital games and those used for other purposes, such as monitoring, screening, diagnosis, and research, were excluded.

The population of interest was elderly people (≥60 years) with cognitive impairment/disorder (eg, MCI, AD, or dementia). Their diagnosis had to be confirmed by examining the inclusion criteria or baseline scores against standardized diagnostic criteria (eg, Mini-Mental State Examination [MMSE] and Montreal Cognitive Assessment [MoCA]). Studies about healthy elderly people without cognitive impairment, health care providers, and caregivers were excluded. No restrictions were applied regarding gender and ethnicity.

The main outcome of interest in this review was global cognition regardless of the tool used for measuring the outcome. Global cognition is a general measure of all cognitive abilities such as memory, language, learning, and attention. Although behavioral outcomes relate to cognitive outcomes, behavioral outcomes are out of the scope of this review. The secondary outcome of interest was adverse events, which we used as an indicator of the safety of serious games. Studies were excluded if they assessed only cost effectiveness, acceptance, feasibility, and satisfaction. This review focused on outcome data that were measured immediately after the intervention rather than follow-up data.

All types of RCTs (parallel, cluster, crossover, or factorial) were included, but pilot or feasibility RCTs, quasiexperiments, observational studies, and reviews were excluded. For practical reasons, only those trials in the English language were eligible for inclusion. Studies published from 2010 onwards were included. Studies published as journal articles, conference proceedings, and dissertations were included. Otherwise, conference abstracts and posters, preprints, commentaries, proposals, and editorials were all excluded. No restrictions related to the country of publication, comparator, and study settings were applied.

Study Selection

Relevant studies were identified in the following steps. To begin, the obtained studies were imported into EndNote to identify and delete duplicate items. Following the PRISMA guidelines, the titles and abstracts of all retrieved studies were evaluated in the second phase by 2 reviewers working independently. Two reviewers independently evaluated the entire text of the studies included in the previous step. Any disagreements were resolved via discussion. The 2 reviewers were the first 2 authors of this paper: A Abd-alrazaq and MA. The interrater agreement (Cohen κ) in steps 2 and 3 were 0.84 and 0.89, respectively, indicating a near-perfect level of interrater agreement [23].

Data Extraction

Data from the included papers were extracted by 2 reviewers (A Abd-alrazaq and MA) independently using Microsoft Excel. Multimedia Appendix 3 outlines the data extraction form used to extract data from the included studies. Furthermore, we pilot tested the form with 2 of the included studies. Disagreements among the reviewers (A Abd-alrazaq and MA) were settled via discussion. An interrater agreement of 0.88 was observed, indicating a near-perfect degree of agreement. Contact was made with the first and corresponding authors in an attempt to retrieve metrics, such as mean, standard deviation, and sample size, if they were unavailable from the published studies.

Risk of Bias Appraisal

Cochrane Collaboration recommends assessment of the risk of bias by 2 independent reviewers using the Risk-of-Bias 2 (RoB-2) tool [24], and as such, these guidelines were followed for this review. The RoB-2 tool appraises the risk of bias in the following 5 domains in RCTs: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result [24]. The risk of bias judgments in these domains are used to determine the overall risk of bias for each included study. Any inconsistencies in decisions between the reviewers were solved via consulting a third reviewer. There was near-perfect interrater agreement between the reviewers (Cohen κ=0.81) [23].

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Data Synthesis

For the purpose of synthesizing the gathered data, a narrative and statistical approach was employed. Texts and tables were used to describe the features of the included studies (demographic, intervention, comparator, and outcome measures) in our narrative synthesis. The results of the experiments were compiled and categorized based on the comparator as follows: control, conventional exercises, conventional cognitive training, and other serious games. A meta-analysis was conducted when at least two studies of the same comparator submitted enough data (ie, mean, standard deviation, and number of participants in each intervention group). Meta-analyses were conducted using Review Manager (RevMan 5.4). The standardized mean difference (SMD) (Cohen *d*) was used to assess the overall effect of each study, as the type of data for the outcome of interest (global cognition) was continuous and the instruments used to evaluate the outcome were diverse among the included trials. Due to the high clinical heterogeneity between the meta-analyzed studies in terms of serious game characteristics (eg, its types, duration, frequency, and period), population characteristics (eg, sample size, mean age, and health condition), and outcome measures (ie, tools and follow-up period), the random effects model was used for the analysis.

If we observed a statistically significant difference between groups when a meta-analysis was conducted, we further sought to examine if it was clinically significant. The term "minimal clinically important difference" (MCID) refers to the smallest change in a measured outcome that a patient would consider worthwhile and significant enough to merit a change in treatment. The MCID bounds were computed as ±0.5 times the meta-analyzed studies' SMD.

In order to examine the degree and statistical significance of heterogeneity in the meta-analyzed studies, we calculated I^2 and the chi-square *P* value, respectively. A chi-square *P* value of .05 or less suggests heterogeneous meta-analyzed studies [25]. When I^2 ranged from 0% to 40%, 30% to 60%, 50% to 90%, and 75% to 100%, the degree of heterogeneity was judged as insignificant, moderate, substantial, and considerable, respectively [25].

In order to assess the overall quality of evidence resulting from the meta-analyses, we used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach [26]. The GRADE approach appraises the quality of evidence based on the following 5 domains: risk of bias, inconsistency (ie, heterogeneity), indirectness, imprecision, and publication bias [26]. Two reviewers assessed the overall quality of the meta-analyzed evidence, and differences in decisions were addressed by discussion. There was near-perfect interrater agreement among the reviewers (Cohen κ=0.92) [23].

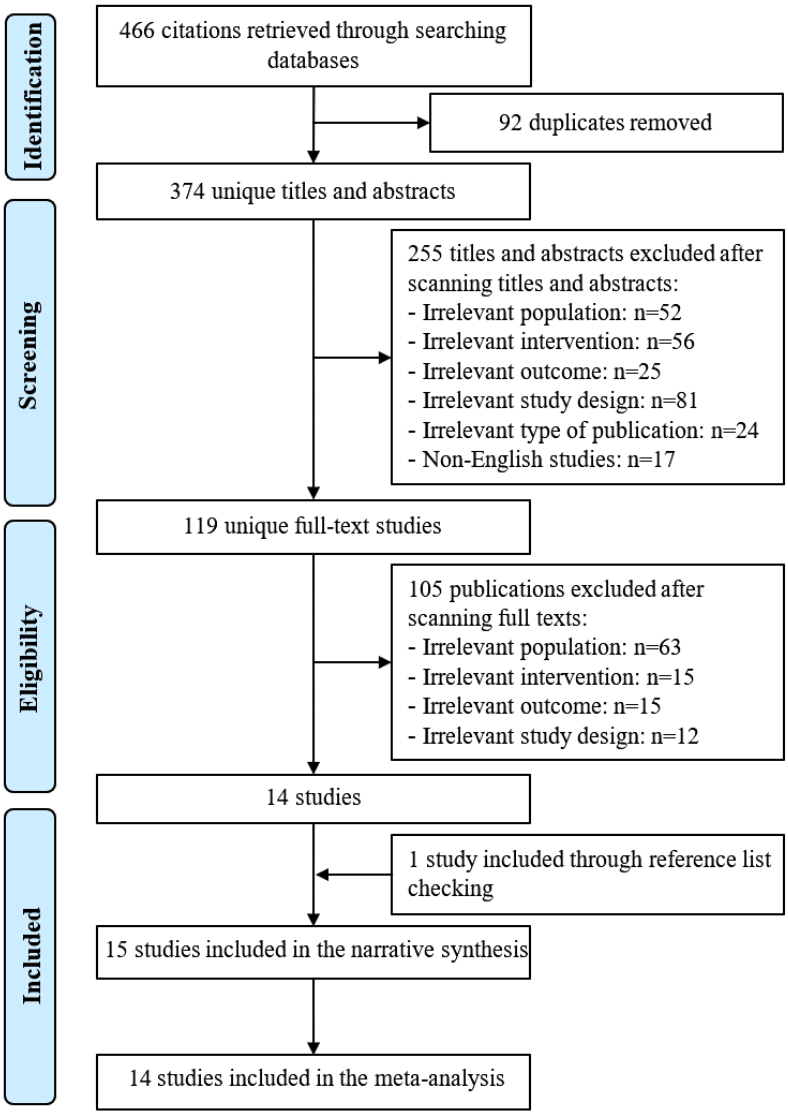
Results

Search Results

By searching the 7 electronic databases, 466 records were retrieved (Figure 1). Of these records, 92 duplicates were identified using the software EndNote and were excluded. Checking titles and abstracts of the remaining articles led to the exclusion of 255 records for the following reasons: (1) participants were younger than 60 years and/or without cognitive impairment (n=52); (2) interventions were not serious games (n=56); (3) the outcome was not global cognition (n=25); (4) the study design was not RCT (n=81); (5) studies were not peer-reviewed articles, theses, or conference proceedings (n=24); and (6) the articles were published in languages other than English (n=17). Reading the full text of the remaining 119 publications led to the exclusion of 105 publications for the following reasons: (1) participants were younger than 60 years and/or without cognitive impairment (n=63); (2) interventions were not serious games (n=15); (3) the outcome was not global cognition (n=15); and (4) study design was not RCT (n=12). One additional study was found through backward reference list checking. In total, 15 RCTs were included in the current review [27-41]. All studies were included in meta-analyses, except 1 study [41].

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Figure 1. Flow chart of the study selection process.



Characteristics of the Included Reviews

The included studies were published between 2013 and 2021 (Table 1). The year in which the largest number of included studies were published was 2020 (n=3). The included studies were conducted in 13 different countries, and there was a general equal distribution of studies in these countries. All included studies were peer-reviewed journal articles, except for 1 book chapter included. The trial type used in most included studies was parallel RCT (n=13).

The sample size in the included studies ranged from 20 to 114, with an average of 70.4. The mean age of participants reported in 14 studies ranged between 67 and 84.2 years, with an average of 75.2 years. The percentage of males reported in 14 studies ranged from 23.5% to 70%, with an average of 44.5%. The mean MMSE score for participants in the included studies varied between 10.2 and 27. Participants in the included studies had MCI (n=10), AD (n=2), dementia (n=1), MCI and dementia (n=1), and neurocognitive disorders (n=1). Participants were recruited from clinical settings in 13 studies and the community in 2 studies.

Serious games alone were used as interventions in 13 of the included studies, whereas the remaining 2 studies used serious games combined with other interventions (Table 2). The included studies used 19 different serious games. Some studies used more than one game. Serious games used in the included studies were grouped into the following 2 types based on the therapeutic modality that they delivered: cognitive training games (n=12) and exergames (n=3). Games were designed with a “serious” purpose from the beginning (designed serious games) in 14 studies. However, in the remaining study, games were not designed as serious games from the start but rather were used for a serious purpose (purpose-shifted games). The most common platforms used for playing the games were computers (n=8). Serious games were played under the supervision of health care providers or caregivers in 9 studies, but were not played under any supervision in 3 studies. In the remaining studies, the serious games were both supervised as well as unsupervised. The duration of the games in the included studies ranged between 25 and 100 minutes, with a 30-minute duration in one-third of the included studies (n=5). The frequency of playing the games varied between 2 times a week and 5 times a week, but it was 2 times a week in about half of the studies

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(n=8). The period of interventions ranged from 4 weeks to 25 weeks, but was less than 13 weeks in two-thirds of the studies (n=10).

The comparison groups received passive interventions in 9 studies, whereas active interventions were received in 8 studies (eg, conventional exercises and conventional cognitive activities) (Table 3). Two studies delivered both active and passive interventions as comparators. The duration of the active comparators ranged between 25 and 100 minutes. The frequency of the active comparators varied between 1 time a week and 7 times a week. The period of the active comparators varied between 6 weeks and 25 weeks. The outcome of interest (ie, global cognition) was measured using 7 different tools, but the most common tool used by the included studies was the MMSE (n=11). The outcome of interest was measured immediately after the intervention in all included studies, and the longest follow-up period was 24 weeks. Participant attrition was reported in 14 studies and ranged from 0 to 28.

Table 1. Characteristics of the studies and population.

First author	Year	Country	Publication type	RCT[a] type	Sample size, n	Mean age (years)	Sex (male), %	MMSE[b] score	Health condition	Setting
Savulich [27]	2017	United Kingdom	Journal article	Parallel	42	76.1	59.5%	26.7	MCI[c]	Clinical
Yang [28]	2017	South Korea	Journal article	Parallel	20	71	70%	23.1	AD[d]	Clinical
Tarnanas [29]	2014	Greece	Book chapter	Parallel	114	70.3	39%	26.4	MCI	Clinical
Cavallo [30]	2016	Italy	Journal article	Parallel	80	76.4	36.3%	22.9	AD	Clinical
Zhuang [31]	2013	China	Journal article	Parallel	33	83.1	24.2%	10.2	MCI, dementia	Clinical
Thapa [32]	2020	South Korea	Journal article	Parallel	68	72.7	23.5%	26.2	MCI	Clinical
Jahouh [33]	2021	Spain	Journal article	Parallel	80	84.2	44%	22.2	MCI	Clinical
Robert [34]	2020	France	Journal article	Parallel	46	79.4	47.8%	21.4	Cognitive disorders	Clinical
Singh [35]	2014	Australia	Journal article	Factorial	100	70.1	32%	27	MCI	Community
van Santen [36]	2020	Netherlands	Journal article	Cluster	112	79	53.5%	18.6	Dementia	Clinical
Liao [37]	2021	Taiwan	Journal article	Parallel	61	81.5	32.6%	22.9	MCI	Community
Amjad [38]	2019	Pakistan	Journal article	Parallel	44	NR[e]	NR	24	MCI	Clinical
Hagovská [39]	2015	Slovakia	Journal article	Parallel	80	67	51.2%	26	MCI	Clinical
Hagovská [40]	2016	Slovakia	Journal article	Parallel	80	67	51.2%	26.4	MCI	Clinical
Gooding [41]	2015	United States	Journal article	Parallel	96	75.6	58.1%	NR	MCI	Clinical

[a]RCT: randomized controlled trial.

[b]MMSE: Mini-Mental State Examination.

[c]MCI: mild cognitive disorder.

[d]AD: Alzheimer disease.

[e]NR: not reported.

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Table 2. Characteristics of the interventions.

First author	Intervention	Serious game name	Serious game type	Platform	Supervision	Duration (min)	Frequency (times/week)	Period (weeks)
Savulich [27]	Serious games	Game Show	Cognitive training game	Tablet	Supervised	60	2	4
Yang [28]	Serious games	Brain-Care	Cognitive training game	PC	Unsupervised	60	2	12
Tarnanas [29]	Serious games	Virtual Reality Museum	Cognitive training game	VR[a] headset	Supervised	90	2	21
Cavallo [30]	Serious games	Brainer	Cognitive training game	PC	Supervised	30	3	12
Zhuang [31]	Serious games	NR[b]	Cognitive training game	PC	Supervised	75	3	24
Thapa [32]	Serious games	Juice making, Crow Shooting, Love house, Fireworks	Cognitive training game	VR headset, hand controllers	Supervised	100	3	8
Jahouh [33]	Serious games	Step, Nodding	Exergame	Wii console	Supervised	40-45	2-3	8
Robert [34]	Serious games	MeMo	Cognitive training game	PC, tablet	Unsupervised	30	4	12
Singh [35]	Serious games	COGPACK	Cognitive training game	PC	Supervised	75	2	25
van Santen [36]	Serious games	NR	Exergame	Stationary bike, screen	Unsupervised	NR	5	25
Liao [37]	Serious games	Tano and LongGood	Exergame	Kinect, VR headset	Supervised	60	3	12
Amjad [38]	Serious games	Body and Brain Exercises	Cognitive training game	Xbox console, Kinect	Supervised	25-30	5	6
Hagovská [39]	Serious games + conventional exercises	CogniPlus	Cognitive training game	PC	Both	30	2	10
Hagovská [40]	Serious games + conventional exercises	CogniPlus	Cognitive training game	PC	Both	30	2	10
Gooding [41]	Serious game	BrainFitness	Cognitive training game	PC	Both	60	2	17

[a]VR: virtual reality.

[b]NR: not reported.

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Table 3. Characteristics of comparators and outcomes.

First author	Comparator	Duration (min)	Frequency (times/week)	Period (weeks)	Outcome measures	Follow-up	Attrition, n
Savulich [27]	Control	N/A[a]	N/A	N/A	MMSE[b]	Postintervention	0
Yang [28]	Control	N/A	N/A	N/A	MMSE, CDR[c]	Postintervention	0
Tarnanas [29]	Control, conventional cognitive activities	90	2	21	MMSE	Postintervention	9
Cavallo [30]	Control	30	3	12	MMSE	Postintervention, 24-week follow-up	4
Zhuang [31]	Control	N/A	N/A	N/A	ACE-R[d]	Postintervention	10
Thapa [32]	Control	30-50	1	8	MMSE	Postintervention	2
Jahouh [33]	Control	N/A	N/A	N/A	MMSE, GDS[e]	Postintervention	NR[f]
Robert [34]	Control	N/A	N/A	N/A	MMSE	Postintervention, 12-week follow-up	3
Singh [35]	1: Conventional exercises + sham cognitive training 2: Serious games + conventional exercises 3: Control	1: 75 2: 100 3: 60	2	25	ADAS-Cog[g]	Postintervention, 74-week follow-up	14
van Santen [36]	Conventional exercises	N/A	5	25	MMSE	Mid-intervention, Postintervention	28
Liao [37]	Conventional exercises	60	3	12	MoCA[h]	Postintervention	15
Amjad [38]	Conventional exercises	25-30	5	6	MMSE, MoCA	Postintervention	6
Hagovská [39]	Conventional exercises	30	7	10	MMSE	Postintervention	2
Hagovská [40]	Conventional exercises	30	7	10	ACE	Postintervention	2
Gooding [41]	Empirically validated serious game, commercially available serious game	60	2	17	MMSE + WAIS-R[i]	Postintervention	22

[a]N/A: not applicable.

[b]MMSE: Mini-Mental State Examination.

[c]CDR: Clinical Dementia Rating Scale.

[d]ACE-R: Addenbrooke Cognitive Examination-Revised.

[e]GDS: Global Deterioration Scale.

[f]NR: not reported.

[g]ADAS-Cog: Alzheimer Disease Assessment Scale-Cognitive.

[h]MoCA: Montreal Cognitive Assessment.

[i]WAIS-R: Wechsler Adult Intelligence Scale-Revised.

Results of Risk of Bias Appraisal

Seven included studies generated an appropriate random allocation sequence for the randomization process. In 4 studies, the allocation sequence was concealed until participants were assigned to interventions. There were no imbalances between groups at baseline in 14 studies. Consequently, the risk of bias due to the randomization process was rated as low in only 4 out of 15 studies (Figure 2).

Participants and those who delivered the interventions were aware of the assigned interventions during the trial in 13 and 14 studies, respectively. In all included studies, there was no evidence that the experimental contexts led to a deviation from the intended intervention. All 15 studies used appropriate analysis methods (eg, intention-to-treat analysis) to estimate the effect of the intervention. According to these judgments, the risk of bias due to the deviations from the intended interventions was low in 13 out of 15 studies (Figure 2).

Missing outcome data were less than 5% in 7 studies. In only 1 study, there was evidence that the findings were not biased by missing outcome data. The missing outcome data could be related to participants' health status in 3 studies. Consequently, 11 studies were judged as having a low risk of bias in the "missing outcome data" domain (Figure 2).

In all included studies, global cognition was assessed using appropriate measures, and measurement methods were comparable across intervention groups. The assessor of the outcome was blinded to the assigned interventions in 9 studies.

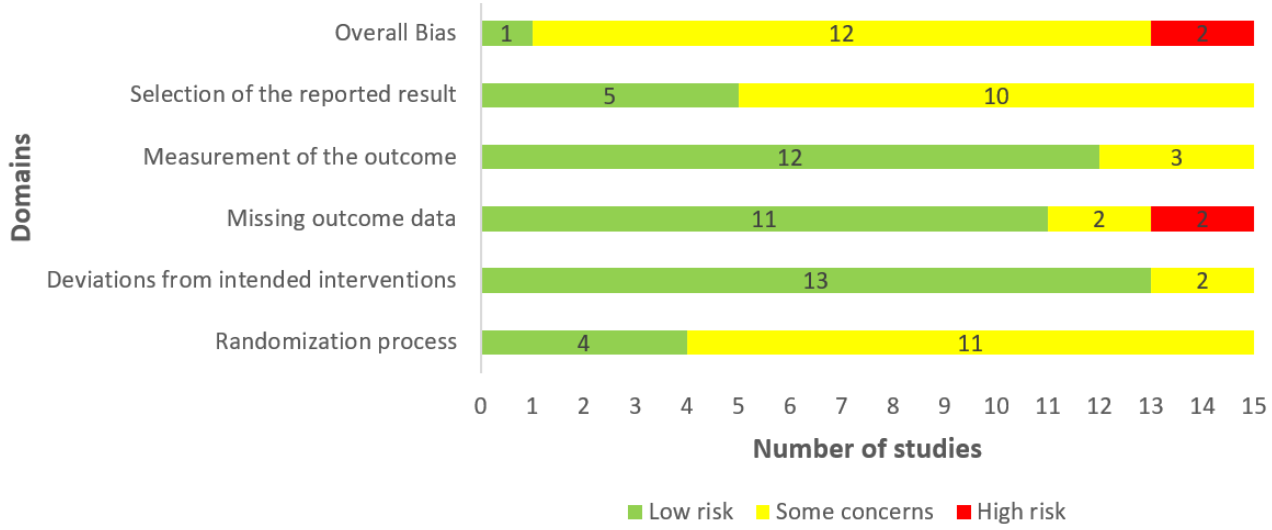
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Assessment of the outcome may have been affected by knowledge of the intervention received in 3 studies. Accordingly, the risk of bias in the "measuring the outcome" domain was rated as low in 13 studies (Figure 2).

Five studies published their protocol in sufficient detail. In all studies, reported outcome measurements did not differ from those specified in the analysis plan, and there was no evidence that studies selected their results from the many results produced from multiple eligible analyses of the data. Based on these judgments, the risk of bias due to the selection of the reported results was considered low in 5 studies (Figure 2).

In the last domain "overall bias," the risk of bias was considered high in 2 studies as they were judged as having a high risk of bias in at least one domain. Twelve studies raised some concerns in the domain of overall bias as they had some issues in at least one of the domains and were not at high risk for any domain. The remaining study was judged to be at low risk of bias for the domain of overall bias given that it was rated to be at low risk of bias for all domains. Reviewers' judgments about each "risk of bias" domain for each included study are presented in Multimedia Appendix 4.

Figure 2. Review authors' judgements about each "risk of bias" domain.



Results of Studies

In this review, serious games were compared with control (no/passive interventions), conventional exercises, conventional cognitive activities, and other serious games. Results of the included studies are shown in the following subsections based on these comparisons. Then, the results of the subgroup analysis are shown. Lastly, the results of the included studies regarding the safety of serious games have been reported.

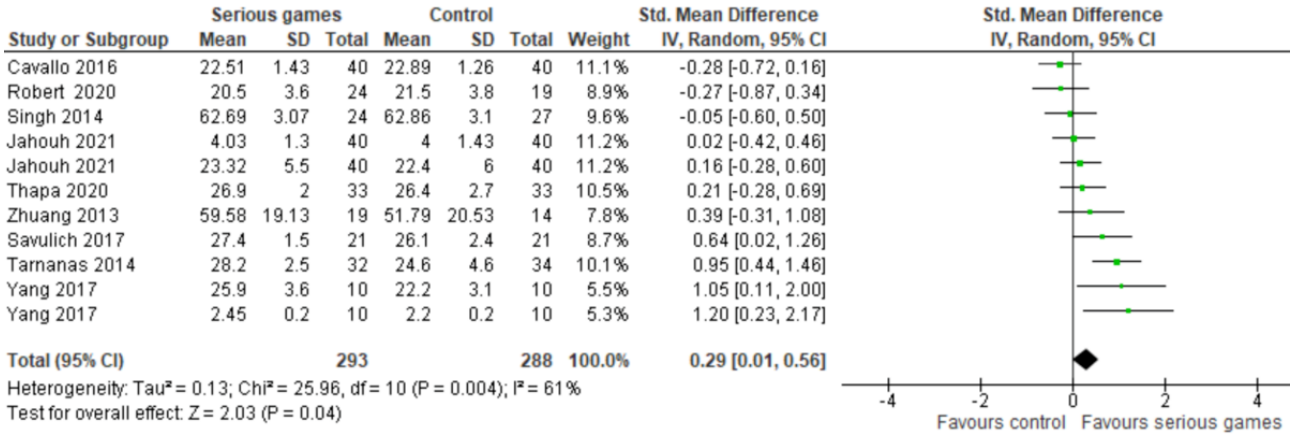
Serious Games Versus No/Passive Interventions

The effect of serious games was compared with a control (no/passive interventions) in 9 studies [27-35]. Passive interventions refer to interventions that do not have a known effect on the measured outcome, such as reading newspapers articles, surfing the internet, and watching a documentary program. While 6 studies did not find a statistically significant difference in global cognition between the groups [30-35], the 3 remaining studies showed a statistically significant difference in global cognition between the groups, favoring serious games over no intervention [27-29].

The results of these 9 studies were included in the meta-analysis. Two of these studies assessed global cognition using 2 different measures (MMSE and Clinical Dementia Rating Scale [28], and MMSE and Global Deterioration Scale [GDS] [33]). Therefore, we included the results of all these measures in the meta-analysis to form 11 comparisons (Figure 3). The meta-analysis showed a statistically significant difference in global cognition (P=.04) between the serious games and control groups, favoring serious games over no/passive intervention (SMD 0.29, 95% CI 0.01-0.56). This difference was also clinically important as the overall effect was outside MCID boundaries (−0.15 to 0.15) and its CI did not cross the "no effect" line (zero effect). For this outcome, MCID boundaries were calculated as ±0.5 times the SMD value (0.29). The statistical heterogeneity of the evidence was substantial (P=.004, I^2=61%). The quality of the evidence was very low as it was downgraded by 5 levels due to a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

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Figure 3. Forest plot of 9 studies (11 comparisons) comparing the effect of serious games to a control in terms of global cognition.

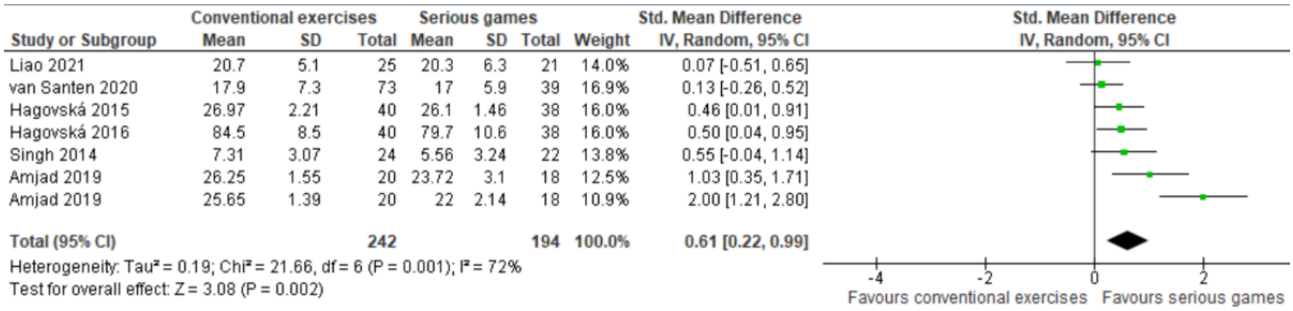


Serious Games Versus Conventional Exercises

The effect of serious games was compared with conventional exercises in 6 studies [35-40]. While 3 studies did not find a statistically significant difference in global cognition between the groups [35-37], the 3 remaining studies showed a statistically significant difference in global cognition between the groups, favoring serious games over conventional exercises [38-40].

The results of these 6 studies were included in the meta-analysis. One of these studies assessed global cognition using the following 2 different measures: MMSE and MoCA [38]. Therefore, we included the results of the 2 measures in the meta-analysis to form 7 comparisons (Figure 4). The meta-analysis showed a statistically significant difference in global cognition (P=.002) between the groups, favoring serious games over conventional exercises (SMD 0.61, 95% CI 0.22-0.99). This difference was also clinically important as the overall effect was outside MCID boundaries (−0.31 to 0.31) and its CI did not cross the "no effect" line (zero effect). For this outcome, MCID boundaries were calculated as ±0.5 times the SMD value (0.61). The statistical heterogeneity of the evidence was substantial (P=.001, I^2=72%). Like the meta-analysis seen in the previous section, the quality of this evidence was very low as it was downgraded by 5 levels due to a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

Figure 4. Forest plot of 5 studies (7 comparisons) comparing the effect of serious games to conventional exercises in terms of global cognition.



Serious Games Versus Other Interventions

One study compared the effect of serious games to conventional cognitive activities in terms of global cognition among patients with MCI [29]. The study found no statistically significant difference between the groups in global cognition as measured by the MMSE (P=.05) and GDS (P=.07) [29].

Gooding et al [41] compared the effect of a serious game (serious game 1 that involves computerized cognitive training [BrainFitness]) to another serious game (serious game 2 that incorporates empirically validated motivational teaching and rehabilitation techniques into computerized cognitive training) and various commercially available computer games and puzzles (ie, BrainAge, Sudoku, and crossword puzzles) [41]. The study found a statistically significant difference in global cognition between the groups, favoring serious game 1 and serious game 2 over commercially available computer games and puzzles. However, there was no significant difference in global cognition between the serious game 1 group and serious game 2 group [41].

Subgroup Analysis

We conducted subgroup analyses to investigate whether different types of serious games (ie, cognitive training games and exergames) have a different effect on global cognition. A subgroup analysis of 11 studies (14 comparisons) showed that cognitive training games had a statistically significant effect on global cognition compared to control (P=.05) and conventional exercises (P<.001) (Figure 5). The overall effect of cognitive training games on global cognition was statistically significant (P<.001) compared with both control and conventional exercises (SMD 0.54, 95% CI 0.24-0.83). This difference was also clinically important as the overall effect was outside MCID boundaries (−0.27 to 0.27) and its CI did not cross the "no effect" line (zero effect). For this outcome, MCID boundaries were calculated as ±0.5 times the SMD value (0.54). The statistical heterogeneity of the evidence was substantial (P<.001,

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I^2=71%). The quality of this evidence was very low as it was downgraded by 5 levels due to a high risk of bias, heterogeneity, and imprecision (Multimedia Appendix 5).

A subgroup analysis of 3 studies (4 comparisons) showed no statistically significant difference (*P*=.38) in global cognition between the exergame group and control or conventional exercise group (SMD 0.10, 95% CI −0.12 to 0.32) (Figure 6). The statistical heterogeneity of the evidence was a concern in this analysis (*P*=.97, I^2=0%). The quality of the evidence was very low as it was downgraded by 4 levels due to a high risk of bias and imprecision (Multimedia Appendix 5).

Figure 5. Forest plot of 10 studies (14 comparisons) comparing the effect of cognitive training games to control and conventional exercises in terms of global cognition.

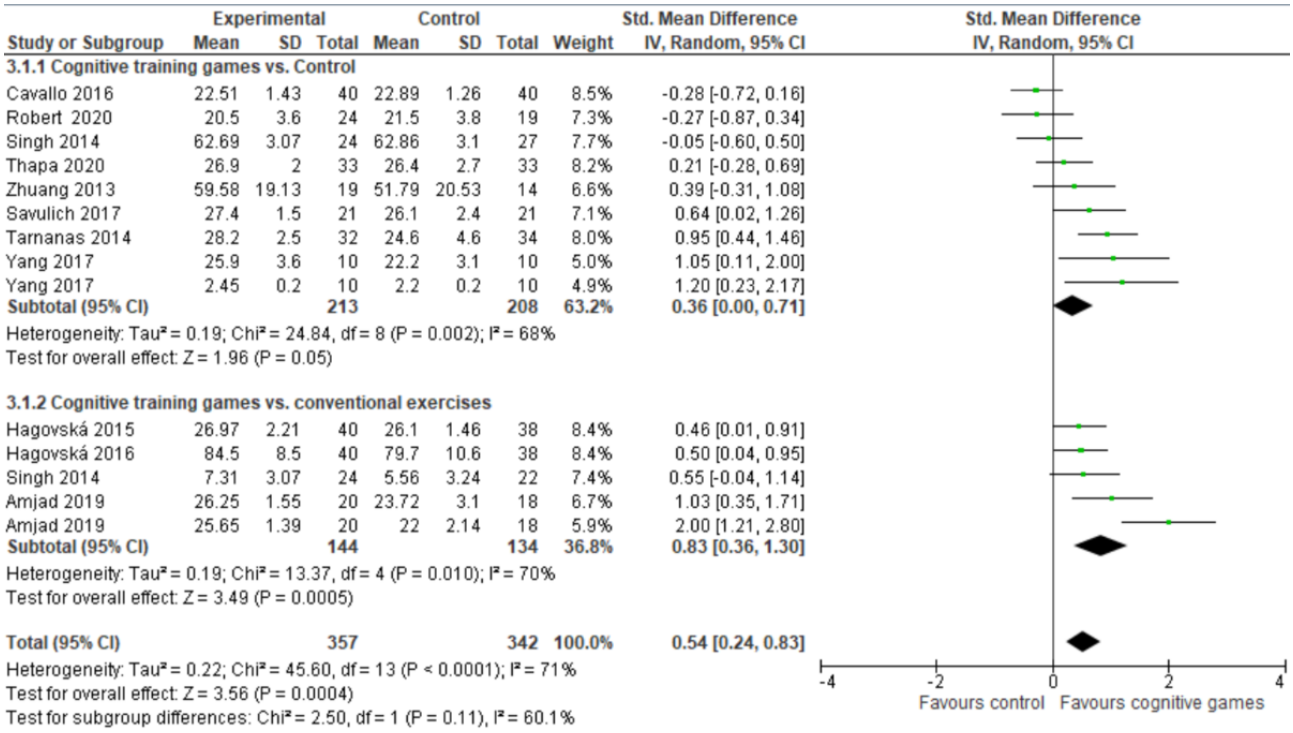
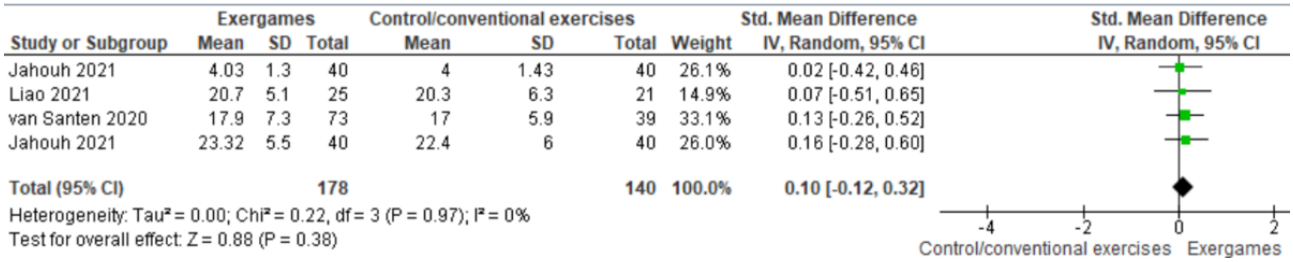


Figure 6. Forest plot of 3 studies (4 comparisons) comparing the effect of exergames to control and conventional exercises in terms of global cognition.



Safety of Serious Games

Five studies assessed the safety of serious games by checking adverse events [34-38]. Of these, 2 studies did not find any adverse events of the interventions during the study period [37,38]. The 3 remaining studies spotted some adverse events, but they were comparable between groups [34-36]. Specifically, Fiatarone Singh et al [35] found 6 adverse events distributed as follows: 3 events in the serious game plus conventional exercises group, 1 event in the conventional exercises group, 0 events in the serious game group, and 2 events in the control group. The adverse events reported in this study were falls during assessment (n=3) and exacerbations of pre-existing arthritis symptoms (n=3). In the second study [36], the mean number of falls was not statistically different between the exergame group and control group after the intervention (1.2 vs 2.0) and after a 6-month follow-up (1.5 vs 1.5). The last study reported that there was 1 adverse event during the study period, which occurred in a participant from the serious game group [34].

Discussion

Principal Findings

This review investigated the effectiveness of serious games for improving global cognition as reported by RCTs. Very low–quality evidence from 9 RCTs (11 comparisons) and 6 RCTs (7 comparisons) showed that the effect of serious games on global cognition was statistically significant in comparison with no/passive interventions and conventional exercises. None of the previous reviews examined the effect of all types of serious games. Due to evidence paucity, no statistical analysis was carried out to compare serious games to other types of interventions (other serious games and conventional cognitive activities).

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Additionally, very low–quality evidence from 11 RCTs (14 comparisons) showed that the effect of cognitive training games on global cognition was statistically significant in comparison with no/passive interventions, conventional exercises, and both. Interestingly, the effect of serious games in comparison with conventional exercises was higher than their effect in comparison with no/passive interventions. Studies in both meta-analyses were comparable in terms of population, intervention, and outcome measures. This paradoxical finding may be attributed to the fact that passive interventions used in the included studies (reading newspapers articles, playing games, solving puzzles, surfing the internet, and participating in educational programs on general health care) improved global cognition among participants, and thereby, the difference in global cognition between the serious game group and passive intervention group decreased. This is evident in Figure 3, where studies that used passive interventions showed either a negative effect size (which means that passive interventions had a higher effect than serious games) [30,35] or a small positive effect size (which indicates that passive interventions and serious games have a comparable effect) [32] in comparison with studies that used no interventions.

Our findings are in line with the findings of a previous review that compared the effect of cognitive training games to passive interventions, active interventions, and both in terms of global cognition among old adults with MCI [19]. Specifically, a meta-analysis of 10 RCTs (12 comparisons) in that review showed a statistically significant difference in global cognition between the groups, favoring cognitive training games over passive interventions, active interventions, and both [19]. It is worth mentioning that the review by Hill et al [19] is different from the current review in several aspects: (1) the review by Hill et al focused only on a specific type of serious games, which is cognitive training games; (2) it included pilot RCTs and/or quasiexperiments; (3) it did not assess the quality of evidence; (4) it conducted the search a long time ago (5 years ago); and (5) it did not assess the safety of serious games.

Very low–quality evidence from 3 RCTs (4 comparisons) showed an insignificant effect of exergames on global cognition in comparison with both control and conventional exercises. Our findings are inconsistent with findings from a previous review that compared the effect of exergames to both active and passive interventions in terms of global cognition among adults with and without health issues [18]. Specifically, a meta-analysis of 17 RCTs in that review showed a statistically significant difference (P<.001) in global cognition between the groups, favoring exergames over both active and passive interventions [18]. This inconsistency in findings can be attributed to several factors: (1) participants had cognitive impairment in only 2 of the 17 studies in that review [18]; (2) the mean age of participants were less than 60 years in 3 studies [18]; (3) the review included pilot RCTs and/or quasiexperiments; (4) the review included a large number of studies in the meta-analysis in comparison to the current review; and (5) the quality of evidence in the current review was very low.

According to 5 of the included studies, there was no significant difference in the number of adverse events between groups, indicating that serious games are safe. This finding was also concluded by a previous review about the use of cognitive training games for improving cognitive abilities among elderly people without cognitive impairment [3].

Strengths and Limitations

Strengths

In comparison with previous reviews [3,17-20], the current review is the only one that assessed the effectiveness of both serious games and their types. Given that this review strictly adhered to highly recommended guidelines for reporting systematic reviews (ie, PRISMA), it can be deemed a transparent and high-quality review. We included only RCTs as it is the most rigorous research method for studying cause-effect relationships [42]; therefore, this review's conclusion is likely more credible.

There is no concern about the risk of publication bias as the authors sought to identify as many relevant studies as possible by searching the most popular databases in the information technology and health fields, searching grey literature databases, conducting backward and forward reference list checking, and using a well-developed search query.

Given that all processes (ie, study selection, data extraction, risk of bias assessment, and quality of evidence evaluation) were carried out by 2 reviewers independently, the risk of selection bias is not a concern in this review. This review enables the reader to draw more accurate conclusions given that we appraised the quality of the evidence using the GRADE approach. When possible, we synthesized data statistically, and this improved the power of studies and increased the estimates of the likely size of the effect of serious games on global cognition.

Limitations

The effectiveness and safety of serious games delivered on nondigital platforms and those used for other purposes (eg, screening or diagnosis) cannot be commented on, because this review excluded studies discussing these types of serious games. This review focused on the effectiveness and safety of serious games for promoting global cognition among elderly people with cognitive impairment; thus, the effectiveness and safety of serious games for improving specific cognitive abilities (eg, memory, learning, and executive functions) or behavioral outcomes (eg, apathy, depression, and agitation) among other age groups without cognitive impairment cannot be commented on.

We excluded numerous studies as they were quasiexperiments, pilot RCTs, published before 2010, or written in non-English languages. Therefore, it is likely that we missed some relevant studies. We excluded these studies as quasiexperiments and pilot RCTs have lower internal validity than RCTs [42]. Because of practical constraints, it was not possible to translate all non-English studies. We included studies published from 2010 onwards given that previous reviews found a few studies published before 2010, and serious games have greatly advanced in the last decade.

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This review focused on the short-term effect of serious games by meta-analyzing only postintervention data rather than follow-up data, because only 3 studies reported follow-up data and the follow-up period was not consistent between studies. Therefore, we cannot comment on the long-term effect of serious games on global cognition. The quality of the evidence in all meta-analyses was very low, and this may decrease the internal validity of our findings.

This review used postintervention data for each group to assess the effect size for each meta-analyzed study rather than the pre-post intervention change for each group, and thereby, it is likely that the effect size was overestimated or underestimated in this review. We used postintervention outcome data because the majority of studies did not report the mean and standard deviation for the pre-post intervention change in global cognition for each group, and there was no statistically significant difference in global cognition at baseline between groups in all studies.

Non-RCTs can be used to assess the safety of interventions, such as serious games. However, such studies were not included in this review. Thus, it is likely that we missed several studies about the safety of serious games.

Research and Practical Implications

Research Implications

Given that this review focused on the effectiveness and safety of serious games for improving global cognition among elderly people with cognitive impairment, it is recommended that researchers conduct further reviews to assess the effectiveness and safety of serious games for improving specific cognitive abilities (eg, executive function, processing speed, memory, and learning) among people from different age groups with or without cognitive impairment.

A few studies were carried out in developing countries, and as such, the generalizability of this review's findings to such countries may be limited. More studies should be conducted in developing countries, especially given the varying nature of their cultures and socioeconomic conditions. A handful of studies assessed the safety of using serious games for improving cognitive abilities; thus, more studies will be helpful to draw more definitive conclusions about the safety of serious games.

This review did not assess the long-term effect of serious games given the lack of studies that reported follow-up data. Researchers should follow-up with participants to assess the long-term effect of serious games on global cognition. The majority of the included studies did not report the mean and standard deviation for the pre-post intervention change in global cognition for each group. It is important that future studies report this information to calculate more accurate effect sizes.

The overall risk of bias was low in only 1 study given that most studies had issues mainly in the randomization process and selection of the reported results. Accordingly, researchers should follow recommended guidelines or tools (eg, RoB-2 [24]) when conducting and reporting RCTs to avoid the above-mentioned biases. Although many studies examined the effect of exergames on global cognition among healthy older people [18], only 3 studies in this review examined their effect among older people with cognitive impairment. We encourage researchers to bridge this gap by conducting more studies about the effect of exergames on global cognition among elderly people with cognitive impairment.

Practical Implications

This review showed that serious games and specifically cognitive training games are more effective than no intervention and conventional exercises for improving global cognition, whereas exergames are as effective as no intervention and conventional exercises. However, these findings should be interpreted carefully because the quality of evidence in all meta-analyses was very low given that the majority of the included studies were judged to have some concerns in overall bias, the heterogeneity of the evidence was high in all meta-analyses except 1, and the total effect sizes were imprecise. Accordingly, psychologists and psychiatrists should consider offering serious games as a complement and not as a substitute to existing interventions until more robust evidence is available.

Still, the emerging evidence from this study presents promising opportunities to leverage serious games to alleviate the burden on health care systems due to exponential growth in the number of elderly people worldwide in the years to come. Serious games can allow elderly people with cognitive impairments to improve their psychological, physiological, sensory/motor, and social functions, thereby enjoying a higher quality of living [12]. Because many elderly people live in isolation and experience a lack of social interactions, which in turn can contribute to mortality and morbidity [43], serious games can promote social bonding with family and friends by being played in a comfortable environment (ie, homes) [44].

Mobile devices (smartphones and tablets) were used as the platform for serious games in only 2 studies. Mobile devices are particularly appealing as they are cheaper than computers and more pervasive than gaming consoles. Mobile devices are also more accessible than computers and gaming consoles. It is estimated that there were about 15 billion mobile devices and more than 7.1 billion mobile users worldwide in 2021 [45]. App and game developers should collaborate to develop serious games that target cognitive abilities and can be played via mobile devices.

When examining the few studies conducted in developing countries, it seems that there is more focus on implementing serious games in developed countries despite the greater shortage of mental health professionals in developing countries (1 per 10,000,000 people [46]). Therefore, more serious games should be developed in developing countries to improve cognitive abilities among elderly people with cognitive impairment.

Conclusion

Serious games and specifically cognitive training games have the potential to improve global cognition among elderly people with cognitive impairment. However, definitive conclusions could not be drawn regarding the effectiveness and safety of serious games for improving global cognition among elderly people with cognitive impairment. This is because the quality

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of evidence in all meta-analyses was very low mainly due to concerns raised about the bias in the majority of the included studies, high heterogeneity of the evidence, and imprecision of total effect sizes. Therefore, psychologists, psychiatrists, and patients should consider serious games as a complement and not as a substitute to existing interventions until further more robust evidence is available. Further reviews are required to assess the effectiveness and safety of serious games for improving specific cognitive abilities (eg, executive function, processing speed, memory, and learning) among people from different age groups with or without cognitive impairment. Additional studies are needed to assess the effect of exergames, the safety of serious games, and their long-term effects.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File , 23 KB - games_v10i1e34592_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 28 KB - games_v10i1e34592_app2.docx]

Multimedia Appendix 3
Data extraction form.
[DOCX File , 25 KB - games_v10i1e34592_app3.docx]

Multimedia Appendix 4
Reviewers' judgements about each "risk of bias" domain for each included study.
[DOCX File , 30 KB - games_v10i1e34592_app4.docx]

Multimedia Appendix 5
GRADE (Grading of Recommendations Assessment, Development, and Evaluation) profile for comparison of serious games to control or conventional exercises for global cognition.
[DOCX File , 18 KB - games_v10i1e34592_app5.docx]

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Abbreviations

AD: Alzheimer disease
CBT: cognitive behavioral therapy
GDS: Global Deterioration Scale
GRADE: Grading of Recommendations Assessment, Development, and Evaluation
MCI: mild cognitive impairment
MCID: minimal clinically important difference
MMSE: Mini-Mental State Examination
MoCA: Montreal Cognitive Assessment

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PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
RoB-2: Risk-of-Bias 2
SMD: standardized mean difference

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Review

The Potential Application of Commercially Available Active Video Games to Cardiac Rehabilitation: Scoping Review

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Abstract

Background: Commercially available active video games (AVGs) have recently been used for rehabilitation in some specific patient populations but rarely in those with cardiovascular disease (CVD). Commercially available AVGs are designed to increase motivation for continuous play, which could be applicable to the long-term cardiac rehabilitation process.

Objective: The objective of this scoping review was to assess the effectiveness of AVG-induced physical exercise, safety management, and patient adherence by applying commercially available AVGs to cardiac rehabilitation.

Methods: Four databases (CINAHL, MEDLINE, PubMed, and SPORTDiscus) were searched for all years up to August 12, 2020. Articles were retained if they were written in English, included patients with CVD who were aged 18 years or older, and used AVGs as part of a physical exercise program. The included studies were then evaluated from the viewpoints of effectiveness as physical exercise, safety, and adherence management.

Results: Among 120 nonduplicate articles reviewed, 5 (4.2%) were eligible for inclusion, of which 3 (2.5%) were reported by the same research group. The AVG consoles used were Xbox Kinect and Nintendo Wii, and sports-related programs were adopted for the intervention. No adverse cardiac events occurred in the identified studies, and dropout rates tended to be low.

Conclusions: AVGs appear to be safe and feasible for promoting an active lifestyle in patients with CVD. However, the effectiveness of AVGs alone as a therapeutic exercise to improve physical function may be limited.

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KEYWORDS

active video game; cardiac rehabilitation; physical exercise; rehabilitation; serious games; CVD; AVG; cardiovascular disease; exercise; safety; adherence

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Introduction

Cardiovascular disease (CVD) is the most prevalent noncommunicable disease and the leading cause of death globally [1]. Despite the proven benefits for the improvement in mortality from cardiac rehabilitation and strong guideline recommendations [2-4], a variety of barriers that reduce adherence to cardiac rehabilitation remain, especially after hospital discharge [5-7]. In particular, barriers related to accessibility are expected to become the major barrier with progressive population aging. Symptoms associated with CVD lead to an excessively sedentary lifestyle, and this physical inactivity reinforces the tendency to be trapped in an age-related downward spiral toward frailty and disability [8,9]. Therefore, approaches that interrupt or help prevent falling into this spiral are urgently needed in cardiac rehabilitation.

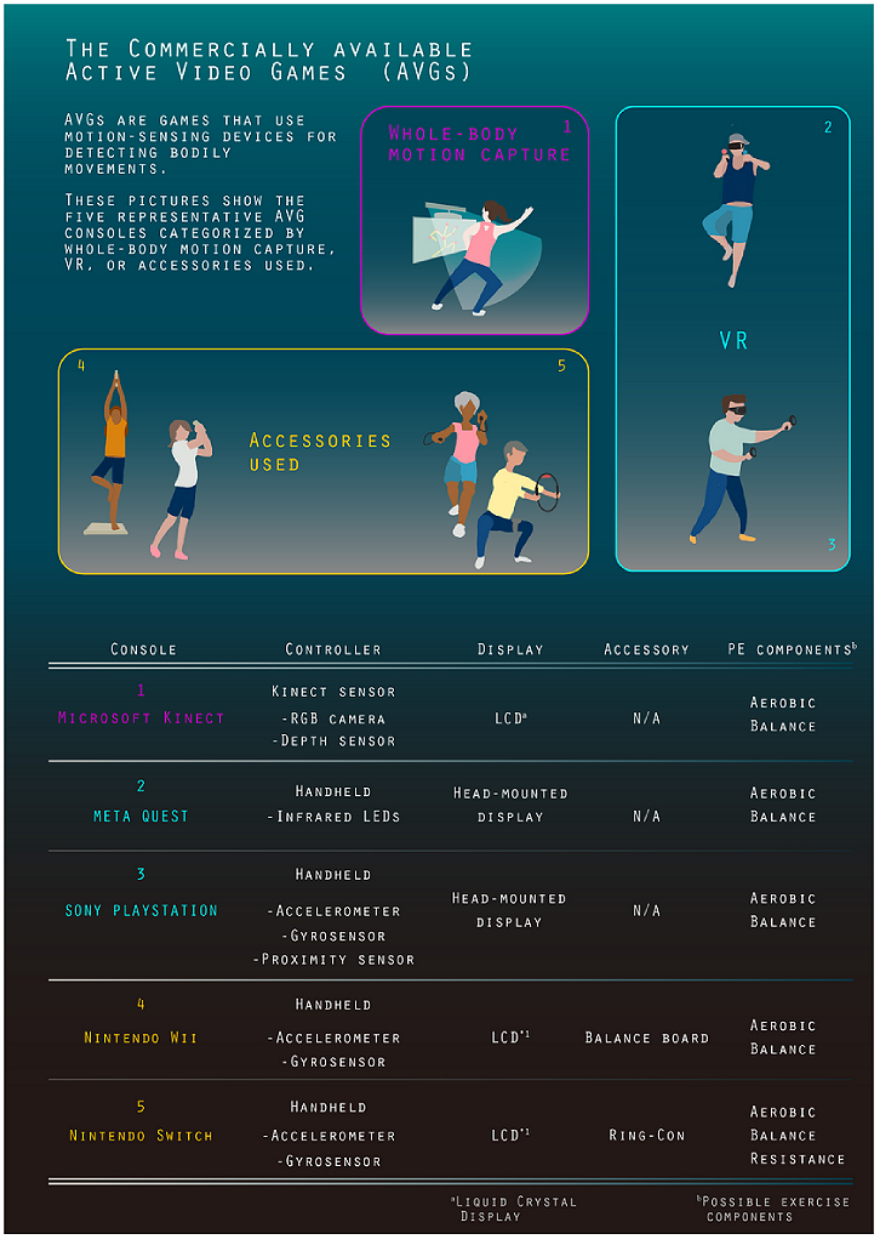
Active video games (AVGs), which are games that require players to interact with objects within a virtual environment using some part of their body as the controller [10], have recently emerged because of the evolution of motion-sensing devices that are designed to detect and measure movements. During the past decade, video game companies have launched several commercially available AVG consoles (Figure 1). Owing to their appealing designs, AVGs can increase motivation and long-term engagement with physical exercise in the general population, including older adults [10-13]. A systematic review has revealed the effectiveness of Nintendo Wii in the rehabilitation of adults with stroke [14]. However, only 6 studies were included in the review, suggesting that the evidence is still in the construction stage.

Therapeutic exercise is a core component in cardiac rehabilitation and aims to improve physical function such as exercise capacity and muscle strength through adequate exercise prescriptions [2]. On the other hand, because of the long-term rehabilitation process, practice guidelines consistently recommend comprehensive rehabilitation programs involving multiple components (eg, health education, advice on CVD risk reduction, physical activity, stress management) [3,4,15]. Furthermore, because of the aging population, it has become more important to provide multicomponent exercise programs as well as to increase patient motivation to engage in physical exercise. A previous systematic review reported that no studies integrated commercially available AVGs with multicomponent physical rehabilitation programs for motor function in patients with CVD [16].

Given this background, the objective of this scoping review was to explore the possibility of applying commercially available AVGs to cardiac rehabilitation. With this in mind, we assessed the available evidence in the literature for the physical effects of using AVGs in patients with CVD to examine ways to manage the safety of and adherence to such interventions.

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Figure 1. Categories and characteristics of commercially available active video game consoles. LED: light-emitting diode; N/A: not available; RGB: red, green, blue; VR: virtual reality.



Console	Controller	Display	Accessory	PE components[b]
1 Microsoft Kinect	Kinect sensor -RGB camera -Depth sensor	LCD[a]	N/A	Aerobic Balance
2 Meta Quest	Handheld -Infrared LEDs	Head-mounted display	N/A	Aerobic Balance
3 Sony PlayStation	Handheld -Accelerometer -Gyrosensor -Proximity sensor	Head-mounted display	N/A	Aerobic Balance
4 Nintendo Wii	Handheld -Accelerometer -Gyrosensor	LCD*1	Balance board	Aerobic Balance
5 Nintendo Switch	Handheld -Accelerometer -Gyrosensor	LCD*1	Ring-Con	Aerobic Balance Resistance

[a]Liquid Crystal Display

[b]Possible exercise components

Methods

Design

We conducted a scoping review in accordance with the guidelines described by PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) [17].

Search Strategy

A literature search of the electronic databases CINAHL, MEDLINE, PubMed, and SPORTDiscus was conducted for all years up to August 2020. The literature search was conducted using search terms covering medical and health science terminology (Multimedia Appendix 1).

Selection Process

Following the removal of duplicates, titles and abstracts were screened by at least 2 independent reviewers (TM, MS, YM, and RS) to exclude irrelevant articles as the first screening step. Articles were included if they focused on the influence of commercially available AVGs on patients with CVD aged 18 years or older. A commercially available AVG was defined as a digital game that video game companies launched into the entertainment market and that have controllers mounting motion-sensing devices for detecting bodily movements as signals. The inclusion criteria were articles that reported original quantitative data including case studies, studies with participants aged 18 years or older, studies that included participants with CVD, and studies that used a commercially available AVG as an intervention tool. Articles were ineligible if they were topic

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news or an editorial, pictorial, perspective, letter, conference paper, or review. Those that reported qualitative data were also ineligible for this review. The exclusion criteria were studies that used commercially unavailable AVGs (research-based AVGs) and articles published in a language other than English. In the second screening step, the articles included from the first screening step were downloaded and screened again by the same independent reviewers using the same criteria as that used in the first screening. Disagreements arising between the reviewers at any stage of the study selection process were resolved through team discussions or by a third reviewer (TT) to reach consensus on whether the article met the inclusion criteria. Reference lists of relevant articles were also hand-searched to identify additional appropriate articles for inclusion in this review. Review articles were not included in this study, but were checked for potentially relevant references.

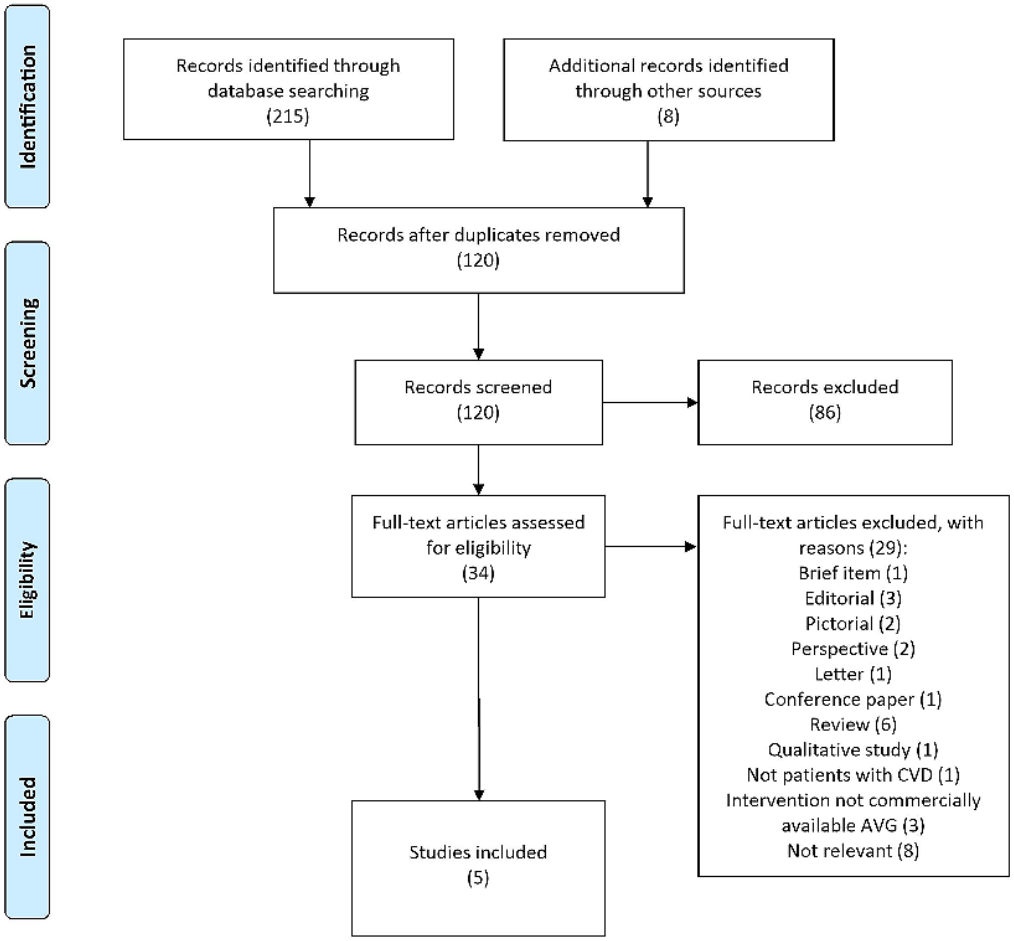
Data Extraction

Using a structured sheet in Excel (Microsoft), data were extracted by 1 reviewer (RS) and subsequently checked for accuracy by the other authors. The extracted data included details about the authors, year of publication, study design, location of the study, aims of the study, sample characteristics, AVG console used in the intervention, AVG programs used in the intervention, details of the AVG intervention (eg, period, frequency, duration, intensity), and the outcome measures related to physical exercise. Physical exercise was defined as bodily movements to enhance or maintain physical activity. Additional data of interest included the study setting, supervision, delivery method for the AVG interventions (AVG alone or AVG with other programs), effectiveness of the AVG in terms of physical exercise, safety management, the number of adverse events, adherence management, the number of patients who dropped out, and reasons for dropout. Safety management was defined as efforts to prevent adverse events during the intervention period. Adherence was defined as performance of the intervention as planned, and efforts to manage patient adherence were extracted as adherence management. These data were grouped and arranged in Excel by the type of setting and the presence of supervision to report the study outcomes.

Results

A flowchart of the systematic screening process with the number of articles included or excluded at each stage is shown in Figure 2.

Figure 2. A flow diagram of studies included according to PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews). AVG: active video game; CVD: cardiovascular disease.



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From the initial 223 identified articles, 5 (4.2%) were retrieved and screened for eligibility. In terms of study design, 3 of the 5 (60%) articles reported randomized studies. The remaining 2/5 (40%) articles were a case study and a pre-post study. The details of the identified articles are shown in Table 1, and a summary of the intervention delivery modes and effectiveness is shown in Table 2. Table 3 shows the summary of adverse events and adherence across studies. One study investigated the impacts of adding AVG-based physical exercise to cardiac rehabilitation programs on acute hemodynamics in 27 outpatients with CVD or CVD risk [18]. That study was a cluster-randomized crossover trial and used the Xbox Kinect as an alternative tool for warm-up and conditioning sessions in center-based cardiac rehabilitation. Similar physiological acute hemodynamic responses to cardiac rehabilitation were found, with higher magnitudes of heart rate, respiratory rate, and the rate of perceived exertion during and after cardiac rehabilitation with the AVG. Another study conducted in 32 outpatients with CVD in a hospital reported that those who had been allocated into the AVG group showed significant improvements after a 6-week intervention period in physical activity measured as accelerometer arbitrary unit (AAU; median baseline, 255 AAU/min; end of program, 322 AAU/min; *P*=.04), whereas those allocated into the conventional cardiac rehabilitation group showed no change (median baseline, 225 AAU/min; end of program, 247 AAU/min; *P*=.99). Measures of energy expenditure also improved significantly in the AVG group compared with those in the conventional cardiac rehabilitation group [19]. These 2 studies took the exercise intensity of AVGs into consideration based on physiological measures such as heart rate. On the other hand, 3 studies reported by the same research group [20-22] focused on the effects of home-based AVGs in patients with heart failure. The research group has published the results from a case study, a pilot study [22], and an open-label randomized study [20]. A total of 605 patients from multiple countries got the same instructions about the time and frequency for playing AVGs but were given no concrete numerical target regarding exercise intensity. Although the intervention through home-based AVGs was safe and feasible, it was not effective in improving the following outcomes: the 6-minute walk test, unilateral isotonic heel-lift, bilateral isometric shoulder abduction, unilateral isotonic shoulder flexion, exercise motivation, exercise self-efficacy, and physical activity.

The effectiveness of the AVG intervention was inconsistent. Another study conducted in the home setting reported that AVGs were ineffective in improving physical function [20], whereas studies in the hospital setting clarified the effectiveness of using AVGs as a supplementary tool for center-based, conventional cardiac rehabilitation programs [18,19]. The adherence rates and occurrence of adverse events showed similar trends in the identified studies. Regarding safety management, studies in the hospital setting controlled exercise intensity by monitoring the participants' physiological changes during the intervention, whereas those in the home setting provided safety guidelines and instructions for adapting AVG play to each patient's physical condition before the intervention. Furthermore, patients could call the research staff to ask questions during a given time period. Although myalgia and osteoarthritic knee pain occurred as musculoskeletal-related events in 2 studies, no cardiac-related adverse events were reported during the interventions. To manage patient adherence, the research staff conducted motivational calls or provided telephone guidance to each patient. The dropout rate seemed to be relatively low (0%-23%).

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Table 1. Summary of study characteristics.

Study	Setting	Age, composition, and disease state	Active video game	Dose and duration	Outcome
Alves da Cruz et al, 2020 [18], cluster randomized controlled trial in Brazil	Hospital	• N=27 • 48% female • Age: 63.4 (12.71) years • Status: CVD,[a] CVD risk	• Console: Xbox Kinect • Program: Just Dance 2015 (warm-up), Shape Up (conditioning)	• Period: 15 min (warm-up), 30 min, (conditioning) • Frequency: Once • Duration: 1 day • Intensity: Based on heart rate reserve and rate of perceived exertion during intervention	• Hemodynamics: systolic blood pressure, diastolic blood pressure, respiratory rate, oxygen saturation, heart rate, rate of perceived exertion
Jaarsma et al, 2020 [20], open-label randomized study in multiple countries	Home	• N=605 • 29% female • Age: 67 (12) years • Status: HF[b]	• Console: Nintendo Wii • Program: Nintendo Wii Sports	• Period: 30 min per day • Frequency: 5 days a week • Duration: 12 weeks • Intensity: not reported	• EC[c]: 6MWT[d] • Muscle function: unilateral isotonic heel-lift, bilateral isometric shoulder abductions, unilateral isotonic shoulder flexion • EM[e]: Questionnaire • Exercise SE[f]: Questionnaire • PA[g]: single question
Klompstra et al, 2013 [21], case study in Sweden	Home	• N=1 • 0% female • Age: 74 years • Status: HF	• Console: Nintendo Wii • Program: Nintendo Wii Sports	• Period: 15 min • Frequency: everyday • Duration: 12 weeks • Intensity: not reported	• PA: accelerometer • EC: 6MWT • EM: questionnaire • Exercise SE: questionnaire • Perceived physical effort: Borg scale
Klompstra et al, 2014 [22], pilot study in Sweden	Home	• N=32 • 31% female • Age: 63 (19-88) years • Status: HF	• Console: Nintendo Wii • Program: Nintendo Wii Sports	• Period: 20 min per day • Frequency: not recorded • Duration: 12 weeks • Intensity: not recorded	• EC: 6MWT • PA: accelerometer
Ruivo et al, 2017 [19], pilot randomized controlled trial in Ireland	Hospital	• N=32 • 18.7% female • Age: 59.9 (10.2) years • Status: CVD	• Console: Nintendo Wii • Program: Nintendo Wii Sports	• Period: 1-hour sessions • Frequency: twice a week • Duration: 6 weeks • Intensity: based on heart rate from a precardiac rehabilitation test	• EC: Bruce ramp protocol • PA: accelerometer

[a]CVD: cardiovascular disease.

[b]HF: heart failure.

[c]EC: exercise capacity.

[d]6MWT: 6-minute walk test.

[e]EM: exercise motivation.

[f]SE: self-efficacy.

[g]PA: physical activity.

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Table 2. Summary of intervention delivery and effectiveness across studies.

Study	Supervision	AVG[a] alone/with other programs	Effectiveness	
			Results	Conclusions
Alves da Cruz et al, 2020 [18]	SV[b]	With cardiac rehabilitation program	• Increased heart rate • Increased respiratory rate • Increased rate of perceived exertion	• Greater heart rate, respiratory rate, and rate of perceived exertion were observed during and 5 min after the AVG session
Jaarsma et al, 2020 [20]	No SV	AVG alone	• No change[c] in exercise capacity, muscle function, exercise motivation, exercise self-efficacy, or PA[d]	• AVG was safe and feasible in patients with heart failure • Not effective in improving outcomes
Klompstra et al, 2013 [21]	No SV	AVG alone	• Increased PA • Increased exercise motivation • Increased exercise self-efficacy • No change in perceived physical effort	• Further research is needed to generalize the results from the case study
Klompstra et al, 2014 [22]	No SV	AVG alone	• Exercise capacity • No change in PA	• AVG has the potential to increase exercise capacity in patients with heart failure
Ruivo et al, 2017 [19]	SV	With conventional program	• Increased PA • Increased energy expenditure per body weight	• Cardiac rehabilitation sessions with AVG are feasible and safe • Significant improvement in PA and energy expenditure

[a]AVG: active video game.

[b]SV: supervision.

[c]After correction for baseline and confounders.

[d]PA: physical activity.

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Table 3. Summary of adverse events and adherence across studies.

Study	Adverse events		Adherence		
	Safety management	Number of adverse events	Adherence management	Dropout rate, n (%)	Reasons for dropout
Alves da Cruz et al, 2020 [18]	• Control exercise intensity	• Cardiac, 0 • Musculoskeletal, 0	NR[a]	0	NR
Jaarsma et al, 2020 [20]	• Instruction for adapting active video games • Phone consultation	• Cardiac, 0 • Musculoskeletal, 0	• Motivational calls	71 (23%)	• Medical-related issues • Practical logistic reasons • Refusal to continue • Loss to follow-up • Death
Klompstra et al, 2013 [21]	• Safety guideline • Phone call to heart failure nurse	• Cardiac, 0 • Musculoskeletal, 0	• Remote guidance • Follow-up visits	0	NR
Klompstra et al, 2014 [22]	• Safety guideline • Phone call to heart failure nurse	• Cardiac, 0 • Musculoskeletal, 1 (myalgia)	• Telephone guidance	1 (3%)	• Moved abroad for work
Ruivo et al, 2017 [19]	• Playing active video games within individual target heart rate zones (55%-70%) • Safety guideline • Supervision at all times • Monitoring by telemetry	• Cardiac, 0 • Musculoskeletal, 1 (osteoarthritic knee pain)	• Motivational calls	1 (6.3%)	• Returned to work

[a]NR: not reported.

Discussion

Overall Findings

This scoping review aimed to explore the possibility of applying commercially available AVGs to cardiac rehabilitation. Only 5 articles with commercially available AVGs were identified. All identified studies involved AVG interventions with a fixed time and frequency; however, exercise intensity was ill-defined in studies performed in the home setting. AVG interventions for patients with CVD may be safe and feasible regardless of the setting. On the other hand, some challenges seem to remain for the application of commercially available AVGs as therapeutic exercise tools in cardiac rehabilitation from the perspective of the balance between effectiveness and safety management, especially in terms of controlling exercise intensity.

Effectiveness

Although 4 identified studies provided interventions involving AVGs in a given period to patients with CVD, the effectiveness of the interventions in improving physical function was inconsistent. Conventional cardiac rehabilitation programs recommend that therapeutic exercise be generally composed of a combination of 2 types of exercise: aerobic and resistance [23]. Aerobic exercise is defined as any activity that uses large muscle groups, can be maintained continuously, and is rhythmic in nature [24], whereas resistance exercise is expected to enhance the strength of major muscle groups by contracting muscles against external resistance [24]. It is essential for AVGs to require both types of exercise during play for adaptation to therapeutic exercise in cardiac rehabilitation. Regarding the game programs, sports-related programs that cause whole body movement during play, such as baseball and golf, were used. Several studies have reported the exercise intensity achieved during play for each game program in older people and patients after chronic stroke [25-27] but not in patients with CVD. Two randomized studies used an AVG as an intervention tool, but the results were inconsistent. An international multicenter study by Jaarsma et al [20] investigated the effects of access to a home-based AVG (Nintendo Wii) in patients with heart failure on submaximal aerobic exercise capacity, as assessed by the 6-minute walk test (6MWT), and muscle function, as measured by unilateral isotonic heel-lift, bilateral isometric shoulder abduction, and unilateral isotonic shoulder flexion. The treatment effects in the 6MWT were not significant at 3 months (4.3 m; 95% CI –6.9 to 15.5), 6 months (1.8 m; 95% CI –10.3 to 14), or 12 months (6.8 m; 95% CI –7.1 to 20.7) after correcting for baseline 6MWT results and confounders. Regarding muscle function, no outcomes were significantly improved except for left heel rise at 6 months. On the other hand, another study reported significant improvement in daily physical activity and related energy expenditure per body weight

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after a 6-week intervention compared with that in the control group [19]. In that study, Nintendo Wii was used as the supplementary tool for the center-based, conventional cardiac rehabilitation program. The results suggest that exercise induced by AVGs without supervision is not sufficient to improve physical function. From the perspective of exercise prescription, it is essential to clarify the exercise intensity of each game program in specific subjects. To implement more effective therapeutic exercises in home-based cardiac rehabilitation, further laboratory-based studies are needed in which exercise intensity is measured in patients with CVD while they play AVGs. Additionally, the AVG consoles used in the identified studies were Xbox Kinect and Nintendo Wii, neither of which provides external resistance to cause muscle contractions. Therefore, it might be better to use AVGs in combination with resistance training. A device that can detect muscle contractions as a signal for controlling AVGs also needs to be developed. Commercially available AVGs are designed to encourage players to engage in physical activity continuously; therefore, AVG-based exercise interventions in the home setting may be applicable to patients with CVD from the perspective of promoting safe physical activity.

Safety Management

Regarding safety management, the identified studies prepared safety guidelines prior to the interventions. Patients could call an instructor or nurse at a given time in studies conducted in the home setting. In addition, in the identified studies, no cardiac-related adverse events were reported. The dropout rates were relatively low compared with those with conventional cardiac rehabilitation [28], partially because of the appealing design of commercially available AVGs such as the Nintendo Wii and Xbox Kinect for increasing motivation and long-term engagement to play the game. The challenges associated with center-based cardiac rehabilitation programs are low participation and high premature dropout rates [28-30]. A variety of barriers that can be characterized at 3 interrelated levelspatient, provider, and health care systemhave been reported in previous studies [6,31-33]. Older age, lower socioeconomic status, schedule conflicts, disinterest in attending a program, and comorbidities were included as barriers with respect to patients' characteristics. Insufficient physician knowledge about the effectiveness of cardiac rehabilitation and inappropriate referrals to cardiac rehabilitation are often described as barriers at the provider level. System-level barriers to cardiac rehabilitation include transportation problems and the limited availability of cardiac rehabilitation programs for outpatients. Potential approaches to overcome these challenges include home-based cardiac rehabilitation and cardiac telerehabilitation [34-36]. Recent systematic reviews have concluded that home- and center-based cardiac rehabilitation have similar benefits in terms of clinical events, exercise capacity, and health-related quality of life among patients after myocardial infarction or coronary revascularization or among patients with heart failure [37,38]. Furthermore, another systematic review concluded that multidisciplinary or exercise-based cardiac telerehabilitation is safe and cost-effective and can be an alternative option to center-based cardiac rehabilitation in patients with coronary artery disease and chronic heart failure [35]. As AVG interventions seem to be safe and feasible for keeping patients with CVD active at home, home-based cardiac rehabilitation and cardiac telerehabilitation in conjunction with AVGs could help such patients achieve and maintain a more active lifestyle.

Future Perspectives

AVGs are rapidly evolving with improvements in motion-sensing technologies, and 2 such AVG consoles, Nintendo Wii and Microsoft Kinect, were used as intervention tools for patients with CVD in the identified studies. Nintendo Wii, released in 2006, uses motion sensing technology in the primary controller to enable users to control game actions through their arm gestures. Nintendo Wii was the first commercially available video game console to induce body movement in the real world to manipulate objects or play sports in a virtual world. Following the Nintendo Wii, Microsoft launched Kinect in 2010 as a line of motion-sensing input devices. Microsoft Kinect, which was introduced to replace traditional game controllers, enables users to play games by using signals from whole-body gestures. A systematic review, published in 2016 [16] on the effectiveness of commercial AVGs for physical rehabilitation of motor function reported that almost 80% of included studies (n=126) used Nintendo Wii as the AVG console, which was a far higher rate than the rate at which Microsoft Kinect was used. The evolution seen in the past decade in motion-sensing systems to detect human body movement has accelerated the integration of commercial AVGs into therapeutic exercise for older people [10-13], patients after stroke [14], and patients with multiple sclerosis [39]. However, the application of AVGs in patients with CVD has yet to be addressed, partially because current AVG consoles do not induce resistance exercise. There could be 2 options to break through this barrier: the use of electromyographic signals and the development of a muscle contraction–induced controller. Some video games have introduced an electromyographic system to detect muscle contractions in the research setting [40,41] but none in the commercial setting. AVG consoles incorporating an electromyographic system in combination with a motion-sensing system could accelerate the application of AVGs in therapeutic exercise. Regarding the development of controllers that induce muscle contractions, Ring Fit Adventure, launched by Nintendo in 2017, is an action role-playing game for the Nintendo Switch that consists of 2 physical components as accessories: The Leg Strap and Ring-Con. The Leg Strap affixes the original controller to the user's thigh to detect leg movement, and Ring-Con is a ring that includes a strain sensor that can detect the bending of the ring by using the original controller as a logger. These accessories enable users to engage in both aerobic and resistance exercise during gameplay. Isometric resistance exercises usually require breath-holding, which elevates blood pressure. Speech recognition systems have the potential for safety management by not requiring users to hold their breath while performing resistance exercises even remotely. However, to our knowledge, no studies have investigated exercise intensity during gameplay using Ring Fit Adventure, which could be the first step in clarifying exercise intensity for its application as a tool in safe therapeutic exercises as a part of cardiac rehabilitation. Concurrently, the feasibility of the combined use of AVGs and other devices for monitoring

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muscle contractions should be investigated to enable safe therapeutic exercise in home-based cardiac rehabilitation.

Subjects in identified articles in this review spanned a wide range of generations, including older generations. With increasing age, digital divide—the gap between individuals who have access to modern information and communication technology, including digital devices, and those who lack access—should be considered. Older generations usually do not have the opportunity or knowledge to use digital devices and therefore could not utilize them properly. In an identified study investigated in the home setting [22], the instructor demonstrated the AVG play at the patients' home and also conducted a 1-hour introduction session at the hospital. Proper introduction of AVGs is essential for its application in therapeutic exercise, especially in older adults.

Limitations

Commercially available AVGs could potentially be applied to cardiac rehabilitation; however, the evidence obtained in this review should be interpreted with caution because research in this field is rapidly growing. In addition, this scoping review excluded studies that used commercially available AVG consoles with programs designed for research, which could offer hints for the next step toward the smooth application of commercially available AVGs in cardiac rehabilitation.

Conclusions

The results of this scoping review suggest that evidence remains lacking for the application of commercially available AVGs in cardiac rehabilitation for patients with CVD in both laboratory-based and clinical studies. Commercially available AVGs may be suitable as a tool for promoting an active lifestyle in patients with CVD even in the home setting. However, commercially available AVGs should be used with caution as an alternative to therapeutic exercise. The need for remotely accessible cardiac rehabilitation programs, including therapeutic exercises, is increasing because of the aging population. Further studies are needed to investigate the appropriate frequency, intensity, and duration of time of commercially available AVGs for effective therapeutic exercises in patients with CVD. In addition, the development of devices that can detect muscle contractions when AVGs are played is recommended for the addition of resistance exercise and institution of more effective therapeutic exercises.

Conflicts of Interest

TT, NK, TK, and HD are affiliated with a department funded by Philips Japan; Asahi Kasei Corporation; Inter Reha Co, Ltd and Toho Holdings Co, Ltd based on collaborative research agreements.

Multimedia Appendix 1
Literature search terminology and number of records included from databases.
[DOCX File , 23 KB - games_v10i1e31974_app1.docx]

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Abbreviations

AAU: accelerometer arbitrary unit
AVG: active video game
CVD: cardiovascular disease
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
6MWT: 6-minute walk test

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